RULEMAKING ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: Brooke P. Clark, Secretary

FROM: Commissioner Caputo

SUBJECT: SECY-23-0021: Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31)

Approved X Disapproved X Abstain ____ Not Participating ____

COMMENTS: Below ____ Attached X None ____

Entered in STAR
Yes XX
No ____

Signature

July 18, 2023
Date

Commissioner Caputo's Comments on SECY-23-0021, "Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31)"

I commend the staff and advanced reactor stakeholders for the significant effort that went into developing this proposed rule. The extensive public interactions identified the major issues that must be addressed by the Commission in approving it for publication. I approve the publication of the proposed rule for comment in the *Federal Register* as edited in the attached. I have provided a red-line strikeout version as well to indicate the reasons for many of the changes I have made from the version provided by the staff. For my colleagues' ease of reference, I have summarized the more significant items in the attached table. I have also provided a second attached table of typographic errors and inconsistencies in our current regulations that were uncovered during the significant examination of the proposed rule. I believe these can be corrected by the staff through administrative rulemaking.

In many ways, the draft proposed rule sacrifices the opportunity to provide the predictable and timely reviews Congress expects and external stakeholders seek. Within my comments and edits, I strive to enable innovation on the part of the regulator and the technology developers, recognizing the inherent safety advantages of advanced designs. I also seek to enable predictable and timely reviews by retaining consistency with current regulatory practices where it makes sense and by reducing subjectivity where possible.

Successful execution of Part 53 will be the biggest innovation achieved by the NRC in many years, on par with the development of Part 52 and implementation of the reactor oversight process. As such, my comments and edits are very detailed in order to provide the staff with specific and clear direction in an effort to speed the publication of a proposed rule that is responsive to Congress, applicants, and stakeholders, and will provide for predictable and timely advanced reactor reviews.

From the beginning, this proposed rule represented an *evolution* rather than a *revolution* in how the NRC would use risk information in licensing and regulating nuclear power plants. The proposed rule builds on the use of risk evaluations to inform the selection of functional design criteria rather than relying on the general design criteria in part 50, appendix A for the selection of principal design criteria. However, the licensing and regulation will continue to rely on a set of deterministic analyses and evaluation of the defense in depth provided by the design's structures, systems, and components in order to address any residual risks and uncertainties. Together, these support a conclusion that a plant built to that design and sited under the regulations proposed in part 53 will provide adequate protection of public health and safety and the common defense and security at a minimum.

In reviewing and editing this proposed rule, I start from the perspective that the NRC's goal in this rulemaking is to follow the Congressional mandate in the Nuclear Energy Innovation and Modernization Act (NEIMA) to establish a risk-informed, performance-based, technology-inclusive regulatory framework for optional use by commercial advanced nuclear reactor technologies. However, in its draft proposed rule, the staff has strayed from the mandates of NEIMA and, contrary to the Commission's repeated direction in SRM-SECY-20-0032,[1] SRM-

[1] In "Staff Requirements – SECY-20-0032 - Rulemaking Plan on 'Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062),'" the Commission approved the staff's rulemaking plan, which included building on the work done under "Staff

SECY-19-0117,[2] SRM-SECY-10-0121,[3] and SRM-SECY-89-102,[4] developed draft proposed requirements far exceeding those of operating reactors and far in excess of the existing regulatory frameworks in Parts 50 and 52. For example, establishing a cumulative risk limit would mean that limits for the constituent individual events would be driven lower to risks on the order of one in a hundred million: lower than it is reasonable to regulate. This dynamic will simply drive advanced reactor applicants to utilize Part 50 or 52 with their more cumbersome reviews rather than the efficient, risk-informed reviews hoped for in a new, streamlined Part 53.

Further, the draft proposed rule fails to recognize the inherent safety benefits afforded by advanced reactor designs. This is evident in the draft proposed operational requirements for the facility safety program and the integrity assessment program, among other examples, that are not imposed on the currently operating fleet of light-water reactors. Another example is transforming operational requirements, as is the case with ensuring that radiation exposures are as low as reasonably achievable (ALARA), into design requirements. This proposal would make compliance subjective and finality difficult for *designers* to achieve in certification, in contrast with existing requirements for the programs currently required of *operators*.

I also take into consideration the wide array of different technologies this rule must address in order to meet the direction from Congress to be technology inclusive. We can anticipate that this will involve a spectrum that runs the gamut from large systems with complexity similar to that of currently operating light-water reactors for which a PRA may be appropriate, to small, simple microreactors for which a PRA may not be. This is consistent with the observation made by the Advisory Committee on Reactor Safeguards (ACRS) that, "The requirement for risk-informed analysis is appropriate if the use of Probabilistic Risk Assessment (PRA) is approached in a graded fashion commensurate with the potential consequences and the simplicity of the

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Requirements – SECY-19-0117 – Technology-Inclusive, Risk-Informed, and Performance-Based Methodology To Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors," May 26, 2020.

[2] In SRM-SECY-19-0117, the Commission directed the staff to "continue to recognize that the Commission's established policy on the application of the safety goals and safety performance expectations provides an acceptable minimum safety standard for new reactors" "[i]n its work on the regulatory framework for advanced reactors."

[3] In "Staff Requirements – SECY-10-0121 – Modifying the Risk-Informed Regulatory Guidance for New Reactors," the Commission "[reaffirmed] that the existing safety goals, safety performance expectations, subsidiary risk goals and associated risk guidance (such as the Commission's 2008 Advanced Reactor Policy Statement and Regulatory Guide 1.174), key principles and quantitative metrics for implementing risk-informed decision making, are sufficient for new plants."

[4] In the staff requirements memorandum (SRM) to "SECY-89-102 — Implementation of the Safety Goals," the Commission stated the following:

> It is important to note that the Commission has made it clear in the advanced plant and severe accident policy statements that it expects that advanced designs will reflect the benefits of significant research and development work and experience gained in operating the many power and development reactors, and that vendors will achieve a higher standard of severe accident safety performance than their prior designs. The industry's goal of designing future reactors to a core damage probability of less than 1 in 100,000 per year of reactor operation (EPRI for ALWRs and GE for the ABWR) is evidence of industry's commitment to NRC's severe accident policy. The Commission applauds such a commitment. <u>However, the NRC will not use industry's design objectives as the basis to establish new requirements.</u> (Emphasis in the original.)

design."[5] The staff's proposal for an alternative evaluation for risk insights (AERI) or some other form of risk evaluation could provide a more appropriate tool for licensing and regulating simple microreactors, for example, or even some moderately sized reactors.

To improve the usefulness of part 53 and recognize that the term "probabilistic risk assessment" has a very specific meaning for the level of detail and standards for a risk evaluation, I have proposed generalizing the requirements for and use of risk evaluation and the standards for their maintenance. This includes recognizing that the acceptability of PRAs under NRC-endorsed guidance already addresses such items as their maintenance and upgrading.[6] Staff should generalize the risk evaluation requirements in the proposed part 53 and work to adapt the draft AERI guidance for use throughout part 53.[7]

I note that the agency has received consistent feedback from stakeholders regarding the need for a more flexible regulatory framework supported by guidance to address the specific tools that may be used. One such example is the guidance developed under the licensing modernization project and approved for use in 2020.[8] Some concern has been expressed that doing so would result in a need for custom reviews rather than a more streamlined review process with applications limited to a single methodology for developing their licensing bases. I do not share those concerns. As noted by Commissioner Wright during the May 2023 Commission briefing on this proposed rule, part 50 was originally much smaller when the vast majority of currently operating reactors were licensed. Effective and timely reviews of reactor license applications are not correlated with the volume of regulations.

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[5] ACRS Letter Report, "Preliminary Proposed Rule Language for 10 CFR Part 53, 'Licensing and Regulation of Advanced Nuclear Reactors,' Interim Report," May 30, 2021 (ML21140A354). The ACRS also noted in its November 22, 2022, letter report, "Final Letter on Draft 10 CFR Part 53 Rulemaking Language" (ML22319A104) that "[i]n terms of streamlining the Rule, this may be a case of two options neither of which is very satisfactory. While it is true that the Rule is shorter in length than 10 CFR Parts 50 or 52, it may still be too long relative to many stakeholder expectations, which threatens the likelihood of its use. The staff emphasized that a tradeoff exists between clarity and overall rule length and that the staff chose clarity. We appreciate that the staff's latest revision did remove extraneous language and transferred some sections to guidance. Additional tightening of the language would be helpful."

[6] See e.g., Regulatory Guide (RG) 1.200, "Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities," Revision 3, December 2020 (ML20238B871). Staff Regulatory Guidance section C.1 provides that "PRA results used to support an application must be derived from a base PRA model that represents the as-built and as-operated plant to the extent needed to support the application. Consequently, the base PRA is maintained and upgraded, where necessary, to ensure it represents the as-built and as-operated plant." Trial use RG 1.247, "Acceptability of Probabilistic Risk Assessment Results for Non-Light Water Reactor Risk-Informed Activities," ML21235A008, March 2022, includes provisions in Staff Regulatory Guidance section C.1.4.

[7] In its November 22, 2022, letter report, "Final Letter on Draft 10 CFR Part 53 Rulemaking Language" (ML22319A104), the ACRS recommended that "[t]he Alternative Evaluation for Risk Insights (AERI) approach should be expanded beyond the Rule and made available for applicants to pursue under 10 CFR Parts 50 and 52." As that recommendation is beyond the scope of SECY-23-0021, staff should inform the Commission if it determines that to be an appropriate course of action through its normal processes.

[8] SRM-SECY-19-0117. Following the Commission direction in this memorandum, the staff issued Regulatory Guide 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology To Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors," for use in licensing and regulating such reactors under Title 10 of the Code of Federal Regulations (10 CFR) parts 50 and 52.

Finally, while the evolution of this regulatory framework should support innovation on the part of both the agency and the regulated industry, it is important that we avoid introducing confusion by using the same or similar words with different meanings from the current rules. There is a long history of understanding and using the current quality assurance criteria, for example. Those criteria are already technology-inclusive. Adding a new set of regulations on quality assurance that are largely duplicative but slightly different could drive increased compliance burden on the entire supply and service chain. It would also drive unnecessary staff work to develop new inspection procedures and largely duplicative compliance inspections. This is an example of how words and phrases similar to those that are currently terms of art in nuclear regulation but with slightly different meanings creates confusion and increased regulatory burden without any safety gains.

My edits reflect how the major issues highlighted by the staff in "Alternative Approaches Considered for Selected Topics During the Development of 10 CFR Part 53"[9] should be resolved. My comments on those selected topics and certain others follow.

Dual Frameworks

Many stakeholders have questioned the need for two frameworks in part 53, and not just external stakeholders. In an August 2, 2022, letter report, the ACRS conveyed the same concern.[10] I, too, share those concerns. The staff has done a respectable job in drafting the proposed Framework B to provide a deterministic framework that is technology-inclusive. However, I do not believe it is truly responsive to the Congressional direction in NEIMA. My edits to the proposed rule remove the second framework for that reason. Parts 50 and 52 are available for applicants who prefer a deterministic approach. Staff should retain the good work done on Framework B for use in future rulemakings on parts 50 and 52 and seek to implement a more technology-inclusive framework there.

Qualitative Health Objectives

The first issue highlighted by the staff is the use of the quantitative health objectives (QHOs) from the Commission's Safety Goal Policy Statement[11] as one of several performance standards within the rule. The staff proposes to require applicants and licensees using the PRA-led portion of the rule to "[m]aintain overall cumulative plant risk from [licensing-basis events] other than [design-basis accidents] … such that calculated risk to an average individual in the vicinity of the commercial nuclear plant remains below" the QHOs.[12] The staff considers this to

[9] SECY-23-0021, "Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31)," Enclosure 4, "Alternative Approaches Considered for Selected Topics During the Development of 10 CFR Part 53."

[10] ACRS Letter Report, "Fourth Interim Letter on 10 CFR Part 53 Rulemaking Language," August 2, 2022 (ML22196A292), recommendation 5, stating, "The current approach with self-contained requirements for each of the two frameworks is very long. Furthermore, the rule has a significant amount of implementation detail that could be better located in regulatory guidance. The optics of this approach run counter to a streamlined more efficient licensing process, which is an expectation for many stakeholders. As a result, the rule may be too cumbersome to implement and may not be used."

[11] "Safety Goals for the Operations of Nuclear Power Plants; Policy Statement (Republication)" (51 FR 28044, 28046; Aug. 21, 1986).

[12] Draft proposed § 53.220, "Safety Criteria for licensing-basis events other than design-basis accidents."

be a natural evolution of the use of QHOs through several Commission Policy Statements and regulatory activities. I disagree.

The NRC Principles of Good Regulation and the Administrative Procedure Act both mandate that the NRC consider other factors besides the risk numbers from a PRA, including the costs and benefits of a regulatory action being taken.[13] The sole exception to the need to consider costs and benefits for regulatory actions the NRC takes is an instance where that regulatory action is the only action that is capable of providing adequate protection of public health and safety or the common defense and security.[14] There is a need for consideration of costs and benefits for all regulatory actions that are not required for adequate protection of public health and safety.

In considering the issue of QHOs it is helpful to reflect on their history, starting with their initial recommendation by the ACRS through the Commission's approval of the use of the Licensing Modernization Project, much of which is discussed in the staff's analysis of the issue.

The ACRS provided its recommendations on QHOs to the Commission on October 31, 1980.[15] Those recommendations included the establishment of a set of decision rules based on criteria to ensure adequate protection of public health and safety, including flexibility to allow for consideration of special cases. The decision rules, which were proposed for new plants, would have placed limits on risk in "the form of an upper nonacceptance limit, a discretionary range, and a goal level of risk. Compliance with the upper limit … is required. Within the discretionary range, the severity of the risk, uncertainties in risk estimation, competing risks, and the regional need for power are considered…. Risk estimates below the goal level will be considered to be in compliance."[16]

The ACRS revisited the function performed by the QHOs in its 449th, 451st, and 452nd meetings in the context of discussions related to whether the subsidiary goal for core damage frequency (CDF) should be elevated to a safety goal and incorporated in the Safety Goal Policy Statement. In a May 11, 1998, letter report,[17] the ACRS reiterated its view as an important conceptual issue on "whether the objectives should be stated in terms of a single goal or a goal and an upper

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[13] See, e.g., the dissent of Judge Kavanaugh in *Mingo Logan Coal Co. v. EPA*, No. 14-5305, 2016 WL 3902663 (D.C. Cir. July 19, 2016), stating "absent a Congressional directive to disregard costs, common administrative practice and common sense require an agency to consider the costs and benefits of its proposed actions, and to reasonably decide and explain whether the benefits outweigh the costs." Judge Kavanaugh dissented because, unlike the majority, he did not believe that the arguments related to cost had been waived—although the judges who joined the majority did not believe it necessary to reach the cost arguments, they nonetheless agreed with the approach to the issue. (*See* 2016 WL 3902663 at *9, stating "[W]e do not quibble with [Judge Kavanaugh's] general premise—and that of the many legal luminaries he cites—that an agency should generally weigh the costs of its action against its benefits.")

[14] See, e.g., paragraph (a)(5) of 10 CFR 50.109 (the Backfit Rule), which requires the Commission to impose backfits it finds necessary for adequate protection. Note that paragraph (a)(7) of the Backfit Rule, which is phrased in a way that seems to merely allow the consideration of costs when there is more than one way to provide adequate protection of public health and safety or the common defense and security, understates it as an allowance to consider costs as that consideration is mandatory under the APA in such a situation as explained by Judge Kavanaugh in *Mingo Logan*.

[15] "An Approach to Quantitative Safety Goals for Nuclear Power Plants," NUREG-0739, October 31, 1980.

[16] NUREG-0739, Section 2.2, pp. 55-56.

[17] "Elevation of CDF to a Fundamental Safety Goal and Possible Revision of the Commission's Safety Goal Policy Statement," (May 11, 1998) (ML20247F735).

limit," acknowledging that the Safety Goal Policy Statement specifies only a single goal. The ACRS further explained the following:

> An upper limit and a goal define three regions. For risk levels above the upper limit, immediate action should be taken. For risk levels between the upper limit and the goal, the possibility of reducing the estimated metric should be investigated, taking into account costs and benefits. For risk levels below the goal, no action would be required. This approach would be consistent with the "risk-informed" philosophy, which recognizes that risk metrics are only part of the decisionmaking process, but if the value of a risk metric were found to be very large, this would lead to immediate action.[18]

The staff evaluated the ACRS suggestion regarding the structure of the safety goals in SECY-00-0077, concluding that no change to the structure of the safety goals was necessary and stating the following:

> We have evaluated this suggestion, considering a similar structure that already exists in our regulatory framework from the Backfit Rule (10 CFR 50.109). This also essentially identifies three regions, viz., (1) a region governed by 10 CFR 50.109 (a)(4) and (a)(5) in which backfits are required if necessary to ensure adequate protection, (2) a region governed by 10 CFR 50.109(a)(3) in which backfits are allowed if there is a substantial increase in overall protection and the direct and indirect costs are justified in view of the increased protection, or are necessary to bring a facility into compliance with a license or the rules or orders of the Commission, and (3) a region in which backfitting is not allowed because it cannot pass the tests above. The existing Safety Goal Policy Statement has been used in developing the Regulatory Analysis Guidelines, which provide guidance on when and how to conduct regulatory analyses for rulemaking and provide a basis for determining the demarcation where costs no longer justify the benefits.[19]

Codifying the QHOs as suggested by the staff would be a sea change in their use. Rather than a line of demarcation where costs must justify the benefits of a requirement, the QHO's would become a floor for the issuance and maintenance of a license. This would afford them the same status as the level of protection regarded as necessary for the adequate protection of public health and safety or the common defense and security. The staff's draft proposed requirements referencing the QHOs, as proposed for use as safety criteria in § 53.220, would result in a licensee needing to take action to meet those criteria without regard to cost or benefits. Such a sea change would contravene repeated Commission direction to the staff to regulate advanced reactors to the same standards as the current fleet of operating reactors.[20]

In addition to violating the Commission's longstanding policy that advanced reactors should be regulated at the same level as currently operating reactors, codifying the QHOs would present a

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[18] *Id.*

[19] SECY-00-0077, "Modifications to the Reactor Safety Goal Policy Statement," page 8 (footnote omitted) (March 30, 2000) (ML003684288).

[20] See, e.g., SRM-SECY-89-102, paragraph 5), stating "the Commission will not use industry's design objectives as the basis to establish new requirements." (Emphasis in the original.) See also, SRM-SECY-10-0121, SRM-SECY-19-0117, and SRM-SECY-20-0032.

number of practical difficulties. These difficulties range from the near impossibility of continuously demonstrating the maintenance of risk levels below the QHOs to the impracticality of avoiding arbitrariness in selecting assumptions for the risk analysis. Were a shopping mall to be built downwind from an advanced reactor, as suggested by the Chair in the Commission meeting on this proposed rule, the real risk levels would fluctuate based on the time of day the mall is open and whether there are any sales or promotions at a store. However, the precise risk represented in that scenario would be exceedingly difficult to determine in real time with any consistency, accuracy, or confidence. We should not be regulating our licensees by requiring compliance with a constantly shifting standard outside the control of either the agency or the licensee.

My edits to the proposed rule eliminate the codification of the QHOs. Instead, the QHO's should continue to be used in their current capacity, retaining their appropriate use as a gauge of safety significance in our regulatory and licensing processes. As such, they provide a useful tool in the determination of the functional design criteria as approved by the Commission in its action approving the Licensing Modernization Project for use in guidance.[21] Codifying the QHOs in rule text is inappropriate. Staff should remove the QHOs from the proposed part 53.

Design Requirements to Keep Dose as Low as is Reasonably Achievable

The second issue highlighted by the staff is the inclusion of design requirements to keep dose to the public and workers as low as is reasonably achievable (ALARA). The staff justifies this position by citing existing requirements for licensees to keep doses ALARA in part 20 as well as the requirements in § 50.34a for an applicant to identify design objectives to keep levels of radioactive effluents as low as practicable. The staff also cites the issuance of appendix I to part 50 in 1975, including the statement in section I of the 1975 version of appendix I that "[d]esign objectives and limiting conditions for operation conforming to the guidelines of [appendix I] shall be deemed a conclusive showing of compliance with the 'as low as practicable' requirement of 10 CFR 50.34a and 10 CFR 50.36a." Based upon these and various requirements in part 52 related to ALARA programs, the staff proposes in §§ 53.260(b) and 53.270(b) to require a combination of design features and programmatic controls to achieve doses to the public and to workers that are ALARA.

The staff reports that:

> "…[s]ome stakeholders have suggested deleting the ALARA-related requirements in Subpart B, 'Technology-Inclusive Safety Requirements,' and Subpart C, 'Design and Analysis Requirements….' Under such a proposal, the regulatory responsibility to minimize doses to the public and plant workers under ALARA principles would be assigned solely to the holders of operating licenses or combined licenses for commercial nuclear plants under Part 53, through the radiation protection program requirements in [Subpart F,] 'Requirements for Operation,' and the related requirements in 10 CFR Part 20."[22]

[21] "Staff Requirements – SECY-19-0117 – Technology-Inclusive, Risk-Informed, and Performance-Based Methodology To Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors," May 26, 2020.
[22] SECY-23-0021, Enclosure 4, page 12.

Deleting the ALARA requirements is appropriate and matches the treatment of those requirements for currently operating reactors. Doing so also avoids the issue of requiring a designer to develop the operational programs that would be used in conjunction with the design features to meet the ALARA requirements to support a fulsome review. To the extent that ALARA requirements exist in current NRC regulations for designers, they serve the purpose of establishing design objectives that can support the ALARA requirements that must be met by holders of operating licenses or combined licenses for commercial nuclear plants. Those provisions do not require the development of operational programs by the designers that would not gain finality through an NRC design review and certification or have any role in subsequent implementation.[23]

My edits to the proposed rule are intended to clarify that ALARA requirements during the design process are limited to the establishment and use of design objectives for radiation dose. Staff should restrict requirements imposed on designers for ALARA to the use of design objectives.

Inclusion of Requirements for Facility Safety Programs

In § 53.890, "Facility Safety Program," the staff proposes to require licensees under part 53 to adopt and implement a program to identify and implement risk reduction measures based on the availability of new, current, or novel technologies to mitigate or eliminate internal or external hazards. Under § 53.9010, the staff's proposal would make actions under the facility safety program subject to criminal penalties. This means licensees would be required to self-impose safety enhancements under the threat of criminal penalties and without consideration of safety significance or cost benefit, contrary to the requirements of our Backfit Rule.[24] The staff views this proposal as "shift[ing] some of the routine responsibility for assessing new risk insights to licensees" and "provid[ing] flexibility in how licensees consider and address new information within programs such as routine PRA updates versus responding to NRC inquiries and other regulatory actions."[25] The staff, however, fails to include a threshold limiting this requirement or to provide relief from requirements that would effectively duplicate this program. The result is a duplicative, but unlimited requirement prone to subjective oversight and enforcement. As a result, the staff correctly identifies in the draft regulatory analysis that a facility safety program would result in increased costs for the applicant, licensee, and NRC,[26] such that it would be a significant industry cost driver.[27] By contrast, the staff identifies no benefits to be derived from

[23] See section VI, "Issue Resolution," paragraph C, to each design certification appendix in part 52, stating that "The Commission does not consider operational requirements for an applicant or licensee who references this appendix to be matters resolved within the meaning of § 52.63(a)(5). The Commission reserves the right to require operational requirements for an applicant or licensee who references this appendix by rule, regulation, order, or license condition."
[24] Under our regulations in paragraph (e)(1) of 10 CFR 2.202, "Orders," if an order involves the modification of a part 50 license and is a backfit, the requirements of § 50.109, "Backfitting" must be followed unless the licensee has consented to the action required. Similar protections exist for orders involving the modification of part 52 licenses in the remainder of paragraph (e) and have been proposed in that paragraph for orders involving the modification of part 53 licenses. Implementation of a Facility Safety Program as suggested by the staff would avoid these protections by mandating that the licensees inform the NRC of potential safety enhancement measures. Such a communication from a licensee could be interpreted as an expression of consent to the changes, thereby evading the need to consider cost.
[25] SECY-23-0021, Enclosure 4, page 15.
[26] SECY-23-0021, Enclosure 3, "Draft Regulatory Analysis," appendices B and C.
[27] SECY-23-0021, Enclosure 3, Section 5.1, "Industry Operation."

the draft proposed requirement. This alone should end any consideration of proposing such a requirement.

In addition to imposing costs without yielding any benefits, the establishment of a facility safety program would be a delegation of the responsibilities of the regulator to a licensee to propose new requirements for a facility, thereby potentially establishing "consent," without the authority to determine whether the new requirements are justified. Furthermore, the agency maintains internal programs for assessing external hazards as necessary for any resulting risk increases, subject to safety significance and cost benefit analysis under our Backfit Rule.[28] I find that the separation of these responsibilities from the necessary authority is particularly inappropriate when coupled with the potential for imposition of criminal penalties. Staff should remove the facility safety programs from the proposed part 53.

As drafted, the proposed part 53 already includes provisions corresponding to those in parts 50 and 52 for addressing operating and construction experience.[29] The addition of a facility safety program to these programs would be inconsistent with the Commission's reaffirmation in SRM-SECY-10-0121, quoted in SECY-23-0021, enclosure 4, "that the existing safety goals, safety performance expectations, subsidiary risk goals and associated risk guidance (such as the Commission's 2008 Advanced Reactor Policy Statement and Regulatory Guide 1.174), key principles and quantitative metrics for implementing risk-informed decision making, are sufficient for new plants."[30] (Footnotes omitted.) The sole gap is whether part 53 should include a requirement for a design experience program. Staff should address this gap in subpart C to the proposed part 53.

Provisions for Generally Licensed Reactor Operators

In draft proposed subpart F to part 53, the staff proposes a variety of provisions for the use of a general license for reactor operators at facilities that meet appropriate criteria. In addition, subpart F includes the licensing provisions for reactor operators and senior reactor operators for designs not meeting the criteria for the use of a general license.

The staff considered several alternatives proposed by stakeholders in this area, including (1) eliminating the general license and licensing reactor operators and senior reactor operators under part 53, (2) eliminating the general license part 53, shifting it to part 55, and licensing reactor operators and senior reactor operators under part 55, and (3) eliminating the general license and licensing reactor operators and senior reactor operators under part 55 coupled with the use of exemptions to address facilities for which a general license would have been used.

I agree with the staff that the draft proposed general license provisions in subpart F to part 53 can address power reactor designs that may not warrant the regulatory burden and attendant costs associated with a traditional operator licensing program. I also agree that part 53 is an appropriate location to propose those provisions. However, I find the ACRS recommendation that "the associated guidance for implementing 10 CFR Part 55 can be amended to

[28] See footnote 24.
[29] See § 50.34(f)(3)(i) as compared to §§ 53.610(a), 53.620, 53.715, and 53.730.
[30] SECY-23-0021, Enclosure 4, page 2.

accommodate the objectives of the proposed rule without the additional voluminous text"[31] to be quite persuasive.

Many of the provisions for the processes of the traditional operator licensing program that have been included in the draft proposed part 53 duplicate longstanding provisions included in part 55. One result of this inclusion in the draft proposed part 53 was the need to define the terms "licensee" and "applicant," for example, differently in this portion of part 53 from the remainder to refer to reactor operator and senior reactor operator licensees and applicants. This can result in unnecessary confusion when the terms refer to facility licensees and applicants in the remainder of part 53. There are certain elements for operator licensing that would need to be different for non-light-water reactor facilities than those that are included in part 55, though.

I believe that the best approach to eliminate the potential for confusion would be to rely on the processes of licensing included in part 55 with the use of training, examination, and proficiency programs implemented under part 53 in lieu of those specified in part 55. This will also allow unifying the conditions on licenses for reactor operators and senior reactor operators with respect to things such as the prohibition on consumption of alcoholic beverages within the protected area of commercial nuclear plants (under part 53), the protected area of power reactors (under part 50 or 52), or the controlled area of non-power reactors (under part 50). That prohibition is not specific to the facility at which the reactor operator or senior operator is licensed and makes more sense to unify in a single requirement.

Staff should rely on the longstanding process for a traditional operator licensing program in part 55 using the training, examination, and proficiency programs for specifically licensed operators in part 53. Staff should retain the provisions for general licensing of reactor operators in part 53.

Consideration of "Beyond-Design-Basis Events" (BDBEs)

Historically, the Commission and its predecessor the Atomic Energy Commission have, on occasion, had to address events for which regulatory action was justified after consideration of the design bases for nuclear power plant types. These types of events have been addressed by a variety of different approaches using equipment qualified to various standards as appropriate to their risk significance. The guidance for the licensing modernization project unfortunately used the terminology generally recognized to describe those types of events, that is "beyond-design-basis events" or "BDBEs," to identify categories of events by their frequencies. Events in that category use different terminology in part 53 but are otherwise consistent with the licensing modernization project methodology approved in SRM-SECY-19-0171.

[31] ACRS Letter Report, "Fourth Interim Letter on 10 CFR Rulemaking Language," August 2, 2022 (ML22196A292), stating "the present operator licensing process using 10 CFR Part 55 and associated NUREGs has proven to reliably provide highly consistent and qualified licensed operators. Detailed guidance exists for power reactors (NUREG-1021), research and test reactors (NUREG-1478), and knowledge and abilities catalogues for pressurized water reactors (PWRs) (NUREG-1122), boiling water reactors (BWRs) (NUREG-1123), AP1000 (NUREG-2103) and advanced BWRs (NUREG-2104). New or revised NUREGs applicable to new technologies, such as molten salt reactors and micro reactors, could be established. This scheme is a flexible approach that can tailor the NUREGs to the specific technology without a rule change to 10 CFR Part 55. 10 CFR Part 55 then continues to be the centralized regulation for operator qualifications."

On the other hand, the staff's approach in Framework B,[32] removed from the proposed rule in my edits, would have required an applicant to identify and assess "additional licensing-basis events" beyond those licensing-basis events identified in the design process due to the limitations that might exist. The staff seeks to provide guidance for this draft proposed requirement along with the existing requirements for the determination of licensing events.[33] The current draft version of that guidance recites the regulations applicable to the identification of licensing events. A review of those regulations reveals that there are no existing requirements for the identification of "additional licensing-basis events" for commercial nuclear plants under parts 50 or 52.[34] The staff, however, would provide a single set of regulatory guidance usable under part 50, part 52, or part 53, stating merely that "the licensing framework determines the appropriate licensing event categories, whether development of a PRA will be required, and how the risk insights from the PRA will be used. The choice of licensing framework is a complex decision made by applicants. Accordingly, this [regulatory guide] RG does not provide any associated guidance."[35]

The difficulty with the staff's proposal in Framework B is that it can appear to a layman as a requirement for a designer to identify the errors they might have made in their design that the regulator might eventually determine warrant regulatory action. This impression is strengthened by reference to the staff's decision to not provide guidance on the identification of hypothetical events that would fall into this category. Without a clear definition, it is impossible to determine a basis for determining whether this requirement is safety beneficial and justified. This is not in alignment with the Clarity Principle of Good Regulation: "Agency positions should be readily understood and easily applied." The NRC should not regulate the unknown and establish requirements for an applicant to "bring me a rock." I disapprove the inclusion of requirements for additional licensing-basis events concurrent with the removal of Framework B in its entirety. While the staff should retain its work on Framework B for use in future rulemakings, staff should limit that use to those requirements that meet the Principles of Good Regulation.

Additional Issues Related to Manufacturing Licenses

In Enclosure 4 to SECY-23-0021, the staff discusses the potential for including provisions allowing the holder of a manufacturing license to fuel the manufactured reactor at the factory. The staff, however, did not include regulatory text in the proposed rule to address that need due to the desire to further refine the text. I agree with the staff's identification of the desirable attributes of a rule that would allow this. I have edited the draft proposed rule to include regulatory text to obtain more fulsome input from stakeholders. However, there exists the potential for confusion between the staff's use of the term "manufactured reactor module" and the existing defined terms "modular design" in § 52.2 and "small modular reactor" in § 171.5, neither of which is related to whether a manufactured reactor is being used. To address this, I have substituted the term "fueled manufactured reactor." Staff should publish the proposed rule with provisions to address loading of fuel into a manufactured reactor at the factory. Staff should work with stakeholders to develop regulatory text that would also allow a holder of a

[32] See the draft proposed § 53.4730(a)(5)(iv).
[33] See Draft version of Draft Regulatory Guide (DG-1413), "Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants," ML22257A173 (version 5 in ADAMS dated March 6, 2023 – not yet public).
[34] *Id.*, Table 1.
[35] *Id.*, Section C.4. (Emphasis added.)

manufacturing license to accomplish low-power nuclear physics testing on a fueled manufactured reactor at the factory prior to delivery to the site where it will ultimately be used.

Other Issues

I have made a variety of other edits to the proposed rule for clarity and simplicity, many of which have been documented in the attached table. Several of those edits are worthy of note here as well.

First, in the draft proposed § 53.440(g) and (h), the staff includes provisions to correspond generally with general design criterion (GDC) 27 from appendix A to part 50. The staff has, however, edited the text from GDC 27 to address the issues discussed in SECY-18-0099, "NuScale Power Exemption Request from 10 CFR Part 50, Appendix A, General Design Criterion 27, 'Combined Reactivity Control Systems Capability.'" These edits appear to be based in part on recommendation 3.d from the May 30, 2021, ACRS Letter Report, "Preliminary Proposed Rule Language for 10 CFR Part 53, 'Licensing and Regulation of Advanced Nuclear Reactors,' Interim Report" (ML21140A354). In that letter report, the ACRS recommended that "[t]he rule should state that safety analyses must demonstrate that Design Basis Accidents (DBAs) achieve and maintain a safe, stable, and subcritical condition." While this may sound like a sensible recommendation, this departs from the longstanding provision of GDC 27.[36] This would represent a change is policy despite the Commission's repeated direction to use the same standards for advanced reactors as are used for currently operating reactors.[37]

I have edited the proposed rule text to better match the criterion as it exists for currently operating reactors and applications under review using parts 50 and 52. Should the staff desire to proceed with modifying what is required under GDC 27, or any other GDC, staff should provide a justification that informs the Commission. The staff should also highlight the changes to stakeholders sufficiently to allow for a fulsome consideration of the changes in keeping with the Openness Principle of Good Regulation.

Second, in the draft proposed § 53.870, the staff includes provisions for an integrity assessment program that would include, amongst other things, aging management in the initial period of plant operations. Our regulations for currently operating facilities do not include aging management in the initial period of plant operations because the qualification of the materials used for structures, systems, and components is addressed in initial licensing under part 50 or part 52 through quality assurance. In draft proposed § 53.440(c), the staff includes a design requirement for the materials used for structures, systems, and components to be qualified for their service conditions over the plant lifetime and in draft proposed subpart K, the staff includes a restatement of the quality assurance requirements from appendix B to part 50.

In contrast to this, the staff omits requirements that would correspond to § 50.49, "Environmental qualification of electric equipment important to safety for nuclear power plants." This is apparently based on the perspective that the risk evaluation may be used to determine what special treatment requirements are appropriate for structures, systems, and components,

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[36] *Criterion 27—Combined reactivity control systems capability*. The reactivity control systems shall be designed to have a combined capability, in conjunction with poison addition by the emergency core cooling system, of reliably controlling reactivity changes to assure that under postulated accident conditions and with appropriate margin for stuck rods the capability to cool the core is maintained.

[37] See, e.g., SRM-SECY-89-102.

including the use of a program for qualifying electric equipment similar to those responsive to § 50.49.

I agree with the staff's assessment that special treatment programs such as electric equipment qualification should be derived from the risk evaluation for a plant. Staff should clarify the acceptability under part 53 of guidance for such programs that exists for parts 50 and 52. As far as the need for an integrity assessment program, I believe that need should also come from the risk evaluation for a plant. There are useful elements discussed in the proposed rule with regard to integrity assessment but given the possibility that the NRC could license evolutionary LWR designs under part 53 it does not make sense to assume that there will be novel degradation mechanisms for all applications. In any case, aging management is an issue considered in the period of extended operation for facilities that have renewed licenses and should not be included in the regulations for the initial period of operation. Staff should remove the proposed integrity assessment program from the regulatory text. Staff should address integrity assessment programs in guidance for cases where an applicant's risk evaluation indicates a need for such a program.

Third, the staff proposes to establish a new set of quality assurance requirements in subpart K of part 53. Indeed, the staff's proposal for an additional framework would have included a third set of quality assurance requirements in subpart U. These new sets of quality assurance requirements were nearly identical to those in appendix B to part 50. While there might be some benefit to including the quality assurance requirements in the same part as the other regulations, doing so can have unintended consequences that would need a fuller consideration. For example, with the different section numbering and the changes in wording, it might be necessary for a supplier of safety-related equipment or services to undergo multiple quality assurance audits or more costly ones than is currently the case. In this case, existing suppliers with programs that comply with appendix B to part 50 may determine that it is not in their interests or within their means to implement these changes such that they could provide safety-related equipment or services to part 53 applicants and licensees. We should not take an action lightly that could restrict the supply base for commercial nuclear plants and currently operating reactors. It seems more appropriate to include citations to part 53 and the use of functional design criteria rather than principal design criteria in appendix B to part 50. I have provided edits to accomplish that. Staff should use appendix B to part 50 and the existing body of knowledge of quality assurance, which are both technology-inclusive, for the licensing and regulation of advanced reactors.

Fourth, in its August 2, 2022, letter report,[38] the ACRS stated the following with regard to safety functions:

> The requirement for identifying critical safety functions should be common to both frameworks because both have the same goals. Critical safety functions are fundamental for:
>
> - establishing the facility safety bases,
> - promoting completeness in the processes used to identify initiating events that could challenge the safe operation of the reactor, and

[38] ACRS Letter Report, "Fourth Interim Letter on 10 CFR Part 53 Rulemaking Language" (ML22196A292).

- developing functional or principal design criteria.

To accommodate the range of anticipated designs, Framework A has adopted a flexible approach for identifying critical safety functions. The primary safety function is "limiting the release of radioactive materials," and applicants are allowed to identify supporting safety functions appropriate for their design, such as control of reactivity, heat generation, and chemical reactions. Using the same approach in Framework B would promote regulatory efficiency, clarity, and consistency. The text describing the Framework A approach should be moved to the common section of the rule, so it applies to both frameworks. In addition, the text regarding critical safety functions should be revised in DG-1413.

In response to this recommendation the staff included a definition of the safety functions for the deterministic licensing process under its Framework B but retained the historical process for developing the principal design criteria for a facility using the general design criteria of appendix A to part 50.[39] As a result, the draft proposed rule text included the additional definition that served no purpose in the regulatory framework and would not have promoted regulatory efficiency or clarity. Staff should work with the ACRS to better understand the desired outcomes for its recommendations and implement solutions that contribute to regulatory efficiency.

Physical Security and Emergency Preparedness

The staff appropriately addresses physical security of special nuclear material (SNM) and the interaction of safety and security for advanced reactor technologies beginning in the design process under draft proposed § 53.440(f). This would require a designer to resolve security issues, where possible, through design and engineered safety features. A designer that does so would, of course, benefit from issue finality in this area under proposed § 53.1263 as it would be part of the certification information. This means of addressing security of SNM for microreactors, for example, can greatly benefit the regulatory efficiency of the agency in considering applications for their use. There is, however, a tension between the treatment of the finality of certification information for a certified design and the operational programs for an application referencing the design.[40] I have included edits to the proposed provisions for physical protection programs in proposed § 53.860 to clarify that to the extent that the Commission grants finality to the issue of SNM security in the design certification process, that issue is resolved within the meaning of proposed § 52.1263(a)(5). In addition, these edits clarify that there is no regulatory gap in the area of SNM security for an applicant that does not reference a standard design who addresses the issue by design and engineered safety features rather than through an operational physical protection program.

I note that there is an interaction between this treatment of physical security and the regulations for emergency preparedness. For currently operating reactors and for advanced reactor technologies with physical protection programs, the potential consequences of security-related events are bounded by the spectrum of non-security-related licensing events. This may not be the case for an advanced reactor that addresses security through design and engineered safety features because of the differences between the dose criterion used for that and the dose criteria used for emergency preparedness. Staff should address the consideration of security-

[39] See also RG 1.232, “Developing Principal Design Criteria for Non-Light-Water Reactors,” (ML20091L698).
[40] See footnote 23.

related events for such reactors when it harmonizes this rulemaking with the Final Rule: Emergency Preparedness for Small Modular Reactors and Other New Technologies.

Conclusion

Staff should provide a copy of the final version of the *Federal Register* Notice for the proposed rule to the Commission ten days before its submittal to the Office of the Federal Register for publication.

To better evaluate the usefulness and useability of part 53, staff should engage with stakeholders during the comment period for the proposed rule using tabletop exercises and workshops.

Attachments:

1. Table of Significant Comments and Edits
2. Edited *Federal Register* Notice for the Proposed Rule for publication
3. Red-line strikeout version of the *Federal Register* Notice for the Proposed Rule
4. Table of typographic errors and inconsistencies in the current regulations

Attachment 1 to Commissioner Caputo's Comments on SECY-23-0021, "Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31)"

Table of Significant Comments and Edits

Summary of Commissioner Caputo's Substantive Edits to SECY-23-0021

Affected Section	Comment
Part 50 Appendix B, introductory paragraph, criteria III and IV	I have inserted conforming changes to these portions that would make the existing quality assurance (QA) requirements in part 50 Appendix B applicable to applicants and licensees under 10 CFR part 53. The QA requirements in Subparts K and U of the draft proposed rule for 10 CFR part 53 are nearly identical to the existing requirements in Appendix B. The differences do not warrant establishment of new QA requirements in 10 CFR part 53. Establishing new QA requirements would have unintended, negative consequences on suppliers and service providers with existing QA programs under Appendix B. These unintended consequences could drive difficulties for licensees and applicants for advanced reactors in the supply chain. Subparts K and U should be deleted concurrent with this change.
53.010	I have deleted this section concurrent with the elimination of Framework B. The usable elements of Framework B should be incorporated into future rulemakings for 10 CFR parts 50 and 52 to achieve technology-inclusive rule text in those parts.
53.020	I have moved the definitions for the following terms from § 53.024 to § 53.020 to reflect that 10 CFR part 53 would only consist of a single framework: a*nticipated event sequence*, *construction*, *design basis accidents, design-basis external hazard level, functional design criteria, licensing-basis events, Non-safety-related but safety-significant (NSRSS) structures, systems, and components (SSCs), Non-safety-significant structures, systems, and components (SSCs), safety criteria, special treatment, unlikely event sequences, and very unlikely event sequences.* Section 53.024 would no longer be required with the elimination of the two-framework concept and all definitions can be placed in § 53.020.
53.020	I have edited the definition of *commercial nuclear plant* to reflect that the "commercial" nature of these is not limited to the nuclear reactor and to allow defining the term *nuclear reactor* in the same manner as it is defined in § 50.2. This would avoid introducing another term to the lexicon and necessitating the deeming provision of equivalency between "commercial nuclear reactor" and "nuclear reactor" included in the draft proposed definition for this term.
53.020	I have moved the definition for *severe accident* from § 53.028 to § 53.020 since § 53.024 would no longer be required with the elimination of the two-framework concept and all definitions can be placed in § 53.020.
53.020	I have moved the definitions for the following terms from Subpart F to § 53.020 to centralize definitions for terms that do not need to be limited to one subpart: *generally licensed reactor operator, interaction-dependent-mitigation facility, load following, reference plant, self-reliant-mitigation facility, simulation facility,* and *systems approach to training.*
53.200	I have deleted this section because it does not convey any requirements and is therefore unnecessary. This deletion eliminates potential confusion, ambiguity, and the possibility of conflict with the Atomic Energy Act.

Affected Section	Comment
53.210	Paragraph 53.450(e) has been moved to § 53.220(a) to better reflect that the requirement to identify safety criteria belongs in the section that outlines safety criteria (i.e., in § 53.220) as opposed to the original location related to analysis requirements.
53.220	I have deleted § 53.220(b). This paragraph would have set risk-based limits inappropriately codifying specific cumulative risk numbers from the Commission's Quantitative Health Objectives (QHOs). The deletion is consistent with Commission policy expressed in SRM-SECY-89-0102 and reiterated periodically (see, e.g., SRM-SECY-00-0077 and the Commission's affirmation in "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement" that the "safety goals are intended to be applied generically and are not for plant-specific applications." 60 FR 42622, 42628; August 16, 1995). The use of risk-based regulation is inconsistent with the need to consider costs under the Administrative Procedure Act for all regulatory actions except those necessary for adequate protection of public health and safety.
53.240	I have edited the requirements for identifying licensing basis events (LBEs) to reflect that the proposed requirements in § 53.450 have also been edited to broaden the scope of acceptable analysis methods under 10 CFR part 53 beyond a probabilistic risk assessment.
53.260 & 53.270	I have edited §§ 53.260 and 53.270 to reflect that doses must meet the existing requirements in 10 CFR part 20. This edit ensures that the requirements in 10 CFR part 53 related to dose are consistent with existing requirements used under 10 CFR parts 50 and 52.
53.415	I have replaced the term "constructed" with "man-related" in the context of external hazards that must be considered in the design of safety-related structures, systems, and components. This will avoid a conflict between the term "construction," as defined in § 53.020 and align the language with 10 CFR part 100.
53.425	I have edited the draft proposed requirements in § 53.425 to focus on compliance with a Radiation Protection Program established to meet the requirements of § 53.850.
53.430	I have deleted § 53.430(c) and (d) since these were duplicative of requirements in 10 CFR part 20 that would already be applicable to applicants and licensees under 10 CFR part 53.
53.440	I have deleted paragraph 53.440(a) because it does not express a design requirement, but rather was drafted as a demonstration requirement that duplicates § 53.090(c)(5) (renumbered as § 53.090(d), as edited) requirements for demonstration of the capabilities of design features.

Affected Section	Comment
53.440	I have deleted § 53.440(b) to be consistent with the discussion in the preamble noting that the use of codes and standards in 10 CFR part 53 should be addressed in regulatory guidance as opposed to regulatory requirements. This is reasonable and appropriate since the intent of this rulemaking is to facilitate licensing advanced reactors. For these technologies, consensus codes and standards are not necessarily available, endorsed, or otherwise found acceptable by the NRC. Therefore, requirements related their use should be eliminated. This will avoid an improper delegation of Commission authority to determine what is necessary to meet a requirement to an external body through a dynamic incorporation by reference.
53.440	I have edited § 53.440(g) to align more closely with the existing language in General Design Criterion (GDC) 27 from appendix A to 10 CFR part 50. The draft proposed language in this paragraph was similar to the existing language in GDC 27, but more stringent in that it would have required an applicant to design a reactor that that achieves and maintains a subcritical condition as opposed to “reliably controlling reactivity.” The preamble did not articulate a reason to impose a stricter requirement on advanced reactors. Additionally, the requirement to be capable of achieving and maintaining a subcritical condition for the waste stores does not make sense as it would allow for them to be critical so long as the capability is maintained.
53.440	I have relocated human factors-related design requirements and load following design requirements that were included in the draft proposed requirements in subpart F to §§ 53.440(n) and (o) to reflect that these are design requirements.
53.450	I have edited § 53.450(a) to generalize the 10 CFR part 53 risk evaluation requirements. The draft proposed rule prescribed the use of probabilistic risk assessment (PRA) for meeting the requirements in § 53.450(b). This would have inappropriately reduced the flexibility for applicants and licensees to use alternate methods that could be used to demonstrate compliance with relative technical requirements. Alternate methods can be used to demonstrate an equivalent level of safety. Generalizing the analysis requirements (i.e., modifying the language to require a risk evaluation rather than specifying that a PRA must be used) will allow applicants and licensees to use a spectrum of approaches to demonstrating that a particular reactor design is safe. This is consistent with the approach that will almost certainly be used by most applicants and licensees in that a combination of deterministic and probabilistic methods inherently serves as the most logical means of identifying licensing basis events, classifying structures, systems, and components, and evaluating defense-in-depth. Subsequent application requirements related to risk evaluations have also been modified in subpart H.

Affected Section	Comment
53.450	I have edited § 53.450(c) to reflect the change in analysis type (i.e., probabilistic risk assessment to risk evaluation) and to reduce the prescriptiveness of the requirements to maintain and upgrade the risk evaluation. Existing codes and standards and guidance that have been endorsed by the NRC can be used to facilitate implementing details regarding maintenance and upgrading of these risk evaluations (e.g., Regulatory Guide 1.200, "Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities," and American Society of Mechanical Engineers (ASME)/American Nuclear Society (ANS) Standard ASME/ANS RA-Sa-2009, "Standard for Level 1/Large Early Release Frequency Probabilistic Risk Assessment for Nuclear Power Plant Applications," Addendum A to RA-S-2008).
53.450	I have moved certain draft proposed requirements in § 53.450(e) to Subpart B for a more logical placement amongst the 10 CFR part 53 safety requirements.
53.460	I have deleted § 53.460(c) because the draft proposed language expresses neither a safety categorization nor a special treatment requirement. Human actions are governed under subpart F and analyzed under § 53.450 to meet the appropriate criteria.
53.470	I have deleted § 53.470 in its entirety because there are no operational flexibilities identified in 10 CFR part 53 that would be granted to an applicant or licensee establishing more conservative safety margins. The lack of identified operational flexibilities would result in a need for an exemption to whatever requirement the flexibilities are granted with relation to; these additional margins could be established in the exemption process as a license condition or through some other means.
53.480	I have edited § 53.480(c)(1)(vi) to reflect that the seismic design requirements permitting strain resulting from earthquake ground motion in excess of yield strain should not be limited to safety related (SR) structures, systems, and components (SSCs). The safety functions required by § 53.230 include those needed to meet the safety criteria of § 53.220, which can be satisfied by non-safety related but safety significant SSCs. Therefore, there does not appear to be a reason to limit this permissibility to SR SSCs.
53.530	I have deleted § 53.530(a)(1) because it is essentially identical to § 53.210(a) and is already required to be met under § 53.450(f)(3).
53.530	I have deleted § 53.530(a)(2) because it is essentially identical to § 53.210(b) (with the exception of the footnote) and is already required to be met under § 53.450(f)(3).
53.605	I have deleted § 53.605(4) to reflect that suppliers of basic components would not be subject to the rules in this section, but rather would be required to follow the existing requirements in 10 CFR part 21.
53.610	I have edited this section to eliminate redundant requirements and proposed requirements that are beyond what is required of currently operating reactors.

Affected Section	Comment
53.615	I have added § 53.615(a) as a requirement for the submittal of a final safety analysis report corresponding to the existing condition in § 50.55(d) on construction permits. This places the requirement in the proper position in the life cycle of a commercial nuclear plant as envisioned by the staff in the organization of 10 CFR part 53.
53.620	I have added provisions to § 53.620(b) that would provide optional capabilities for manufacturing license holders to load fuel in a manufactured reactor at a manufacturing facility. Additional requirements for manufacturing license holders opting to exercise this flexibility are included under § 53.620(b) and include provisions for items such as facility staffing, fire protection, and monitoring for criticality accidents. These edits are consistent with original proposals made by the staff during development of the draft preliminary proposed rule text for 10 CFR part 53. I have also added appropriate cross-references to transportation and security requirements under 10 CFR parts 71 and 73, respectively.
53.620	I have moved relevant portions of the draft proposed requirements under § 53.620(f) to a more appropriate location in § 53.610(d) since "acceptance and installation at the site" is reflective of a construction activity. This places the requirement in the proper position in the life cycle of a commercial nuclear plant as envisioned by the staff in the organization of 10 CFR part 53.
53.725	I have edited §§ 53.725 & 53.760 to reflect that the existing requirements for specifically licensed operators (reactor operators and senior reactor operators) in 10 CFR part 55 should be used in lieu of repeating many of the 10 CFR part 55 provisions in 10 CFR part 53. I have included conforming changes to 10 CFR part 55 to reflect these edits have been proposed as part of this vote. I have concurrently deleted the requirements for licensing of these operators that would have been included in §§ 53.765 through 53.795.
53.800	I have edited the draft proposed requirements for classifying self-reliant mitigation facilities to reflect the elimination of Framework B and the associated Alternative Evaluation for Risk Insights methodology. The criterion for classifying a facility as a self-mitigating type has been simplified in § 53.800(a)(1) as that which a risk evaluation has shown demonstrates compliance with the evaluation criteria in §§ 53.210 and 53.220 without reliance on human actions.
53.845	I have deleted § 53.845(b), which would have been redundant to the requirement for administrative controls in the technical specifications that would be required under §§ 53.710(a)(5) and (c)(5) and the controls for non-safety related but safety significant structures, systems, and components under § 53.710(b).

Affected Section	Comment
53.850	I have deleted the draft radiation protection program requirements in § 53.850(a) because they are redundant to the requirements of 10 CFR part 20, which would be made applicable by the conforming changes proposed in § 20.1002. Additionally, its inclusion in subpart F while omitting it from subpart G runs the risk of unintended consequences by conveying that 10 CFR part 20 is made applicable during the operations phase by this section rather than by its own terms and that no radiation protection program is required for a commercial nuclear plant no longer in the operations phase.
53.850	I have deleted the draft requirements related to Offsite Dose Calculation Manuals (ODCMs) in § 53.850(b), which would represent an unnecessary increase in burden when compared to the limited regulatory requirements related to ODCMs in 10 CFR parts 50 and 52. I have similarly deleted the draft requirements related to a Process Control Program in § 53.850(c) since they would represent an unnecessary increase in burden when compared to 10 CFR parts 50 and 52. These draft proposed requirements would be better placed in regulatory guidance.
53.855	I have edited § 53.855 to reflect that the development and implementation of an emergency response plan should take place prior to the operations phase of a commercial nuclear plant. The draft proposed requirement appears to be misplaced due to the limitation of § 50.47(a) that had been included in the draft proposed § 53.855(b), which would prevent issuing a license authorizing operation of the commercial nuclear plant without the emergency response plan. As a result, the development of the plan, which is the sole proposed requirement in this paragraph, would have taken place prior to the operation phase that is the subject of this subpart.
53.860	I have edited § 53.860(a) to reflect that the requirement, as drafted, would have required a licensee to develop, implement, and maintain a physical security program under 10 CFR part 73 regardless of the outcome of the analysis in § 53.860(a)(2)(ii) with respect to the criterion in § 53.860(a)(2)(i). The proposed edits to this paragraph make the need for development, implementation, and maintenance of a physical security program under 10 CFR part 73 contingent on the status of the optional analysis with respect to the criterion.
53.865	I have edited § 53.865 to use 10 CFR part 50 appendix B for the quality assurance program (QAP) requirements concurrence with the deletion of subpart K. The edits to the QAP requirements in 10 CFR part 53 will avoid the unintended consequences of establishing new QAP requirements in subpart K that are nearly identical to those in 10 CFR part 50 appendix B. Use of the latter would ensure minimal to no impacts to the existing commercial nuclear plant infrastructure for equipment and services covered by 10 CFR part 50 appendix B. I have also deleted the second sentence of § 53.865, which was more prescriptive than the requirements in 10 CFR parts 50 or 52. In addition, that sentence would have been an improper incorporation by reference of unnamed codes and standards in the regulations.

Affected Section	Comment
53.870	I have deleted the draft requirements for developing, implementing, and maintaining an integrity assessment program under this section. In particular, the aging management element of the draft proposed program would impose requirements on advanced reactors during the initial term of operation. This is an additional imposition on advanced reactors in this part that does not exist in 10 CFR parts 50 or 52 and is therefore in conflict with Commission direction to regulate advanced reactors no more strictly than currently operating reactors. I have also deleted the related application requirements for the integrity assessment program from subpart H.
53.880	I have deleted requirements for the use of generally accepted consensus codes and standards from § 53.880(a). The use of generally accepted consensus codes and standards should be addressed in guidance or identified with sufficient specificity in the rule to meet the Office of the Federal Register requirements for incorporation by reference in the regulations. Further, as drafted, this paragraph would require inclusion of all inspections and tests required by the codes and standards used in the design without regard to any limitations and conditions the NRC determines necessary for those codes and standards to be acceptable. I have deleted the final sentence of § 53.880(a) regarding the documentation of an inservice inspection and inservice testing program and the qualifications of those responsible for the management of the program as this level of prescriptiveness if not currently imposed in 10 CFR parts 50 or 52. I have moved the draft proposed requirement in § 53.880(b) for the provision of sufficient room and support for inservice inspection and inservice testing activities to § 53.440(p) since this is a requirement that should be considered in design and not operations. This places the requirement in the proper position in the life cycle of a commercial nuclear plant as envisioned by the staff in the organization of 10 CFR part 53. I have deleted the draft proposed requirements in § 53.880(b) related to providing the results of inservice inspection and inservice testing activities to the plant manager. The allocation of responsibilities to particular individuals in the organization of the commercial nuclear plant is prescriptive and should be left to the licensee to decide as a part of their inservice inspection and inservice testing program or QAP development.
53.890	I have deleted the draft proposed requirements in § 53.890 regarding a facility safety program. This program is a new regulatory requirement that is not imposed on the currently operating fleet of reactors under 10 CFR parts 50 or 52. Further, the regulatory analysis provided with the draft proposed rule indicates that the program would provide no benefit to a licensee. Rather, the licensee would only incur costs as a result of implementing the program which calls into question why it was included in the draft proposed rule. Subsequent application requirements related to the facility safety program have also been deleted in subpart H.

Affected Section	Comment
53.910	I have deleted the draft proposed requirements for procedures and guidelines in § 53.910. This section duplicates requirements from a variety of other places, including but not limited to appendix B to 10 CFR part 50, subpart F of the draft proposed 10 CFR part 53, and administrative controls in technical specifications. The need for this type of listing, which does not attempt to be comprehensive in this draft section, should be addressed in regulatory guidance.
53.1030	The draft proposed requirement in § 53.1030 for annual adjustment factors used in determining decommissioning cost estimates would not set a generic adjustment factor. Instead, it would set a minimum adjustment factor because of the use of the phrase "must be at least." The corresponding wording used in § 50.75(c)(2) is similar to this wording but distinct because it does not identify anything as a "generic adjustment factor" but instead merely sets a minimum for adjustment factors to use. I have edited this section to address this issue.
53.1030	I have deleted the draft requirements for developing a site-specific decommissioning cost estimate in § 53.1030(a) because they exceed the requirements imposed on currently operating reactors under the parallel requirements in § 50.75. These considerations should be placed in regulatory guidance.
53.1040	I have moved § 53.1045(b) to § 53.1040(g) (new paragraph) because the subject requirements are required terms of prepayment or external sinking fund arrangements rather than limitations on uses of the funds. I have similarly moved § 53.1045(c) to § 53.1040(h) (new paragraph) for the same reason. I have moved § 53.1045(d) to § 53.1040(i) (new paragraph) because the subject requirements are required terms of trusts rather than limitations on uses of the funds.
53.1070	I have deleted the draft proposed requirements for defueled technical specifications in § 53.1070(a)(2). The draft proposed requirements appear to be sensible to expect a licensee to take but are not required under 10 CFR parts 50 or 52. The draft proposed requirements should instead be moved to regulatory guidance. I have moved the draft proposed requirements regarding staffing for a decommissioned commercial nuclear plant in § 53.1070(a)(3)(ii) to § 53.1075 for a more logical placement among programmatic requirements for commercial nuclear plants undergoing decommissioning.
53.1120	I have deleted § 53.1120 in its entirety since it is redundant to the existing requirements in § 50.11, with conforming edits to refer to part 53.
53.1124	I have edited the draft proposed requirements for the relationships between construction permits, operating licenses, and combined licenses and standard design approvals and standard design certifications to more simply and succinctly state the restrictions between these license types.

Affected Section	Comment
53.1221	I have deleted § 53.1221(d) because there are no parallel information requirements in 10 CFR part 52 for standard design approvals; these only exist for applications that reference standard design certifications. Further, there does not appear to be a need for this due to the provisions of § 53.1221(b) that limit the effects on the authority of the Commission with respect to such applications.
53.1239	I have edited the prefatory text to § 53.1239 related to application documentation to match that of the existing requirements in the prefatory text to § 52.47. As drafted, this provision would require the preparation of procurement specifications and other such documents by the standard design certification applicant prior to submittal of an application. This is a more stringent standard than in 10 CFR part 52, which only requires the provision of the information that would be contained in such documents, which would be expected to be prepared by the combined license applicant rather than the standard design certification applicant.
53.1251, 53.1254, 53.1257, & 53.1260.	I have deleted §§ 53.1251(a) and (b) to reflect that standard design certifications would not expire (indefinite duration). Elimination of the duration of a standard design certification would reduce unnecessary regulatory burden on applicants and save Commission resources. Because of these changes, I have also deleted §§ 53.1254, 1257, and 1260 as unnecessary.
53.1279	I have included § 53.1279(d) as part of this vote to provide proposed requirements for manufacturing license applicants that may elect to load fuel into a manufactured reactor at a manufacturing facility. These proposed requirements are consistent with those previously discussed by the staff during development of the draft preliminary proposed rule text.
53.1309	I have edited the construction permit application requirements for emergency preparedness to align with the requirements of § 50.34(a)(10) in light of the reliance on appendix E to 10 CFR part 50 and § 50.47 in § 53.855
53.1369	I have added §§ 53.1369(b), (c), and (d) to clarify the requirements for operating license applicants that reference early site permits, standard design certifications, and standard design approvals. The proposed paragraphs have been modeled after those that were proposed for combined license applications in § 53.1416.
53.1455	I have added § 53.1455(b) regarding the completion date for a combined license to parallel the § 50.55(b) condition for construction delays under a combined license that is recognized under § 50.100.
53.1550	I have edited the evaluation criteria in § 53.1550(a)(2) to align with the criteria in § 50.59(b)(2) and avoid imposing tighter regulatory controls on changes for licensees under 10 CFR part 53 than exists for licensees under 10 CFR parts 50 and 52 (i.e., the need for amendments based on comparison to the QHOs). This will also align with the guidance under development for change control screening and evaluation for licensees electing to use the Licensing Modernization Project approach under 10 CFR parts 50 and 52.
53.1710	This section has been deleted, consistent with the proposed deletion of § 53.1730 (see below).

Affected Section	Comment
53.1710, & 53.1730	I have deleted these sections as unnecessary. The requirements of 10 CFR part 140 are self-executing on applicants for and holders of licenses to operate nuclear reactors and would be extended to cover 10 CFR part 53 by this rulemaking. Compliance with 10 CFR part 140 is an element of the necessary findings for an operating license applicant under § 53.1387 and is an area of review for combined license applicants under § 53.1422. 10 CFR part 53 should require no further notice than 10 CFR parts 50 and 52 and there is no corresponding requirement in this area in either.
Subpart K	I have deleted subpart K in its entirety. Conforming changes have been proposed in this vote that would require applicants and licensees under 10 CFR part 53 to use the existing quality assurance program requirements in appendix B to 10 CFR part 50. These conforming changes have been proposed in this vote to avoid the unintended consequences of establishing new quality assurance program requirements that are essentially identical to those already used throughout the nuclear industry. These unintended consequences would include a likely reduction in the number of equipment and service providers available to applicants and licensees under 10 CFR part 53. Edits have been made throughout the rule text to reflect deletion of subpart K and the proposed use of appendix B to 10 CFR part 50.

Attachment 2 to Commissioner Caputo's Comments on SECY-23-0021, "Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31)"

Edited Federal Register Notice for the Proposed Rule for Publication

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 1, 2, 10, 11, 19, 20, 21, 25, 26, 30, 40, 50, 51, 53, 55, 70, 72, 73, 74, 75, 95, 140, 150, 170, and 171

[NRC-2019-0062]

RIN 3150-AK31

Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to revise the NRC's regulations by adding a risk-informed, performance-based, and technology-inclusive regulatory framework for commercial nuclear plants in response to the Nuclear Energy Innovation and Modernization Act (NEIMA). The NRC plans to hold a public meeting to promote full understanding of the proposed rule and facilitate public comments.

DATES: Submit comments by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking website:** Go to https://www.regulations.gov and search for Docket ID NRC-2019-0062. Address questions about NRC dockets to Dawn Forder; telephone: 301-415-3407; e-mail: Dawn.Forder@nrc.gov. For technical questions

contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic e-mail reply confirming receipt, then contact us at 301-415-1677.
- **Fax comments to:** Secretary, U.S. NRC at 301-415-1101.
- **Mail comments to:** Secretary, U.S. NRC, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Robert Beall, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-3874; email: Robert.Beall@nrc.gov; or Jordan Hoellman, Office of Nuclear Reactor Regulation, telephone: 301-415-5481; email: Jordan.Hoellman2@nrc.gov. Both are staff of the U.S. NRC, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

EXECUTIVE SUMMARY:

A. Need for the Regulatory Action

On January 14, 2019, the President signed NEIMA into law (Pub. L. 115-439). NEIMA section 103(a)(4) directs the NRC to "complete a rulemaking to establish a technology-inclusive, regulatory framework for optional use by commercial advanced nuclear reactor applicants for new reactor license applications." NEIMA defines a

"technology-inclusive regulatory framework" as one that is "developed using methods of evaluation that are flexible and practicable for application to a variety of reactor technologies, including, where appropriate, the use of risk-informed and performance-based techniques." NEIMA defines the term ''advanced nuclear reactor" as "a nuclear fission or fusion reactor, including a prototype plant (as defined in sections 50.2 and 52.1 of title 10, Code of Federal Regulations (as in effect on the date of enactment of this Act)), with significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of this Act, including improvements such as—

(A) additional inherent safety features;

(B) significantly lower levelized cost of electricity;

(C) lower waste yields;

(D) greater fuel utilization;

(E) enhanced reliability;

(F) increased proliferation resistance;

(G) increased thermal efficiency; or

(H) ability to integrate into electric and nonelectric applications."

The NRC initially considered establishing the scope of proposed part 53, "Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants," of title 10 of the *Code of Federal Regulations* (10 CFR) as being for "advanced nuclear plants" consisting of one or more "advanced nuclear reactors" as defined in NEIMA. Based on public discussions on the use of the term, the NRC determined that the NEIMA definition, although broad, did not define "significant improvements" with enough specificity to implement in NRC regulations. Additionally, a number of stakeholders suggested that the descriptor, "advanced," implied enhanced safety, while the NEIMA definition includes improvements in areas other than safety enhancements. In response

to this feedback, and to be technology inclusive, the NRC staff determined that the broader term “commercial nuclear plant” would be preferable.

The current application and licensing requirements in 10 CFR part 50, “Domestic Licensing of Production and Utilization Facilities,” and 10 CFR part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” were primarily developed to address license requests concerning water-cooled reactors, and to address operational requirements for those types of reactors. This rulemaking responds to NEIMA by creating an alternative regulatory framework for licensing future commercial nuclear plants. The new alternative requirements and implementing guidance would adopt technology-inclusive approaches and use risk-informed and performance-based techniques to ensure an equivalent level of safety to that of operating commercial nuclear plants while providing flexibility for licensing and regulating a variety of technologies and designs for commercial nuclear reactors.

B. Major Provisions

Major provisions of this proposed rule, supported by accompanying guidance, include the following:

- A new alternative technology-inclusive, risk-informed, performance-based framework that includes requirements for licensing and regulating nuclear plants during the various stages of their life cycles.
- A new alternative technology-inclusive, risk-informed, and performance-based framework in 10 CFR part 26, “Fitness for Duty Programs” developed from existing requirements in subpart K, “FFD Programs for Construction,” of part 26.
- A new alternative technology-inclusive and performance-based security framework in 10 CFR part 73, “Physical Protection of Plants and Materials” that includes requirements for protection of licensed activities at commercial nuclear plants.

C. Costs and Benefits

The NRC prepared a draft regulatory analysis to determine the expected quantitative costs and benefits of this proposed rule and associated guidance as well as qualitative factors to be considered in the NRC's rulemaking decision. The conclusion from the analysis is that this proposed rule and associated guidance would result in net averted costs to the industry and the NRC ranging from $ 22.0 million using a 7-percent discount rate to $ 31.9 million using a 3-percent discount rate, using an assumption of one applicant. As the number of applicants increases, so do the estimated averted costs.

The draft regulatory analysis also considered qualitative factors, such as greater regulatory stability, predictability, and clarity to the licensing process. These benefits would result from incorporating advances in probabilistic risk assessment (PRA) and other risk-informed analyses. Another qualitative factor is promoting a performance-based regulatory framework that specifies requirements to be met and provides flexibility to an applicant or licensee regarding the information or approach needed to satisfy those requirements.

For more information, please see the draft regulatory analysis (available in the NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML21165A112).

TABLE OF CONTENTS:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2019-0062 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- **Federal Rulemaking website:** Go to https://www.regulations.gov and search for Docket ID NRC-2019-0062.
- **NRC's ADAMS:** You may obtain publicly available documents online in the ADAMS Public Documents collection at https://www.nrc.gov/reading-rm/adams.html. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by e-mail to pdr.resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in section XIX, "Availability of Documents."
- **NRC's PDR:** You may examine and purchase copies of public documents at the

NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include **Docket ID NRC-2019-0062** in your comment submission. To facilitate NRC review, please distinguish between comments on the proposed rule and comments on the proposed guidance. The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at https://www.regulations.gov as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

A. NRC Advanced Reactor Readiness

In its "Policy Statement on the Regulation of Advanced Nuclear Power Plants," dated July 8, 1986, the Commission stated that it considered the term "advanced" to apply to reactors that are significantly different from current (i.e., current in 1986) generation LWRs then under construction or in operation, and that "advanced" includes reactors that provide enhanced margins of safety or utilize simplified inherent or other innovative means to accomplish their safety functions. At the time, certain high temperature gas-cooled reactors, liquid metal reactors, and LWRs of innovative design

were considered to be “advanced.” The 1986 policy statement provided the Commission’s policy regarding the review of, and desired characteristics associated with, advanced reactors. The NRC updated this statement in the “Policy Statement on the Regulation of Advanced Reactors,” dated October 14, 2008 (Advanced Reactor Policy Statement).

The agency has undertaken many activities related to advanced reactors, including issuing an advance notice of proposed rulemaking titled, “Approaches to Risk-Informed and Performance-Based Requirements for Nuclear Power Reactors,” dated May 4, 2006 (71 FR 26267). These efforts were often done in parallel, and sometimes interwoven, with the NRC’s efforts to improve risk-informed and performance-based approaches within the agency (e.g., the Commission’s policy statement, “Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities,” dated August 16, 1995 (PRA Policy Statement)).

In 2016, the NRC issued “NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light-Water Mission Readiness” (Advanced Reactor Vision and Strategy Document), in response to increasing interest in advanced reactor designs. The NRC considered the Department of Energy’s (DOE) advanced reactor deployment goals in developing the Advanced Reactor Vision and Strategy Document. Since publication of the document, the NRC continues to manage its activities to support the DOE’s deployment goals. The Advanced Reactor Vision and Strategy Document identified initiating and developing a new risk-informed, performance-based, and technology-inclusive regulatory framework as a possible long-term goal. However, the NRC staff’s initial efforts were focused on resolving policy issues and developing guidance for licensing non-LWR technologies under the existing regulatory frameworks (parts 50 and 52). The NRC staff issues annual Commission papers on the status and

progress of the NRC staff's activities related to advanced reactors (e.g., SECY-22-0008, "Advanced Reactor Program Status," dated January 31, 2022). These Commission papers provide status updates for advanced reactor activities undertaken both prior to and after initiation of this rulemaking.

In 2017, the NRC staff prioritized activities to support the development of technology-inclusive, risk-informed, and performance-based licensing approaches that could be implemented under the existing regulatory framework in parts 50 and 52. One key element of these efforts was the Licensing Modernization Project (LMP), a cost-shared initiative led by nuclear utilities and supported by DOE. The LMP is a technology-inclusive, risk-informed, and performance-based methodology developed for non-LWR designs. The LMP provides a systematic and reproducible process for licensing-basis event (LBE) selection and evaluation; classification of structures, systems, and components (SSCs); and assessment of defense in depth. The LMP refined the DOE's Next Generation Nuclear Plant Program methodologies to reflect interactions with the NRC, to address feedback from industry, and to broaden the scope of the approach to ensure applicability to various non-LWR technologies. The LMP activities led to the publication and submittal of Nuclear Energy Institute (NEI) 18-04, Revision 1, "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," issued August 2019. NEI 18-04 indicates that controlling the frequencies and potential consequences of a wide spectrum of events is the primary focus of the LMP approach.

The NRC staff sought Commission approval of the use of LMP and NEI-18-04 in SECY-19-0117, "Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors," dated December 2, 2019.

In that paper, the staff described the relationship between the LMP and NEI-18-04 and previous relevant Commission decisions, including those described in SECY-93-092, "Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and their Relationship to Current Regulatory Requirements," dated April 8, 1993. The Commission approved the use of the LMP methodology and NEI-18-04 as a reasonable approach for establishing key parts of the licensing basis and content of applications for licenses, certifications, and approvals for non-LWRs in Staff Requirements Memorandum (SRM) SRM-SECY-19-0117, dated May 26, 2020. Although the LMP approach is technology-inclusive, the industry and NRC staff initially focused the LMP's applicability on non-LWRs, both for efficiency and to support near-term non-LWR applications under the existing regulatory framework, such as the Advanced Reactor Demonstration Projects supported by DOE. The NRC endorsed the principles and methodology in NEI 18-04, with clarifications, in RG 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors."

As stated in the part 53 rulemaking plan, SECY-20-0032, the NRC staff developed part 53 by building upon recent and ongoing activities such as the LMP approach described in SECY-19-0117. Such an approach supports implementing the NEIMA requirement to use, where appropriate, risk-informed and performance-based techniques, and it also capitalizes on previous initiatives by the industry, DOE, and the NRC, including the LMP. The approach highlights the role of risk evaluation in risk-informed and performance-based approaches to identifying enhanced safety margins that can be used to justify operational flexibilities. The proposed framework is

largely based on the methodology described in SECY-19-0117 and facilitates a prominent role for PRA.

As discussed in section II.B, “Stakeholder Views on Part 53 Preliminary Proposed Rule Language,” of this document, the NRC conducted extensive public outreach on early versions of the rule text. Those early versions provided an approach to licensing that became the basis for the proposed rule. However, stakeholders indicated that some designers might find the role of PRA contemplated by initial versions of the rule unduly restrictive, either because of the simplified scope of their designs or because their business plans contemplated marketing in countries that would require a different, more deterministic, safety analysis. In light of these stakeholder views, the NRC revised the initial discussion drafts of the proposed rule to be a higher level requirement that would not require a PRA to be used to the extent contemplated initially. Instead, the proposed rule would require applicants to use a risk evaluation such as a PRA or an alternative evaluation for risk insights (AERI).

B. Stakeholder Views on Part 53 Preliminary Proposed Rule Language

In SRM-SECY-20-0032, the Commission directed the NRC staff to prepare and release preliminary proposed rule language, followed by public outreach and dialogue, and then further revise the language until the NRC staff had established the rudiments of its proposed rule for Commission consideration. To implement the Commission’s direction, the NRC staff undertook an unprecedented program of stakeholder engagement, recognizing the importance of this rulemaking to the advanced reactor community and interested stakeholders from a broad range of backgrounds and organizations.

On November 6, 2020, the NRC published a *Federal Register* notice (85 FR 71002) describing plans for the periodic release of preliminary proposed rule language,

meetings with stakeholders, and the ability of stakeholders to provide input during the development of this proposed rule. Sections of the preliminary proposed rule language were subsequently released, and the NRC held numerous public meetings to discuss the preliminary proposed rule language and obtain input from stakeholders. On December 10, 2021, the NRC published a second *Federal Register* notice (86 FR 70423) announcing that the development of the proposed rule and related interactions with stakeholders were being extended until August 31, 2022.

By the close of the public stakeholder interactions on August 31, 2022, the NRC staff had held 24 public meetings since September 2020. The NRC staff also met with the Advisory Committee on Reactor Safeguards (ACRS) in 16 public meetings during this period. By the close of the public engagement period on the preliminary proposed rule language, 126 letters were received on the preliminary proposed rule language. Of these 126 letters, 21 were from non-governmental organizations, 31 were from the public, one was from Congress, and the remaining 73 letters were from NRC licensees, the NEI, and other industry groups. The letters from stakeholders provided various points of view and suggestions for clarifications, additions, and deletions to the preliminary proposed rule language. In addition, the ACRS wrote four interim letter reports to the Chair on this rulemaking and issued its final letter report on November 22, 2022. Copies of these letters may be viewed and downloaded from the Federal Rulemaking Web site *http://www.regulations.gov,* under docket number NRC–2019–0062. The inputs received were considered in the development of this proposed rule. However, as described during the various public interactions related to this rulemaking and in supporting documents, the NRC will not formally disposition the questions and suggestions related to the preliminary proposed rule language as it will for public comments received following the publication of this proposed rule.

III. Discussion

A. Objective and Applicability

The NRC is proposing to add a new, alternative part to its regulations that would set out a risk-informed, technology-inclusive framework for the licensing and regulation of commercial nuclear plants. This new approach would achieve the following: (1) continue to provide reasonable assurance of adequate protection of public health and safety and the common defense and security; (2) promote regulatory stability, predictability, and clarity; (3) reduce requests for exemptions from the current requirements in parts 50 and 52; (4) establish new requirements to address non-LWR technologies; (5) recognize technological advancements in reactor design; and (6) credit the possible response of some designs of commercial nuclear plants to postulated accidents, including slower transient response times and relatively small and slow release of fission products. The proposed rule would add 10 CFR part 53; subpart M, "Fitness for Duty Programs for Facilities Licensed Under 10 CFR Part 53," of part 26; § 73.100, "Technology-inclusive requirements for physical protection of licensed activities at commercial nuclear plants against radiological sabotage," § 73.110, "Technology-inclusive requirements for protection of digital computer and communication systems and networks," and § 73.120, "Access authorization program for commercial nuclear plants," and make conforming changes throughout 10 CFR chapter I, "Nuclear Regulatory Commission."

B. Need for Changes to the Existing Regulatory Framework

The NRC has long recognized that the licensing and regulation of a variety of nuclear reactor technologies would present challenges because the existing regulatory framework has evolved primarily to address the LWR designs that compose the current operating fleet (widely referred to as Generation II reactors). The NRC has had many

interactions with designers of various reactor technologies under development, sometimes collectively referred to as advanced reactors (widely referred to as Generation III/III+ (i.e., evolutionary light-water) and Generation IV (i.e., non-light-water) reactors). The interactions have informed the development of policies and guidance to support the potential licensing of new and different types of reactor facilities, some of which may not utilize LWR designs. The NRC issued its Advanced Reactor Policy Statement to provide all interested parties, including the public, with the Commission's views concerning the desired characteristics of advanced reactor designs. The NRC further described its early efforts to establish a technology-inclusive approach to the regulation of nuclear reactors in the advance notice of proposed rulemaking published in 2006. The NRC acknowledged in its "Report to Congress: Advanced Reactor Licensing," issued August 2012, that while the safety philosophy inherent in the current regulations applies to all reactor technologies, the specific and prescriptive aspects of those regulations clearly focus on the current fleet of LWR facilities.

Congress similarly recognized the potential benefits of developing a regulatory infrastructure to support the development and commercialization of advanced nuclear reactors. Consequently, Congress passed NEIMA in late 2018, and the President signed it into law in January 2019. NEIMA directed the NRC to undertake a rulemaking to establish a technology-inclusive regulatory framework for optional use by applicants for new commercial nuclear reactors.

The requirements in part 53 would support a wide variety of potential commercial nuclear reactor technologies. As noted in this discussion, the current regulatory framework in parts 50 and 52 evolved in the context of the current operating reactor fleet dominated by LWRs and as a result includes provisions specific to LWR technologies. While the NRC can license other reactor technologies under the current framework by

using existing regulatory flexibilities and the exemption process, there is significant interest in developing a regulatory framework that is flexible enough to accommodate multiple technologies and robust enough to ensure a level of safety equivalent to parts 50 and 52, consistent with the Commission's Advanced Reactor Policy Statement. The Commission reiterated its safety expectations for new reactors in the SRM for SECY-10-0121, "Modifying the Risk-Informed Regulatory Guidance for New Reactors," dated March 2, 2011:

> Because new plant designs incorporate operating experience from current generation reactors, severe accident research, and risk insights from design probabilistic risk assessments, the Commission expects that the advanced technologies incorporated in new reactors will result in enhanced margins of safety. However, the Commission continues to expect (consistent with the 2008 Advanced Reactor Policy Statement), as a minimum, at least the same degree of protection of the public and the environment that is required for current-generation light-water reactors. New reactors with these enhanced margins and safety features should have greater operational flexibility than current reactors.

However, developing a regulatory framework that can accommodate a wide range of technologies while maintaining an acceptable level of safety presents significant regulatory challenges. The existing regulations have been developed over the course of decades and reflect changes to address events discovered through operating experience. In contrast, part 53 is being developed to accommodate technologies that, in some cases, lack significant operating experience. To address these challenges, the NRC drew on well-developed approaches to licensing to produce a regulatory framework that is risk-informed and performance-based, part 53. This new part would provide options for the use of risk assessment techniques and design approaches in establishing licensing basis information. The proposed regulatory part would provide a framework that can support the LMP, which is a technology-inclusive approach to licensing that leverages insights from a detailed PRA to provide applicants with significant design and operation flexibilities.

This rulemaking consists of several major components, including a new part, part 53, to be added to 10 CFR, revisions for part 26 and part 73, and conforming changes throughout 10 CFR chapter I.

Proposed part 53 is organized to provide high-level performance criteria and to specify requirements to demonstrate compliance with those performance criteria throughout major stages of the life cycle of commercial nuclear plants. This organization reflects a systems-engineering style approach to the design, licensing, operation, and ultimately decommissioning of future commercial nuclear plants. Organizing requirements in this manner also supports performance-based approaches. Required programs (e.g., radiation protection) and monitoring (e.g., technical specification (TS) surveillance) during the operations phase that are similar to those required by part 50 would complement the design and analysis requirements in subpart C. The performance-based approach proposed in part 53 also includes regulatory requirements that would allow applicants to use a flexible and graded approach to the performance of safety functions based on the role of a particular SSC, human action, or program in limiting the risk of an immediate threat to public health and safety or maintaining the overall risks to the public below accepted standards through balanced measures to prevent and mitigate possible events.

Proposed subpart M of part 26 would be new. The requirements in proposed subpart M would be largely consistent with the objective-based fitness for duty (FFD) requirements in current subpart K, "FFD Programs for Construction," of part 26 supplemented by select requirements from subparts A through I, N, and O of part 26. These requirements are designed to ensure program effectiveness, maintain protections afforded to individuals subject to the FFD program, and align with FFD program implementation by part 50 and 52 licensees. The proposed requirements are not entirely

equivalent because current subpart K of part 26 only applies during construction of the commercial nuclear plant, whereas proposed subpart M of part 26 would apply during construction, operation, and decommissioning. Furthermore, proposed subpart M of part 26 would allow the use of a variety of biological specimens for drug testing as well as innovative technologies for drug and alcohol screening and testing that are not described or allowed by the requirements in subparts A through K, N, and O of part 26, except under limited conditions.

Proposed revisions to part 73 would establish a new technology-inclusive consequence-based approach for a range of security areas, including physical security, cyber security, and access authorization (AA) for commercial nuclear reactors. The NRC used operating experience to include additional regulatory flexibility for a part 53 licensee's implementation of security requirements.

In addition, this proposed rule would make conforming changes throughout 10 CFR chapter I, such as adding "and part 53" where appropriate to account for the addition of the proposed part 53.

IV. Part 53

New Requirements in 10 CFR Part 53

Proposed § 53.000, "Purpose," would describe the purpose of part 53 and would be equivalent to § 50.1, "Basis, purpose, and procedures applicable."

Subpart A – General Provisions

Subpart A would provide the general provisions applicable to all applicants and licensees that would be established in part 53 for the issuance, amendment, and termination of licenses, permits, certifications, and approvals for commercial nuclear plants licensed under Section 103 of the Atomic Energy Act of 1954, as amended (AEA) and title II of the Energy Reorganization Act of 1974 (88 Stat. 1242). Subpart A would

include purpose, scope, definitions, written communications, employee protections, completeness and accuracy of information, exemptions, standards for review, jurisdictional limits, consideration of attacks and destructive acts by enemies of the United States, and information collection requirements.

The requirements in subpart A would be largely equivalent to the general requirements in part 50 that are applicable to all part 50 applicants and licensees (specifically, §§ 50.1 through 50.13) but would reference the corresponding regulations in part 53 in place of references to part 50.

Discussion of Definitions in Proposed Part 53

Section 53.020 would define terms used in part 53 and would include terms such as: Commercial nuclear plant, Nuclear reactor, Defense in depth, Design features, Event sequence, Licensing basis information, Manufactured reactor, Normal operation, PRA, Quality assurance, Safety function, and Site characteristics. The definitions of most of these terms in § 53.020 would be equivalent to the corresponding terms defined in: (1) §§ 50.2, 52.1, and other NRC regulations; (2) NEI 18-04, as endorsed by RG 1.233; or (3) American Society of Mechanical Engineers (ASME)/American Nuclear Society (ANS) Risk Assessment Standard (RA-S)-1.4-2021, as endorsed for trial use by RG 1.247, "Acceptability of Probabilistic Risk Assessment Results for Non-Light Water Reactor Risk-Informed Activities." This is intended to provide clarity and consistency in terminology among all licensing frameworks where possible and to utilize past and ongoing NRC initiatives to support the licensing of new reactors. Specific deviations from existing definitions are further explained in the following paragraphs.

Regarding the definition of "Commercial nuclear plant" and "Commercial nuclear reactor" in proposed § 53.020, as noted previously, the NRC initially considered establishing the scope of part 53 as being for "advanced nuclear plants." The preliminary

proposed rule language defined “advanced nuclear plant” as “a utilization facility consisting of one or more advanced nuclear reactors” as defined in NEIMA. NEIMA defines the term ‘‘advanced nuclear reactor’’ as “a nuclear fission or fusion reactor, including a prototype plant (as defined in sections 50.2 and 52.1 of title 10, Code of Federal Regulations (as in effect on the date of enactment of this Act)), with significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of this Act, including improvements such as— (A) additional inherent safety features; (B) significantly lower levelized cost of electricity; (C) lower waste yields; (D) greater fuel utilization; (E) enhanced reliability; (F) increased proliferation resistance; (G) increased thermal efficiency; or (H) ability to integrate into electric and nonelectric applications.”

Based on public discussions on the use of the term, the NRC determined that the NEIMA definition, although broad, did not define “significant improvements” with enough specificity to implement in NRC regulations. Additionally, a number of stakeholders suggested that the descriptor, “advanced,” implied enhanced safety, while the NEIMA definition includes “significant improvements” in areas other than safety enhancements. In response to this feedback, and to be technology inclusive, the NRC staff determined that the broader term “commercial nuclear plant” would be preferable. The NEIMA definition of advanced nuclear reactor also includes fusion technologies. Fusion energy systems have not been included, at this time, in the scope of the proposed part 53 but could be addressed in a future revision to part 53 or other NRC regulations.

The NRC proposes to allow use of part 53 by any “commercial nuclear plant.” The use of the term "plant” versus “reactor,” as used in existing regulations (i.e., § 50.2), recognizes that co-located support facilities and radionuclide sources need to be considered in the licensing of a facility. The phrase “commercial purposes,” as used in

the definition of “commercial nuclear plant,” includes purposes such as providing process heat for a variety of industrial applications (e.g., desalination, oil refining, hydrogen production). The NRC has not compiled a complete list of such commercial purposes. The definition of “commercial nuclear plant” refers to a “nuclear reactor,” which is defined based on the definition of “nuclear reactor” in § 50.2. However, the phrase “in a self-supporting chain reaction” was removed from the definition to enable applying part 53 to accelerator driven systems that use special nuclear material (SNM) but that do not involve self-sustaining chain reactions. The definition of “nuclear reactor” in proposed § 53.020 includes an exception for fueled manufactured reactors that have redundant means in place to prevent criticality to support the Commission finding that they are not utilization facilities. Relatedly, “utilization facility” is also defined in § 53.020 based on paragraph (1) of the definition of that term in § 50.2, omitting reference to accelerator driven systems in paragraph (2) of that definition as allowed by the change to the definition for “nuclear reactor.”.

The NRC proposes to include a definition of “consensus code or standard” in part 53 that is based on the use of these terms in the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Public Law 104-113) and the Office of Management and Budget (OMB) Circular No. A-119, “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.” As required by NTTAA, the NRC undertakes the following activities: (i) consults with voluntary consensus standards bodies; (ii) participates with voluntary consensus bodies in the development of consensus standards; and (iii) uses consensus standards as a means to carry out the NRC’s policy objectives. In part 53, the NRC is not proposing to incorporate by reference specific codes and standards as is done under the existing regulations in § 50.55a, “Codes and standards,” because some codes and standards are

LWR-specific. Part 53 would require that applicants describe their use of generally accepted consensus codes and standards but would not incorporate the specific code or standard into the NRC's regulations. During public meetings, significant discussions with stakeholders indicated that future reactor designers were interested in the use of international consensus standards that have not yet been endorsed by the NRC. The definition proposed in part 53 would allow for the use of international codes and standards not previously used in NRC licensing but recognizes that the use of any consensus code or standard would ultimately need to be found acceptable by the NRC, either through generic efforts to endorse a code or standard or on an application-specific basis during an individual licensing review.

Section 53.020 would also add definitions such as terms related to event selection (LBEs, design-basis accidents (DBAs), anticipated event sequences, unlikely event sequences, and very unlikely event sequences); equipment classifications (SR, NSRSS, and non-safety-significant SSCs); performance metrics (safety criteria and functional design criteria); and special treatments.

The regulation would define "safety criteria" in terms of the plant-level performance-based metrics that would be provided in or established under §§ 53.210 and 53.220. The term "functional design criteria" would be defined as metrics for the performance of specific SSCs that are determined from the role of the SSC in meeting the safety criteria. These are new terms that have not previously been defined or used in NRC regulation.

The term "safety-related structures, systems, and components" would refer to those SSCs needed to meet the safety criteria in § 53.210. The term "non-safety-related but safety-significant structures, systems, and components" would mean those SSCs that are not SR because they do not perform any function necessary to demonstrate

compliance with § 53.210 but warrant special treatment because they are relied on to achieve adequate defense in depth or perform risk-significant functions. The term “special treatments” would be defined as items, such as quality assurance and programmatic controls, identified for each design feature to ensure that the safety criteria are satisfied and the safety functions are fulfilled. These treatments would also ensure that SR and NSRSS SSCs will provide defense in depth, or perform risk-significant functions, under service conditions and with SSC reliabilities that are consistent with the analysis required in proposed subpart C. The term “non-safety-significant SSCs” would mean those SSCs that are not SR or NSRSS.

The terms “design-basis accidents,” “anticipated event sequences,” “unlikely event sequences,” and “very unlikely event sequences” would be defined to be different types of “licensing-basis events” and would also be largely equivalent to the LMP’s definitions of DBAs, anticipated operational occurrences (AOOs), design-basis events (DBEs), and beyond-design-basis events, respectively. The term “design-basis accidents” would be defined as postulated event sequences that are used to set functional design criteria and performance objectives for the design of SR SSCs through deterministic analyses. DBAs would be derived from the unlikely event sequences from the risk evaluation and then analyzed in a conservative approach by prescriptively assuming that only SR SSCs are available to mitigate postulated accident scenarios. Within the LMP methodology, event sequences with mean frequencies of 1×10^{-2}/plant-year and greater would be classified as anticipated event sequences. Within the LMP methodology, infrequent event sequences with mean frequencies of 1×10^{-4}/plant-year to 1×10^{-2}/plant-year would be classified as unlikely event sequences. “Very unlikely event sequences” would be less likely to occur than unlikely event sequences. Within the LMP methodology, rare event sequences with mean frequencies of 5×10^{-7}/plant-year to

1×10^{-4}/plant-year would be classified as very unlikely event sequences. While the proposed terminology for these event sequences would create some differences between part 53 and the LMP, part 53 would use new terms for these event sequences specifically to avoid conflicts with terms already used within part 50 and part 52 to represent different concepts. Further, because some stakeholder comments demonstrated confusion related to the history of beyond-design-basis accidents terminology, these definitions seek to clarify the event categories. The sections of this document related to subparts B and C provide additional discussion of LBEs.

Other General Provisions

Section 53.040 would govern written communications and how applications and other required information must be submitted to the NRC. These requirements would be equivalent to those in § 50.4.

Section 53.050 would establish requirements for enforcement action to which a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, or an employee of any of them may be subject for engaging in deliberate misconduct. These requirements would be equivalent to those in § 50.5.

Section 53.060 would prohibit discrimination against an employee of a holder or applicant for an NRC license, permit, design certification (DC), or design approval, or a contractor or subcontractor of a holder or applicant for an NRC license, permit, DC, or design approval for engaging in certain protected activities. Section 53.060 also would prescribe a procedure for seeking a remedy for an employee who believes he or she has been discriminated against for engaging in such protected activities. These requirements would be equivalent to those in §§ 50.7 and 52.5.

Section 53.070 would govern the completeness and accuracy of information provided to the NRC. These requirements would be equivalent to those in §§ 50.9 and 52.6.

Section 53.080 would govern exemptions from the requirements of the regulations in this part. These requirements would be equivalent to those in §§ 50.12 and 52.7.

Section 53.90 would establish requirements for standards that the NRC would consider in determining whether a construction permit (CP), operating license (OL), early site permit (ESP), combined license (COL), or manufacturing license (ML) under part 53 would be issued to an applicant. These requirements would be equivalent to those in §§ 50.40, 50.42, 50.43 and 50.22, respectively. Requirements equivalent to those in §§ 50.41 and 50.21 would not be included in part 53 because they apply to Class 104 licenses, and part 53 would not apply to those licenses.

Section 53.100 would require that no license issued under part 53 would cover activities which are not under or within the jurisdiction of the United States. These requirements would be equivalent to those in § 50.53.

Section 53.110 would state that licensees and applicants would not be required to provide design features or other measures for the specific purpose of protection against the effects of attacks and destructive acts by enemies of the United States directed against the facility or deployment of weapons incident to U.S. defense activities. These requirements would be equivalent to those in § 50.13.

Section 53.115 would establish requirements for rights related to SNM. These requirements would be equivalent to those in § 50.54(b) and (c).

Section 53.117 would establish requirements for license suspension and rights of recapture of the material or control of the facility in a state of war or national emergency declared by Congress. These requirements would be equivalent to those in § 50.54(d).

Section 53.120 would establish requirements for information collection requirements and OMB approval. These requirements would be equivalent to those in § 50.8.

Subpart B – Technology-Inclusive Safety Requirements

Proposed subpart B, “Technology-Inclusive Safety Requirements,” would provide technology-inclusive safety criteria that would serve as performance standards for the subsequent performance-based requirements used throughout part 53. Subsequent subparts would define how specific activities during various stages of the life cycle of a commercial nuclear plant contribute to satisfying these high-level performance standards. The performance standards in subpart B would also establish a means to determine appropriate regulatory controls for SSCs, human actions, and programs in the following subparts. For example, the classification of SR SSCs would be built upon the proposed safety criteria in § 53.210, “Safety criteria for design-basis accidents.” The more detailed requirements for those SSCs would then be further defined in the design and analysis requirements in subpart C, “Design and Analysis Requirements.” The activities for manufacturing, constructing, and maintaining the SR SSCs would be governed by subpart E, “Construction and Manufacturing Requirements,” and subpart F, “Requirements for Operation.”

Requirements for NSRSS SSCs warranting special treatment would likewise be determined under § 53.220, “Safety criteria for licensing-basis events other than design-basis accidents,” in subpart B and § 53.460, “Safety categorization and special treatment,” in subpart C. Regulatory requirements related to the NSRSS SSCs would be

distinguished from the regulatory requirements for SR SSCs throughout part 53. Part 53 would afford more flexibility to applicants and licensees regarding how NSRSS SSCs would be used in the design and maintained during plant operations, as compared to SR SSCs.

Section 53.210 would provide safety criteria for DBAs that would be required to be identified under § 53.240 and analyzed under § 50.450(f) in subpart C of part 53. Subsequent sections in part 53 would require that the SSCs relied upon to demonstrate compliance with the criteria in § 53.210 be classified as SR. The use of SR SSCs and the 25 rem reference values for potential radiological consequences would align with traditional deterministic approaches for LWRs from §§ 50.34, 52.79, and 100.1 for evaluating the effectiveness of plant design features with respect to postulated reactor accidents so as to limit the possibility of an immediate threat to public health and safety. A footnote similar to that included in § 50.34(a)(1)(ii)(D)(*1*) and § 52.79(a)(1)(vi)(A) would be included in § 53.210 to explain that the use of the 25 rem value would not be intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this proposed section as a reference value that would be used in the evaluation of plant design features with respect to DBAs to verify that the proposed designs would provide assurance of low risk of public exposure to radiation in the event of an accident. The inclusion of the safety criteria for DBAs in subpart B would provide a logical structure supporting the identification and treatment of SR SSCs and establishing the corresponding functional design criteria for those SSCs.

Section 53.220 would require the applicant or licensee to identify safety criteria for LBEs other than DBAs that would be required to be identified under § 53.240 and analyzed under § 53.450(e) in subpart C. Whereas § 53.210 and the related

requirements for SR SSCs would provide that a defined success path exists for DBAs, the safety criteria for LBEs other than DBAs would establish the connections between SSC design, human actions, and programmatic controls and a broader set of potential internal and external hazards. These safety criteria would also address defense-in-depth matters such as a balanced consideration of prevention and mitigation. The safety criteria in § 53.220(b) could include a cumulative risk measure and support a performance-based approach to developing an appropriate combination of design features and programmatic controls to prevent or mitigate LBEs other than DBAs.

The proposed use of multiple performance standards, including deterministic criteria and defense-in-depth measures, reflects an integrated decision-making process similar to that described in RG 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” Revision 3. The NRC initially considered establishing the quantitative health objectives from “Safety Goals for the Operation of Nuclear Power Plants; Policy Statement; Republication” (51 FR 30028; August 21, 1986) as the safety criteria under § 53.220 but consistent with longstanding Commission Policy on the subject as discussed in SECY-89-102, “Implementation of the Safety Goals,” determined that while the use of “partitioned” objectives such as consequence estimates from PRA level calculations can be useful in making regulatory decisions and improving regulatory practices, the Commission determination that “partitioned objectives are not to be imposed as requirements themselves but may be useful as a basis for regulatory guidance” remains valid.

Section 53.230 would require safety functions needed to ensure that the safety criteria under §§ 53.210 and 53.220 can be met if a commercial nuclear plant experiences an LBE. Section 53.230 would specify that limiting the release of radioactive

materials from the facility is the primary safety function, and therefore, limiting potential offsite consequences (i.e., dose to a hypothetical individual) would be used as the primary performance metric throughout part 53. The additional or subsidiary safety functions needed to limit the release of radionuclides may include, without limitation, controlling processes related to reactivity, heat generation, heat removal, and chemical interactions. This proposed rule provides flexibility to applicants and licensees in identifying, implementing, and maintaining the safety functions supporting retention of radionuclides for commercial nuclear plants of varying sizes and technologies.

Proposed § 53.240 would require applicants to identify and address LBEs. LBEs are unplanned events, resulting from both internal and external hazards, that are used in the design and analyses required under part 53 for licensing commercial nuclear plants. This ensures estimates of offsite consequences from analyses performed under proposed § 53.450 are below the safety criteria identified under proposed §§ 53.210 and 53.220 and that SSCs, personnel, and programs address the safety functions from proposed § 53.230. Including a high-level performance requirement related to the identification and analysis of LBEs in subpart B would reflect the historical and continuing importance of evaluating unplanned events as part of the licensing of commercial nuclear plants. Proposed § 53.240 would require identification and analysis of LBEs under § 53.450, which would require a risk evaluation. Examples of acceptable methods of using risk evaluations to identify and assess LBEs would be the methodology in RG 1.233, as discussed in Draft Regulatory Guide (DG)-1413, "Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants."

Section 53.250 would establish defense-in-depth requirements based on the longstanding philosophy of providing defense in depth to address uncertainties about the design, operation, and performance of commercial nuclear plants. For example, parts 50

and 52 address defense in depth through layered prescriptive technical requirements (e.g., fuel performance, cladding integrity, reactor coolant system integrity, containment performance) for LWRs. In contrast, the flexibility afforded to applicants in how they propose to demonstrate compliance with the high-level safety criteria within part 53 would necessitate this specific requirement to ensure defense in depth is provided. The requirements in this section would state that no single engineered design feature, human action, or programmatic control, no matter how robust, should be exclusively relied upon to address LBEs other than DBAs. The phrase “engineered design feature” would not preclude the possible crediting of inherent characteristics within the design and analysis for commercial nuclear reactors. While defense in depth would only be assessed for LBEs other than DBAs, the need to ensure dedicated success paths for DBAs would contribute to the overall defense in depth for each commercial nuclear plant under part 53.

Section 53.260 would govern normal operations and establish a level of safety based on current requirements in 10 CFR part 20, “Standards for Protection Against Radiation,” which limits doses to members of the public.

Section 53.270 would provide for the protection of plant workers. This section would include the part 20 limits on occupational exposures to ensure that protection of plant workers is addressed within the high-level safety criteria for part 53.

Subpart C – Design and Analysis Requirements

This subpart would provide requirements for the design of commercial nuclear plants and the supporting analyses, including the analyses of LBEs, to demonstrate that the performance standards in proposed subpart B can be satisfied. The sections within subpart C would reflect the overall hierarchy throughout part 53, which would cover: (1) plant-level safety criteria (§§ 53.210, 53.220, and 53.470); (2) safety functions (§ 53.230)

needed to demonstrate compliance with the safety criteria; (3) design features (§ 53.400), human actions, and programmatic controls needed to fulfill the safety functions; and (4) functional design criteria (§§ 53.410 and 53.420) that must be defined for each design feature relied on to demonstrate the safety criteria (§§ 53.210 and 53.220) are met. Subpart C would also contribute to the logic and structure of part 53 by distinguishing between SR SSCs and NSRSS SSCs and licensee-controlled programs that address LBEs other than DBAs. Specifically, SR SSCs, human actions, and programmatic controls needed to protect against DBAs are used to satisfy the safety objective of limiting the possibility of an immediate threat to the public health and safety. NSRSS SSCs, human actions, and licensee-controlled programs that address LBEs other than DBAs generally make up the appropriate measures considering potential risks to public health and safety.

Section 53.400 would establish a requirement that design features be provided for each commercial nuclear plant to satisfy the safety criteria and fulfill safety functions from proposed subpart B during LBEs. Other sections in subpart C would, in turn, further address the necessary capabilities and reliabilities for SSCs by establishing functional design criteria, fulfilling design requirements, performing analyses of LBEs, performing other supporting analyses, and categorizing SSCs based on their roles in preventing or mitigating LBEs.

Section 53.410 would require that functional design criteria be defined for design features relied upon to demonstrate that the consequences from DBAs would be below the criteria in § 53.210 through analyses performed under § 53.450(f), which includes insights from both PRAs and deterministic analyses. Other sections within part 53 would establish appropriate controls on these design features (e.g., safety classification, protection from external hazards, quality assurance, and TS) to ensure the functional

design criteria are satisfied. The performance requirements for the SSCs needed to address DBAs and the corresponding human actions and programmatic controls would contribute to ensuring that a commercial nuclear plant licensed under part 53 would demonstrate compliance with the safety objective that the plant poses no immediate threat to public health and safety.

Section 53.415 would require that SR SSCs be protected against or designed to withstand the effects of natural phenomena (e.g., earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches) and constructed hazards (e.g., from dams, transportation routes, and military or industrial facilities). Specifically, § 53.415 would require that SR SSCs remain capable of performing the safety functions stated in § 53.230 for which they are credited up to the design-basis external hazard levels as determined under § 53.510. As used in § 53.415 and subpart D of part 53, a hazard level would refer to such things as the magnitude and recurrence rate of an earthquake and the resultant ground motions, the height of a flood, the force of hurricane winds, or the concentrations of chemicals resulting from a release from a nearby facility. These requirements would support either traditional deterministic approaches for determining and protecting against external hazards or probabilistic approaches that are being developed for seismic and some other external hazards.

Section 53.420 would require that functional design criteria be defined for design features that play a significant role in demonstrating that the safety criteria for LBEs other than DBAs are satisfied. The analyses required for this demonstration would be described in proposed § 53.450(e), which would require that those events be identified and assessed using a risk evaluation methodology. The SSCs determined to be safety significant (i.e., either SR or NSRSS) would have associated special treatment requirements as specified in § 53.460. Special treatment would be defined in subpart A

of part 53 and generally refers to measures (e.g., quality assurance, testing, monitoring) taken beyond the procurement and installation of commercial grade products to provide confidence that the SSC will comply with the applicable functional design criteria. The inclusion of a systematic approach to identifying the functional design criteria for SSCs and tailoring the special treatments to specific LBEs and safety functions is an important contributor to satisfy the safety objectives in the Atomic Energy Act. As explained above, other sections in part 53 that address DBAs would require protection against an immediate threat to public health and safety. Therefore, designers and licensees for commercial nuclear plants would be provided flexibility on how LBEs other than DBAs are either prevented or mitigated and how the plant risks remain below the safety criteria in § 53.220.

Section 53.425 would establish requirements for design features and related functional design criteria limiting the release of radionuclides during normal operations to satisfy the criteria in part 20. Section 53.430 would provide similar requirements for design features and related functional design criteria for protection of plant workers to meet the safety criteria in part 20. Similar to existing regulations, the NRC considers that licensees would generally comply the requirements of part 20 to keep doses as loss as is reasonably achievable by meeting a design objective of keeping doses to the public from routine plant effluents less than 10 millirem per year. This goal is similar to that provided by appendix I to part 50 and would assist designers, applicants, and licensees in performing the evaluations of possible reductions in public dose from routine effluents when considering costs and other factors. As emphasized in existing regulations in part 50, the design objective of keeping doses to the public from routine plant effluents less than 10 millirem per year should not be construed as a radiation protection standard. The NRC anticipates that future guidance will continue to reflect this performance goal.

Section 53.440 would address various design requirements that warrant specific mention to ensure that the design features required by § 53.400 comply with the functional design criteria required by §§ 53.410 and 53.420. These requirements would be met through design practices, consideration of testing and operating experience, and various assessments of LBEs and other potential challenges to commercial nuclear plants. Discussions of some of the key design requirements included in this section follow.

- § 53.440(c): The design requirements in subpart C would require the materials used for SR and NSRSS SSCs to be qualified for their service conditions over the plant lifetime.
- § 53.440(d): The requirements in § 53.440 would include the need to consider possible degradation mechanisms for materials and equipment to inform the design process. The inclusion of requirements related to designing for possible degradation mechanisms reflects important lessons learned from the history of LWRs as well as operating experience with structures and systems in other engineering endeavors.
- § 53.440(e) and (f): The design requirements in subpart C would state specific design requirements similar to existing requirements in parts 50, 52, and 73 for protections against fires and explosions and consideration of safety and security together in the design process.
- § 53.440(g) and (h): Specific design requirements are proposed to ensure that commercial nuclear reactors under part 53 have the capability to reliable control reactivity and provide long-term cooling. The requirements would be included to address the potential that some reactor designs may be able to achieve a stable end state for the purpose of event analyses but might need further actions to completely shut down and service the facility.

- § 53.440(i): The design, analysis, and development of programmatic controls under part 53 would consider the number of reactor units and other significant inventories of radioactive materials contributing to the risks to public health and safety. This would reflect the definition of “commercial nuclear plant” in subpart A and reinforce that the evaluation of LBEs is performed on a plant-wide basis. This aspect of part 53 would be different from parts 50 and 52, which generally define safety requirements on the assumption of events involving only individual reactor units.
- § 53.440(j): A design requirement is proposed to provide a technology-inclusive requirement that would be equivalent to the requirements in § 50.150 to address the possible impact of a large commercial aircraft.
- § 53.440(k): The inclusion of a specific proposed requirement to address the risks to public health from potential chemical hazards of licensed material is appropriate given the diversity of reactor technologies and designs that might be licensed under part 53. The requirement in part 53 would be similar to the existing requirements in 10 CFR part 70, “Domestic Licensing of Special Nuclear Material,” that address both potential radiological and chemical hazards for licensed materials at fuel cycle facilities.
- § 53.440(l): Provisions are proposed to require that measures be taken during the design of commercial nuclear plants to minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the generation of radioactive waste in accordance with § 20.1406.
- § 53.440(m): A design requirement is proposed to provide a technology-inclusive equivalent to the requirements in § 50.68 by including options for commercial nuclear plants to either have a monitoring system capable of detecting a criticality as described in § 70.24 or to have restrictions on SNM handling and storage that would prevent inadvertent criticality events.

- § 53.440(n): The design would need to reflect state-of-the-art human factors principles for safe and reliable performance in all settings that human activities are expected for performing or supporting the continued availability of plant safety or emergency response functions.

HFE is essential to facilitate the role of personnel in facility safety in a manner that is both effective and reliable. The NRC proposes to adapt § 53.440(n)(1) from the HFE design requirements of § 50.34(f)(2)(iii). A key difference would be that the requirement would now be focused on settings where personnel fulfill their safety or emergency response roles wherever they may occur. The NRC additionally proposes to include within the scope of this requirement activities for assuring the continued availability of plant equipment that is needed for safety, and envisions that this may encompass relevant maintenance, inspections, and testing as well. The NRC intends that this requirement would be associated with staff guidance for conducting scalable reviews of HFE that is planned to accompany part 53.

Human-system interfaces provide vital information to operators across a spectrum of operating conditions that can range from normal operations through severe accident conditions. The specific types of information that must be available to support operations staff during such conditions include, in part, those associated with safety function parameters, safety system status, possible core damage states, barrier integrity, and radioactive leakage. Due to the importance of such information, the NRC proposes under § 53.440(n)(2) to require such human-system interface design features for all facilities, irrespective of other flexibilities proposed under part 53. Therefore, the NRC proposes to adapt specific post-Three Mile Island requirements of § 50.34(f) in a technology-inclusive manner as detailed in the following:

- Paragraph (n)(2)(i) would be adapted from § 50.34(f)(2)(iv).

- Paragraph (n)(2)(ii) would be adapted from § 50.34(f)(2)(v).
- Paragraph (n)(2)(iii) would be adapted from § 50.34(f)(2)(xi), 50.34(f)(2)(xii), and 50.34(f)(2)(xxi).
- Paragraph (n)(2)(iv) would be adapted from § 50.34(f)(2)(xvii), 50.34(f)(2)(xviii), 50.34(f)(2)(xix), and 50.34(f)(2)(xxiv).
- Paragraph (n)(2)(v) would be adapted from § 50.34(f)(2)(xxvi).
- Paragraph (n)(2)(vi) would be adapted from § 50.34(f)(2)(xxvii).
- § 53.440(o): Load following where plant output automatically changes in response to externally originated instructions or signals is not permitted under the existing regulations of § 50.54. However, new technological considerations and concepts of operation may justify such an operational approach under appropriate circumstances. The NRC recognizes that, beyond electrical power generation, load following may also affect other applications of plant output, such as hydrogen production, desalination, or district heating. For load following to be permissible, measures must be in place to provide assurance that plant output considerations are not permitted to lead to challenges to safe reactor operations. These measures may consist of automated control systems, automatic protective features, or the continuous oversight and immediate intervention capability of an appropriately qualified and authorized individual. Section 53.440(o) would provide the measures to allow for load following under § 740(f). In considering the acceptability of the measures associated with load following, the NRC expects that any automatic protection relied upon would be separate from that credited for reactor protection purposes and would employ setpoints that are set so as to prevent actuation of the reactor protection system while accomplishing its functions to the extent practical.

Section 53.450 would establish analysis requirements and would center upon the use of a risk evaluation such as a PRA in combination with other generally accepted approaches for systematically evaluating engineered systems. The reliance on risk evaluation as a key component in the proposed analysis requirements for part 53 would reflect the decades of improvements in risk methodologies and the increasing use of risk techniques in the design, licensing, and oversight of both operating and future nuclear reactors. Part of the Commission's PRA Policy Statement is that the use of PRA technology should be increased in all regulatory matters to the extent supported by the state of the art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy. The need to supplement PRA insights with other engineering approaches and judgments reflects the NRC's longstanding policy described in the SRM to SECY-98-144, "Staff Requirements—SECY-98-144—White Paper on Risk-Informed and Performance-Based Regulations," dated February 24, 1999, for regulatory decision-making to be risk-informed but not solely based on numerical results of a risk assessment (i.e., not a risk-based approach). Part 53 would maintain a role for NRC's traditional deterministic approaches (particularly for DBAs) and defense-in-depth philosophy by including specific requirements utilizing these regulatory tools in subparts B and C.

Risk assessment would be used in combination with other techniques in part 53 to identify and categorize LBEs, classify SSCs, and evaluate defense in depth. This increased role for the risk evaluation necessitates that it would be developed, performed, and maintained. The computer codes used to model the plant response and the behavior of the barriers to the release of radionuclides would need to be qualified for the range of conditions being simulated across a wide range of unplanned events. These

analyses would need to use realistic approaches and address uncertainties associated with states of knowledge, modeling, and performance of SSCs.

The categories of LBEs used in part 53 would include anticipated event sequences, unlikely event sequences, and very unlikely event sequences. The unlikely event sequences would include those events with estimated frequencies well below the frequency of events expected to occur during the lifetime of a commercial nuclear plant. An important aspect of the analysis requirements is that, under proposed § 53.450(e), the analyses of LBEs other than DBAs would be used to show that evaluation criteria defined under § 53.220 for each LBE or category of LBEs would be satisfied. Such evaluation criteria for specific LBEs or categories of LBEs would be defined in terms of limits on the release of radionuclides or maintaining the integrity of one or more barriers used to limit the release of radionuclides and reflect a graded approach of allowing lesser potential consequences from more frequent events. An example of such evaluation criteria for a range of LBEs that could likely be expanded for part 53 is provided in RG 1.233. Another proposed requirement for the proposed § 53.450(e) analyses is that the methodology would need to include a means to identify event sequences deemed risk-significant such that those event sequences can be given special attention within other sections of part 53.

Part 53 would maintain an important role for a deterministic analysis of DBAs in the performance criteria of § 53.210 and the related analytical requirements in § 53.450(f). The analysis of DBAs would be required to address event sequences drawn from those with estimated frequencies below the expected lifetime of a generation of reactors (e.g., event sequences with frequencies as low as one in ten thousand years). As proposed in this section, DBAs would need to be analyzed using deterministic methods and ensure a safe, stable end state with reliance upon only SR SSCs and

human actions, if needed, to be performed by operators licensed under the provisions of §§ 53.760 through 53.780 and part 55.

While the DBAs analyzed under part 53 would be similar to the traditional DBAs analyzed under parts 50 and 52, there are important distinctions between their roles. In part 53, the role of the DBA analysis would be more narrowly focused on selecting SR SSCs and determining functional design criteria for those SSCs to ensure the commercial nuclear plant poses no immediate threat to public health and safety. The overall control of risks posed by commercial nuclear plants under part 53 would be provided by the analyses of and measures taken for both DBAs and other LBEs, including very unlikely event sequences. This would contrast with the traditional deterministic approach in part 50 wherein the analyses of DBEs such as DBAs were used to provide bounding assessments, incorporate standard design rules such as principal design criteria based upon the general design criteria of appendix A to part 50 coupled with assumptions related to single failures to define conservative performance requirements for SR SSCs. Limitations related to the traditional deterministic approach were addressed in part 50 through case-by-case assessments and specific actions for beyond-design-basis events such as anticipated transients without scram (ATWS) and station blackout (SBO).

Section 53.450 would also include provisions to ensure that analyses are performed to support the design requirements of § 53.440(e) on fire protection, § 53.440(j) on aircraft impact assessments, and § 53.425 on controlling effluents. The proposed analysis requirements related to fire protection would support either a traditional, deterministic approach or a more risk-informed approach where the risks from fires are addressed within the identification and analyses of LBEs.

Section 53.460 would establish criteria for the safety classification of SSCs and determination of appropriate special treatments. As noted in subpart A, the term “special treatments” would be defined to mean those items, such as measures taken to satisfy functional design criteria, quality assurance, environmental qualification of electrical equipment, integrity assessment, and programmatic controls, which provide assurance that certain SSCs will provide defense in depth or perform risk-significant functions. These requirements would also provide confidence that the SSCs will perform under the service conditions and with the reliability credited in the analysis performed in accordance with § 53.450 to satisfy the safety criteria in §§ 53.210 and 53.220. The terminology used in part 53 would include the following categories for SSC classification: (1) SR; (2) NSRSS; and (3) non-safety significant. Requirements for SR SSCs would be defined in other sections of part 53 and would include using technical specifications for controls during operation and the application of quality assurance requirements from appendix B to part 50.

Requirements for NSRSS SSCs would include the need to identify necessary special treatments such as performance measures on reliability. Licensees would generally be afforded flexibility in maintaining and changing special treatments for SSCs categorized as NSRSS. Non-safety-significant SSCs would be addressed under normal licensee programs for commercial grade equipment and typical industry practices for general plant design and maintenance.

Section 53.480 would establish seismic design considerations. This proposed section would relate to the safety criteria in subpart B, the analytical requirements related to external hazards in § 53.450, and subpart D, “Siting Requirements.” For licenses issued under part 53, this section in subpart C would support a variety of approaches to seismic design. For example, a design for a commercial nuclear plant

could show that SSCs are able to withstand the effects of earthquakes by adopting an approach similar to that in appendix S to part 50. Alternatively, an applicant could follow the more recent risk-informed alternatives afforded by standards development organizations (e.g., American Society of Civil Engineers (ASCE)/Structural Engineering Institute (SEI) 43-19, “Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities.”) Because the agency has not endorsed ASCE/SEI-43-19, an applicant can propose to use ASCE/SEI 43-19 on an application specific basis to meet § 53.480 and the NRC would evaluate the adequacy of the standard as applied in that application. The design could also be done with the full integration of seismic PRAs into the design and licensing of a particular commercial nuclear plant. This section has been developed to accommodate a variety of potential risk-informed, performance-based seismic design approaches. The analyses required by § 53.450 would need to address seismic hazards as well as other external hazards. The expected responses of SSCs to a range of seismic events would be included in the analyses when ensuring that the safety criteria defined under § 53.220 would be met. The potential SSC responses to seismic hazards could be addressed in the analyses using a fragility model (conditional probability of its failure at a given hazard input level), a high confidence of low probability of failure value, or other method endorsed or otherwise found acceptable by the NRC.

Subpart D – Siting Requirements

Proposed subpart D would state requirements for the siting of commercial nuclear plants and would serve the role provided by 10 CFR part 100, “Reactor Site Criteria,” for nuclear reactors licensed under parts 50 and 52. As reflected in proposed § 53.500, the reason for establishing siting requirements would remain the same as it has been historically—to ensure that licensees and applicants assess what impact the site environs may have on a commercial nuclear plant (e.g., external hazards) and,

conversely, what potential adverse health and safety impacts a commercial nuclear plant may have on nearby populations in view of the site characteristics.

Proposed § 53.510 would require that design-basis external hazard levels be identified and characterized based on site-specific assessments of natural and man-related hazards with the potential to adversely affect plant functions. The site-specific assessments would be used in the proposed § 53.415, which would require that SR SSCs be designed to withstand the effects of natural phenomena and man-related hazards of levels or severities up to design-basis external hazard levels. The design-basis levels for external hazards relevant to a site would need to account for uncertainties and variabilities in data, models, and methods used to characterize those hazards. Existing approaches could be used to demonstrate compliance with this requirement. The historical importance of assessing seismic events as risks to commercial nuclear plants and the associated development of risk-informed approaches to address seismic events would be reflected in proposed § 53.480, “Earthquake engineering,” and specific requirements in subpart C. The NRC staff describes in the pre-decisional draft regulatory guide, “Technology-Inclusive, Risk-Informed, and Performance-Based Methodology for Seismic Design of Commercial Nuclear Plants,” issued on October 3, 2022, its efforts to develop a graded approach for seismic design by grouping SSCs into different seismic design categories (SDCs) based on their risk significance

The evaluation of seismic hazards under subpart D would need to be sufficient to inform a site-specific design (e.g., a CP or custom COL) or confirm the use of a standard design for a commercial nuclear plant under § 53.480 and other sections of subpart C. Section 53.510(d) would state that geologic and seismic siting factors must also include

related hazards such as seismically induced flooding that may affect the design and operation of a proposed commercial nuclear plant for the proposed site.

Section 53.520 would require applicants to identify and assess site characteristics related to topics which might include meteorology, geology, hydrology, or other areas in the design and analyses required under subpart C.

Proposed section 53.530 would set requirements for population-related considerations and maintain requirements and definitions similar to those currently in part 100 for an exclusion area, low population zone, and population center distance. The NRC recognizes that some applicants may propose to essentially collapse the exclusion area and low population zone to the site boundary. This approach would rest on a demonstration that the calculated consequences of DBAs remain below the proposed dose guidelines used in part 53, which are the same as those in the existing regulations in parts 50, 52, and 100. The proposed definitions in § 53.020 would allow such configurations, assuming they were justified by the design and analyses from subpart C. This approach should provide flexibility to justify alternative exclusion areas and low population zones without foreclosing the option for an applicant to define more conventional exclusion areas and low population zones outside of a defined site boundary. The NRC's long-standing preference for siting reactors in areas of low population density would be maintained in part 53 by using the current language from part 100 in proposed § 53.530(c). The NRC plans to revise guidance related to population densities surrounding a commercial nuclear plant to reflect Commission direction in SRM-SECY-20-0045, "Population Related Siting Considerations for Advanced Reactors." Site-related requirements in part 20 (restricted area) and part 73 (protected and owner-controlled areas) would remain applicable to commercial nuclear plants licensed under part 53.

Proposed section 53.540 would require that site characteristics be appropriately considered in other activities such as the design and analysis performed under proposed subpart D, the emergency planning and security programs under proposed subpart F, and the facility safety program under proposed subpart F.

Subpart E – Construction and Manufacturing Requirements

The proposed part 53 language would establish construction and manufacturing requirements in subpart E. The proposed language for construction-related activities would largely reflect current requirements in part 50 without any fundamental changes. Limited changes would be made in several places, as described in the following paragraphs, to be technology-neutral and for consistency with the organization and language of part 53. The proposed language for requirements for manufacturing activities would largely mirror those for construction-related activities. However, the proposed manufacturing requirements have been updated from the current requirements in subpart F of part 52 to better accommodate the possible factory fabrication of manufactured reactors. The manufacturing of specific components outside the scope of an ML would not be addressed by these proposed subparts.

Sections 53.600 would establish that subpart E provides the overall construction and manufacturing requirements for CPs, OLs, COLs, MLs, and limited work authorizations (LWAs).

Section 53.605 would establish requirements for the reporting of defects and instances of noncompliance during construction equivalent to those in § 50.55(e).

Section 53.610(a) would establish the requirement to have in place a construction experience program corresponding to the requirements of § 50.34(f)(3)(i)

Section 53.610(b) would provide requirements governing construction activities, including the equivalent of the requirement in § 50.10(e) that prohibits starting

construction until the NRC has authorized the activities by issuing a CP, COL, ESP, or LWA. Section 53.610(b)(1)(iii) would require procedures to be in place prior to beginning construction to ensure that construction-related activities do not undermine important features such as slope stability and that construction-related activities such as backfilling of excavated portions of the site appropriately address potential pre-construction activities such as the emplacement of retaining walls or drainage systems. Other requirements in these paragraphs would be equivalent to requirements in parts 50 and 52 for protecting operating units from construction activities for commercial nuclear plants with multiple reactor units and having a redress plan in case LWA activities are terminated.

Sections 53.610(c) would address inspection and acceptance activities for manufactured reactors delivered to a site for installation under a COL.

Section 53.615 would establish a requirement corresponding to the requirements of §§ 50.30(d) and 50.55(d) for a CP holder to submit additional information to bring the application up to date and apply for an operating license at or about the time of completion of construction.

Section 53.620(a) would include proposed requirements covering the activities performed under an ML issued under part 53. Provisions related to MLs were first adopted by the NRC in 1973 through the addition of appendix M to part 50. The regulation supported the manufacture of a nuclear power reactor to be incorporated into a commercial nuclear plant under a CP and operated under an OL at a different location from the place of manufacture.[1] The regulations and processes for MLs were changed substantially in the part 52 rulemaking in 2007 (72 FR 49352). The most important shift

[1] On December 17, 1982, the NRC issued “Manufacturing License ML-1 to Offshore Power Systems for the manufacture of a maximum of eight floating nuclear plants,” dated September 30, 1982, but the project was subsequently canceled.

in the ML concept in that rulemaking was that a final reactor design, which would be equivalent to that required for a standard DC under part 52 or an OL under part 50, must be submitted and approved before issuance of an ML. The rationale for that change was that approval of a final design ensures early consideration and resolution of technical matters before there is any substantial commitment of resources associated with the actual manufacture of the reactor, which greatly enhances regulatory stability and predictability.

The proposed part 53 sections in subpart E for manufacturing and in subpart H for licensing matters would maintain requirements equivalent to those in part 52 for MLs. The NRC approval of a standard design and related manufacturing processes, coupled with a stable workforce and established procedures, has the potential for maintaining and even improving the quality and consistency of manufacturing, as compared to the traditional method of constructing reactors onsite by a variety of contractors and subcontractors.

Subpart E would include requirements that would apply to portions of a manufactured reactor in recognition that some activities covered by an ML may occur at different fabrication facilities.

Section 53.620(b) in subpart E would propose requirements for the control of radioactive materials if the holder of an ML plans to load fuel into a manufactured reactor as part of the manufacturing process. Under the proposed requirements in this section, the Commission would find that a manufactured reactor would not be a utilization facility or part of a utilization facility until it is installed at a commercial nuclear plant and all ITAAC are complete. The regulation of the manufactured reactor with fuel loaded in it during transportation would be governed under part 70. Several specific requirements to address the potential hazards of radioactive materials are proposed in areas such as

having a fire protection program, an emergency plan, training programs, and procedures to minimize contamination.

Section 53.620(c) would propose to limit the transport of a manufactured reactor or major portions of a manufactured reactor to only the site of a licensee with a COL that authorizes the construction of a commercial nuclear plant using a manufactured reactor under the specific ML. This proposed requirement is similar to the limitations in § 52.153, with the difference being that part 53 would propose to allow the installation of a manufactured reactor at the site of a COL but would not propose to support installation at the site of a CP. The NRC does not have information suggesting that potential applicants under part 53 would be interested in a possible combination of a manufactured reactor and the licensing option of CP and OL. Additionally, this combination would introduce complexity into the licensing process by potentially needing to resolve ITAAC identified for the manufactured reactor within the licensing provisions for CP and OL. Additional proposed paragraphs in §§ 53.620(e) would provide requirements for protecting manufactured reactors or major portions thereof during transport to the site of the commercial nuclear plant.

Subpart F – Requirements for Operation

Proposed subpart F would provide the requirements for the operations phase of a commercial nuclear plant to ensure that the safety criteria in subpart B are satisfied throughout the plant's lifetime and during all modes of normal operation and unplanned events.

Proposed § 53.710 would provide the requirements for technical specifications (TS) and controls for NSRSS SSCs are required to be addressed with licensee-controlled documents and procedures.

The general content and control of TS under part 53 would be similar to the requirements in part 50. The proposed requirements for TS would include limits on the inventories of radioactive materials, plant operating limits, and specific requirements for each SR SSC, including limiting conditions for operation (LCO) and required surveillances. The proposed requirements for TS would also include a section on important design elements, which is similar to design features in § 50.36, and a section for administrative controls.

The proposed requirements for TS under part 53 would not carry over safety limits or associated limiting safety system settings from § 50.36, which contains TS requirements for operating reactors under parts 50 and 52. As discussed in SECY-18-0096, systematic assessments and more mechanistic approaches to evaluating source terms support an alternative approach to establishing barrier-based safety limits. An example provided in that paper is a comparison of: (1) the traditional specified acceptable fuel design limits (SAFDL) that support protecting a specific barrier from potential failure mechanisms (e.g., departure from nucleate boiling to protect fuel cladding); and (2) the specified acceptable system radionuclide release design limit (SARRDL) concept, which limits the possible increase in circulating radionuclide inventory during normal operations or an AOO as part of an integrated or “functional containment” approach. Additional discussion of the use of SARRDL in the design and licensing of advanced reactors is provided in RG 1.232. The SARRDL could be addressed as an operating limit within this proposed construct of requirements for TS. In cases, such as LWRs, where a SAFDL approach might be used as part of a mechanistic approach to meeting the design and analysis requirements in subpart C, the associated functional design criteria proposed in § 53.410 and TS under the proposed § 53.710(a)

would define similar requirements as those provided by the safety limit and limiting safety system setting requirements in § 50.36.

The proposed requirements for TS under part 53 would not include specific criteria for identifying when LCOs must be established (i.e., would not include an equivalent to § 50.36(c)(2)(ii)). Instead, consistent with subparts B and C, the TS requirements in subpart F would define TS LCOs as providing limits on SR SSCs. The SR SSCs protect against an immediate threat to public health and safety to demonstrate compliance with the safety criteria in the proposed § 53.210. In the proposed construct for part 53, risk significant SSCs would be addressed through a combination of TS for the SR SSCs and establishment and monitoring of performance standards for NSRSS SSCs.

In addition to addressing TS for SR SSCs, proposed § 53.710 would require appropriate controls be developed and implemented for NSRSS SSCs. Examples include appropriate surveillances and controls established through reliability assurance programs. Configuration management and other special treatments would provide that the capabilities, availabilities, and reliabilities of NSRSS SSCs are maintained consistent with the underlying risk assessments while providing flexibility to licensees through maintaining the management functions within licensee-controlled programs. Controls on NSRSS SSCs are appropriate as part of the overall performance-based approach within proposed part 53. Additionally, these controls justify proposed changes in part 53 from the traditional or deterministic approaches in parts 50 and 52 in areas such as replacing the single-failure criterion with a probabilistic reliability criterion (see SRM-SECY-03-0047, “Policy Issues Related to Licensing Non-Light-Water Reactor Designs,” dated June 26, 2003). This approach could also support the incorporation of risk insights and

analytical margins to gain operational flexibilities in areas such as siting and staffing requirements described in subsequent sections of proposed subpart F.

Proposed § 53.715 would provide the requirements for developing and implementing a program to do the following: (1) control maintenance activities; (2) take appropriate corrective action when performance issues are identified; (3) conduct routine evaluations of effectiveness; and (4) assess and manage risks resulting from maintenance activities. These proposed requirements are similar to those included in § 50.65 (maintenance rule). While, for the maintenance rule, specific criteria must be developed to capture both SR and non-safety-related but otherwise important SSCs, the proposed § 53.715 would cover SR SSCs and NSRSS consistent with other subparts in part 53.

Proposed § 53.720 would provide the requirements for responding to a seismic event during the operating phase of the life cycle of a commercial nuclear plant and would be equivalent to the requirements in paragraph IV(a)(3) of appendix S, “Earthquake Engineering Criteria for Nuclear Power Plants,” to part 50.

The proposed part 53 would include provisions to address staffing, training, personnel qualifications, and HFE in a manner that is risk informed, technology inclusive, performance based, and flexible in nature. During the development of part 53, the staff prepared a draft white paper on “Risk Informed and Performance Based Human-System Considerations for Advanced Reactors,” to support interactions with stakeholders and the ACRS. Key considerations within both frameworks include the recognition that staffing, operator qualifications, and HFE are interconnected areas that must be approached in an integrated manner and, furthermore, that safety functions, including the means by which they are fulfilled, provide an effective method for informing technology-inclusive requirements.

The requirements associated with this approach would be in §§ 53.725 through 53.830. Section 53.725 discusses applicability and defines specific terms. Some definitions draw from those in § 55.4. Several new definitions would be introduced for use within the context of subpart F..

Sections 53.725 to 53.830 would be divided into four portions that would cover general operational requirements, operator and senior operator licensing requirements, generally licensed reactor operator (GLRO) requirements, and general training requirements for plant staff. The NRC intends to provide guidance addressing the review of operator staffing plans; the review of operator, senior operator, and GLRO examination programs; and the implementation of scalable HFE reviews. Licensees would be required to use GLROs upon demonstrating compliance with the criteria in § 53.800.

Certain routine communications are necessary to facilitate the operator licensing process. The NRC is proposing to adapt the requirements of §§ 55.5 and 50.74 to § 53.726 to accomplish this.

Section 53.730 would provide performance-based and technology-inclusive requirements for assessing the role of personnel in facility safety, applying human-system considerations within facility design, and incorporating operational approaches that are consistent with design-specific safety considerations. Most of these requirements would be adapted from portions of §§ 50.34(f) and 50.54 and 10 CFR part 55, “Operators' Licenses,” with considerable modification in order to reflect the introduction of new technologies and possible changes in the roles of personnel in preventing and mitigating events. The NRC is proposing that these technical requirements would, together, serve as a component of the required content of applications for OLs and COLs under part 53. Additionally, the NRC proposes that the

specific technical requirements associated with HFE, human-system interface design, concept of operations, functional requirements analysis, and function allocation would serve as a component of the required content of applications for both standard DCs and standard design approvals as well.

The NRC proposes § 53.730(c) to require the submittal of a concept of operations that is of sufficient scope and detail to appropriately inform the staff. The development of a concept of operations can facilitate a clear understanding on the part of the NRC for potential novel operating concepts. Additionally, such information is likely to reduce the degree of resources and interactions needed for the NRC to obtain the understanding necessary to enable flexible requirements in areas such as staffing, operator qualifications, and HFE.

The NRC proposes § 53.730(d) to require the submittal of both a Functional Requirements Analysis and a Function Allocation. The identification of design-specific safety functions and how they are fulfilled serves as a primary means for achieving technology-inclusive requirements within areas such as staffing, operator qualifications, and HFE. The Functional Requirements Analysis and Function Allocation processes (which are both HFE methods derived from systems engineering principles), provide an effective means to identify both how safety functions will be satisfied and how to characterize any associated operator role in doing so. A Functional Requirements Analysis shows what features, systems, and human actions are relied upon to demonstrate safety (i.e., fulfill safety functions). A Function Allocation then describes how safety functions are assigned to both personnel and automatic systems. However, an important adaptation of the Function Allocation for use under the proposed rule would be the further need to not only describe allocations of safety functions to human action

and automation, but also to identify allocations made to active safety features, passive safety features, or inherent safety characteristics as well.

Operating experience provides an important source of information by which to inform various aspects of facility design and operations. Accordingly, the NRC proposes in § 53.730(e) to adapt the requirements of § 50.34(f)(3)(i) for requiring an operating experience program.

New technologies may involve concepts of operations that are more conducive to customizable licensed operator staffing requirements than the prescriptive requirements of § 50.54(m). Analyses and assessments that are based on HFE principles provide a performance-based means of determining licensed operator and senior operator staffing needed to support safe operations. In contrast, for those facilities required to be staffed by GLROs, the NRC anticipates that the operator staffing plans will reflect a simpler approach of showing that a continuity of responsibility will be maintained for facility operations throughout the operating phase, with at least one GLRO providing continuous oversight and remaining immediately available when any units are fueled. Additionally, a revised approach to the traditional position of the shift technical advisor that focuses on the availability of engineering expertise as a means of addressing uncertainties and abnormal circumstances is more suitable within the context of part 53 and is intended to be applicable to all facilities, irrespective of other design and staffing considerations. Consistent with this approach, the NRC proposes under § 53.730(f) to require the submittal of a staffing plan that details operations staffing, how engineering expertise will be provided, and what staffing will be available to provide other needed support functions. The NRC intends that this requirement would be associated with staff guidance for reviewing operations staffing plans that is planned to accompany part 53 and that, following NRC approval of the OL or COL, the staffing plan would become a

condition of the facility license. The NRC intends that, at a minimum, the approved licensed operator and senior operator (or, if applicable, GLRO) staffing, positions, and personnel locations will be incorporated into corresponding requirements within the facility TS and that a license amendment would thus be required for any subsequent changes. Operator training and qualification programs provide an essential component of supporting human performance in implementing tasks with safety implications. Such programs must include components that cover the stages of initial training, examination, and continuing training. Additionally, recognizing the potential for varying concepts of operations to affect traditional, prescriptive approaches to operator proficiency, the NRC proposes under part 53 to allow facilities to develop operator proficiency programs based on facility-specific considerations.

Therefore, the NRC proposes in § 53.730(g)(1) to require approval as part of its approval of the OL or COL, of the programs that will be used for the initial training, initial examination, requalification training and examination, and proficiency of both licensed operators and senior operators. In a corresponding manner, the NRC proposes in § 53.730(g)(2) to require approval of the programs that will be used for the GLRO equivalents of each of these programs for facilities with such staffing. The NRC intends that examination program requirements would be associated with staff guidance for the review of tailored examination processes that are planned to accompany part 53. Following the completion of an initial training program, continuing training programs provide an important means of sustaining the knowledge and abilities of individuals. The NRC is proposing to adapt the requirements of § 50.54(i-1) in § 53.730(g)(3) to require that operator continuing training programs be in effect to support operator performance. Under part 53, the NRC proposes to require these programs to be in effect concurrent with when the initial operator examinations first commence, in effect putting the

programs in place only when they are needed. This represents a modification of the comparable requirement of § 50.54(i-1), which links the commencement of these programs to a timeline driven by the licensing of the facility.

The authorization to manipulate controls of the facility that directly affect reactivity or power level is restricted to individuals who are either licensed operators, licensed senior operators, or GLROs. However, for practical purposes, situations in which an individual is participating in an approved training program or reestablishing proficiency may also call for them to operate the controls of the facility under the cognizance of a licensed individual. The NRC is proposing to adapt the requirements of § 55.13 in § 53.735 to accomplish this, with a notable difference being the incorporation of GLROs.

Section 53.740 would provide requirements for OL and COL holders under part 53. Portions of § 53.740 would be adapted from the conditions of § 50.54. In general, the conditions for operations staffing under part 53 would reflect considerations for potential technological differences and varying concepts of operation that are expected among part 53 facility licensees. Additionally, certain requirements would be specific to the operating phase while others would remain in effect following the permanent cessation of facility operations during the decommissioning phase.

Because operation of facility controls directly affects reactivity or power level, only those individuals who possess appropriate levels of qualification and authorization are permitted to operate those controls. The NRC is proposing to adapt the requirements of § 50.54(i) in § 53.740(c) to require that only specifically licensed operators and senior operators or, alternatively, GLROs, may operate facility controls, with allowance for specified exceptions for the purposes of operator training or proficiency.

Senior operators, by virtue of their license level, are qualified and authorized both to perform certain important responsibilities and to direct the licensed activities of

licensed operators. Therefore, facilities that are required to be staffed by specifically licensed operators must also include senior operators within their staffing. In contrast, facilities staffed with GLROs only have a single license level available and, therefore, there is no equivalent provision for such facilities. The NRC is proposing to adapt the requirements of § 50.54(l) in § 53.740(d) to require the licensing and designation of senior operators at facilities staffed by specifically licensed operators.

In contrast with control manipulations that directly affect reactor power and reactivity (e.g., control rod movement, control drum rotation, recirculation pump speed adjustment, reactor coolant system boration or dilution, etc.) and are therefore restricted to performance only by licensed operators, other types of plant operations that may result in reactor power and reactivity changes via means that are indirect in nature (e.g., electrical generation changes, turbine bypass valve operation, steam usage by process heat applications, etc.) may be implemented by non-licensed personnel. However, due to the potential influence of such operations on reactor power and reactivity, the continuous oversight of reactor parameters by a licensed operator is necessary during these operations. The NRC is therefore proposing to adapt the requirements of § 50.54(j) in § 53.740(e) to require appropriate oversight of operations, other than those associated with the controls themselves, that may affect reactivity or power level.

Section 53.740(f) would allow for load following, provided that appropriate measures are in place.

Core alterations such as refueling are associated with specific considerations that warrant limiting the oversight of such operations to appropriately qualified and authorized individuals. Unlike other types of fuel handling operations, core alterations occur within the confines of a reactor vessel that is specifically designed to support and sustain nuclear criticality, thereby justifying the imposition of higher qualification levels

within such contexts. The NRC is proposing to adapt the requirements of § 50.54(m)(2)(iv) in § 53.740(g) to require the supervision of core alterations by either a specifically licensed senior operator, a specifically licensed senior operator whose license is limited to fuel handling, or by a GLRO, as applicable to the facility. Because certain commercial reactor designs may be capable of refueling while at power and, in any event, overall facility oversight would already be required by either a specifically licensed senior operator or by a GLRO, the NRC proposes to omit this requirement as redundant during periods where core alterations occur while the plant is operating.

The NRC is proposing to adapt the requirements of § 50.54(x) and (y) in § 53.740(h) to permit specific individuals to authorize departures from facility license conditions or technical specifications when emergency conditions warrant doing so for the protection of the public health and safety. Recognizing that certain facilities licensed under part 53 may be staffed by GLROs in lieu of specifically licensed senior operators, the NRC proposes to extend this authority to GLROs. While it is not anticipated that GLROs will have a role in the fulfillment of safety functions at self-reliant-mitigation facilities and, furthermore, that operators at such facilities would not be in a position by which to significantly influence radiological safety outcomes, the very nature of the § 50.54(x) and (y) and the proposed § 53.740(h) provisions concerns situations that are unanticipated and, therefore, unforeseeable. Thus, it is appropriate to grant GLROs a comparable authority to that of senior licensed operators and certified fuel handlers as it relates to invoking this provision under emergency conditions as a means of accounting for such possibilities.

Due to the unique authorities and responsibilities of both specifically and generally licensed reactor operators, it is essential that any individual fulfilling such a role demonstrate compliance with the regulatory requirements for operator licensing.

Section 107 of the AEA authorizes the Commission to prescribe conditions for the licensing of operators and to issue licenses consistent with those conditions. The NRC is proposing to adapt the requirements of § 55.3 in § 53.745 to require that any person performing the function of an operator, senior operator, or GLRO must be authorized by a license issued by the Commission.

The NRC proposes to license individuals as operators under both specific and general licensing frameworks. Specific licenses would be for licensed operators (i.e., reactor operators) and senior operators (i.e., senior reactor operators) and would be issued to a named person upon approval by the Commission of an application for that named person. In contrast, GLROs would perform duties under the provisions of a general license that would be effective without the filing of an application with the Commission or the issuance of licensing documents to a particular person. The NRC proposes requirements for the use of the specific licensing process in part 55 for licensed operators and senior operators under §§ 53.760 through 53.780, with § 53.760 addressing applicability.

The NRC proposes overall programmatic requirements for specifically licensed operator and senior operator training, examination, and proficiency in § 53.780. In general, the proposed requirements are adapted from those in part 55, with several additional flexibilities being incorporated to better account for potential variations in reactor technologies and concepts of operations. The requirements proposed in § 53.780 cover, in part, the initial training, initial examination, requalification training, requalification examination, and proficiency of specifically licensed operators and senior operators.

The initial training process provides individuals with the knowledge and abilities needed to subsequently fulfill assigned duties as licensed operators or senior operators

in a safe and reliable manner. The use of a systems approach to training (SAT) ensures that the training program is based upon job requirements in a manner that can be adapted to account for differences in plant technology, concepts of operations, and operator roles in the fulfillment of design-specific safety functions. The NRC is proposing under § 53.780(a) to require facility licensees to implement a SAT-based training program for the initial training of licensed operator and senior operator applicants. The program must be adequate to ensure that applicants will be capable of performing the duties necessary both to protect public health and safety and to maintain plant safety functions. The NRC further proposes that such programs be subject to NRC approval and subsequent change control processes of an appropriate nature.

Examinations provide a means of assessing that individuals have achieved a degree of knowledge and ability that is sufficient to carry out assigned duties as licensed operators or senior operators in a manner that is safe and reliable. The NRC is proposing to adapt the requirements of §§ 55.40, 55.41, 55.43, and 55.45 in § 53.780(b) to require that facilities establish and implement an initial examination program. However, a key difference from the comparable requirements of part 55 would be that facilities have the flexibility to propose, subject to NRC approval, the examination methods and criteria to be used in assessing satisfactory applicant performance. Such examination programs (including those used within the scope of requalification training) would need to provide for acceptable levels of both test validity and test reliability in order to be considered acceptable. The NRC intends that staff guidance would be available to facilitate the review of licensing examination programs that are proposed by facility licensees and that, following NRC approval, initial examination programs would be subject to an appropriate change control process. Furthermore, the NRC proposes that holders of licenses to operate commercial nuclear plants under part 53 be provided

the alternative of administering their own approved licensing examinations. The NRC would continue to exercise appropriate oversight of the program, make operator licensing decisions based upon the examination results, and reserve the right to administer the examinations in lieu of permitting the facility to do so. However, irrespective of the provided flexibilities in examination format and structure, at a minimum, topics from the following general categories of knowledge and abilities should be sampled in such examinations:

- Reactor Theory, Thermodynamics, and Chemical Interactions
- Plant Systems and Components
- Reactivity Management and Manipulations
- Radiation Control and Safety
- Emergency, Abnormal, and Normal Operations
- Administrative Requirements and Conditions of the Facility License

Requalification training programs provide for the continuing training and examination of specifically licensed operators and senior operators to ensure that they maintain the knowledge and abilities needed to support the safe and reliable performance of job duties following the completion of an initial training and examination program. The NRC is proposing to adapt the requirements of § 55.59 in § 53.780(c) to require that facilities implement both a SAT-based requalification training program and a biennial requalification examination program. However, a notable difference from the biennial requalification examinations required under part 55 would be that distinct annual operating test and biennial written examination components would not be mandated, with the facility licensee instead proposing the examination methods and criteria to be used in assessing satisfactory performance. The NRC intends that guidance would be available to facilitate the review of the requalification examination programs that are

proposed by facility licensees and that, following NRC approval, requalification examination programs would be subject to an appropriate change control process.

For examinations to provide for valid assessments of the knowledge and abilities of individuals, the examinations must remain free from compromises that could affect their underlying integrity. The NRC is proposing to adapt the requirements of § 55.49 in § 53.780(d) to require that examinations and related activities remain free from any compromise that might affect the integrity of the examination process.

Simulators provide a valuable means of training and evaluating plant operators, and the NRC is specifically authorized under the Nuclear Waste Policy Act of 1982, as amended (NWPA), section 306 (42 U.S.C. 10226) to establish regulations for the use of simulators within such context. The NRC is proposing to adapt the requirements of § 55.46 in § 53.780(e) to address the use of simulation facilities for training, examinations, and applicant experience requirements, as well as to address the maintenance of simulator fidelity. However, the proposed requirements of part 53 would not mandate that full scope, plant-referenced simulators be used and would allow the use of alternative simulation facilities consisting of, for example, partial scope simulators or the plant itself, provided that all associated requirements can be demonstrated to be met using alternative approaches and methods. Additionally, in allowing for the possibility that an applicant or licensee might demonstrate compliance with training, examination, or experience requirements using the plant itself, the NRC is not allowing the initiation of transients on the actual plant. Consistent with this, aside from controlled reactivity manipulations that are conducted for the purposes of demonstrating compliance with experience requirements, actual plant components may not be operated for these purposes. Rather, the NRC perspective is that the use of the plant for training and examination purposes should be restricted to techniques such as walkthroughs, job

performance measures, simulated tasks, use of augmented reality technology, and similar approaches that provide training and examination value while avoiding the operation of actual plant components.

There may be situations in which applicants for operator or senior operator licenses have previous training and experience that justifies waiving some, or all, of the initial examination requirements. The NRC is proposing to adapt the requirements of § 55.47 in § 53.780(f) to allow for consideration of requests for waivers of examinations requirements. In contrast with the part 55 requirements, the NRC proposes to locate certain details associated with such waiver requests within guidance documentation in lieu of placement within the rule itself.

For licensed operators and senior operators to perform their assigned duties safely and reliably, it is essential that they perform those duties frequently enough so as to maintain a sufficient degree of proficiency. The NRC is proposing to adapt the requirements of § 55.53(e) and (f) in § 53.780(g) to require that specifically licensed operators and senior operators maintain proficiency and, if proficiency is not maintained, regain proficiency prior to resuming licensed duties. However, in recognition of the fact that varying concepts of operations are possible for advanced reactor facilities, the NRC is proposing, in contrast with the requirements of part 55, to allow facility licensees to establish their own programs for operator proficiency, subject to NRC approval.

The licenses issued to specifically licensed operators and senior operators are valid for a period of six years, after which they expire, unless otherwise renewed. The NRC is proposing to adapt the requirements of §§ 55.55 and 55.57 in § 53.795 to address the expiration and renewal of licenses issued to specifically licensed operators and senior operators.

In developing this proposed rule, the NRC has discussed with stakeholders the considerations that might justify the omission of the specifically licensed operators and senior operators. However, even for an inherently safe reactor with autonomous operation features, certain important administrative functions (e.g., compliance with TS, operability determinations, NRC notifications, emergency declarations, risk assessment, maintenance oversight, and radiological release limit compliance) would still need to be accomplished by appropriately qualified and authorized individuals. Additionally, the NRC recognized that manual manipulations of facility reactivity controls must only be performed by individuals who have been appropriately licensed by the Commission. The NRC therefore proposes under § 53.800 to establish a new class of facility (defined as a self-reliant-mitigation facility) and the criteria for classification of such a commercial nuclear plant. These facilities would employ GLROs rather than specifically licensed operators and senior operators. The GLRO regulations offer enhanced flexibilities and targeted relaxations in a manner that is commensurate with the modified role of such operators to ensure the safe operation of the associated facilities. In contrast, those commercial nuclear plants not meeting the criteria of § 53.800 would instead be considered interaction-dependent-mitigation facilities and would require staffing by specifically licensed operators and senior operators. The terminology used to designate these facility types reflects differences in how operators are anticipated to need to interact with their plant systems in mitigating events and achieving safe outcomes; such systems may either need operators to interact with them in some manner (i.e., be interaction-dependent) or may instead be able to rely fully upon their own capabilities independent of operator interaction (i.e., be self-reliant).

Generally licensed reactor operators would differ from specifically licensed operators because the latter would be directly and independently evaluated by the NRC

as part of their licensing process. This direct and independent evaluation remains appropriate when operators may reasonably be expected to exert a significant influence on public health and safety outcomes. Therefore, a key determinant as to whether generally licensed reactor operators can be utilized in facility staffing is the assessment of the operator's role in maintaining and fulfilling safety functions at the facility, such as through the performance of credited actions for the mitigation of plant events.

The criteria proposed in § 53.800 would designate self-reliant-mitigation facilities. These criteria are structured to address facilities under part 53 and are derived from a common set of considerations:

- no human action needed to satisfy radiological consequence criteria;
- no human action needed to address LBEs;
- safety functions not allocated to human action;
- reliance upon robust and highly reliable safety features; and
- adequate defense in depth achieved without reliance on human action.

It should be noted that those facilities not meeting the criteria proposed in § 53.800 would instead be classified as interaction-dependent-mitigation facilities and would require staffing by specifically licensed operators and senior operators instead.

GLROs would perform duties under the provisions of a general license that would be effective without the filing of an application with the Commission or the issuance of licensing documents to a particular person. The NRC proposes requirements for the general licensing process for GLROs under §§ 53.805 through 53.820. The requirements for GLROs would parallel those for senior operators in regard to their comparable administrative responsibilities. Nonetheless, the requirements for GLROs would be relaxed and incorporate greater flexibilities compared to the requirements for

specifically licensed operators in a manner that is consistent with the GLRO's role in safety at self-reliant-mitigation facilities.

Section 53.785 would require that the holder of a license to operate a commercial nuclear plant that is a self-reliant mitigation facility under part 53 to maintain GLRO qualifications for the performance of important functions and tasks; to administer the related programs for training, examination, and proficiency; and to ensure that the relevant provisions of parts 26 and 73 are met. Additionally, to provide for an accurate accounting of what individuals are licensed under the general license, facility licensees would be required to report the identities of all generally licensed reactor operators to the NRC on an annual basis. Furthermore, a facility licensee must ensure that the facility design and performance continue to meet the technological criteria to be classified as a self-reliant-mitigation facility (i.e., the criteria of § 53.800) on a continual basis during the operating phase, as the relaxations afforded to such facilities in the areas of operator licensing, staffing, and HFE would be predicated on this assumption. The failure of a self-reliant-mitigation facility to subsequently meet the criteria of § 53.800 after the issuance of an OL or COL would constitute a reportable event (i.e., an unanalyzed condition that significantly degrades plant safety) under the provisions of § 53.1630.

The NRC proposes the general license for GLROs under § 53.810. GLROs would be licensed as a class of individuals under the provision of § 53.810(a) and would be subject to the conditions specified in § 53.810(b) through (g). Portions of these conditions are adapted from § 55.53 and from those conditions currently included in the licenses issued to specifically licensed operators and senior operators. The NRC would retain the ability to suspend or prohibit individuals from operating under the general license should such action be warranted.

The NRC proposes overall programmatic requirements for GLRO training, examination, and proficiency under § 53.815. In general, these proposed requirements are adapted from those of part 55 and parallel those also proposed for specifically licensed senior operators in § 53.780. These requirements include increased flexibilities and several targeted relaxations that reflect the limited role of GLROs in facility safety. The requirements proposed under § 53.815 cover, in part, the initial training, initial examination, continuing training, requalification examination, and proficiency of GLROs. Section 53.805 would require the facility licensee to develop, implement, and maintain these programs. Section 53.810, in turn, would prescribe that the requirements of § 53.805 would need to be met as a requirement of the general license. The implication of this structure is that the facility licensee would need to implement these programs for training, examination, and proficiency, and GLROs would need to participate in these programs to demonstrate compliance with the requirements of the general license.

The initial training process provides GLROs with the knowledge and abilities needed to fulfill assigned duties as GLROs. The use of a SAT serves to ensure that the training program is based upon job requirements in a manner that can be adapted to account for differences in plant technology and concepts of operations. The NRC is proposing under § 53.815(b) to require facility licensees to implement a SAT-based training program for the initial training of GLROs that is adequate to ensure that they have the necessary knowledge, skills, and abilities to perform their duties. The NRC further proposes that such programs would be subject to NRC approval, oversight, and appropriate change control processes. The training program must ensure that GLROs maintain the necessary knowledge, skills, and abilities.

Examinations provide a means of assessing that individuals have achieved a degree of knowledge and ability that will be sufficient to enable them to carry out

assigned duties as GLROs in a manner that is both safe and reliable. The NRC proposes to adapt the requirements of §§ 55.40, 55.41, 55.43, and 55.45 in § 53.815(b) to require that facility licensees establish and implement an initial examination program. A key difference from the comparable requirements of part 55 would be that facility licensees would be afforded the flexibility to propose, subject to NRC approval, the examination methods and criteria to be used in assessing satisfactory individual performance. Such examination programs (including those used within the scope of continuing training) would need to provide for acceptable levels of both test validity and test reliability in order to be considered acceptable. The NRC intends that staff guidance would be available to facilitate the review of initial examination programs that are proposed by facility licensees and that approved initial examination programs would be subject to an appropriate change control process. In contrast with both the requirements of part 55 and the proposed requirements of § 53.780, the NRC does not intend to administer or evaluate these initial examinations. However, the examination processes themselves will continue to be subject to ongoing NRC oversight. Irrespective of the provided flexibilities in examination format and structure, topics from the following general categories of knowledge and abilities should be sampled in such examinations:

- Reactor Theory, Thermodynamics, and Chemical Interactions
- Plant Systems and Components
- Reactivity Management and Manipulations
- Radiation Control and Safety
- Emergency, Abnormal, and Normal Operations
- Administrative Requirements and Conditions of the Facility License

Continuing training programs provide the ongoing training and examination of GLROs to ensure that they maintain the knowledge and abilities needed to support the

safe and reliable performance of job duties following the completion of an initial training and examination program. The NRC is proposing to adapt the requirements of § 55.59 in § 53.815(b) to require that facility licensees implement both a SAT-based continuing training program and a requalification examination program. However, a notable difference from the examinations required under part 55 would be that distinct annual operating test and biennial written examination components would not be mandated. The facility licensee would instead propose examination methods and criteria to be used in assessing satisfactory performance. Furthermore, unlike the comparable requirements of part 55 and those proposed for specifically licensed operators and senior operators, a biennial periodicity for requalification examinations would not be prescribed. However, adequate justification for the proposed periodicity of requalification examinations would be required. The NRC intends that staff guidance would be available to facilitate the review of the requalification examination programs that are proposed by facility licensees. Approved requalification examination programs would be subject to an appropriate change control process.

For examinations to provide for valid assessments of the knowledge and abilities of individuals, the examinations must remain free from compromises that could affect their underlying integrity. The NRC is proposing to adapt the requirements of § 55.49 in § 53.815(d) to require that examinations and related activities remain free from any compromise that might affect the integrity of the examination process.

Simulators provide a valuable means of training and evaluating plant operators and the NRC is specifically authorized under the NWPA, section 306 (42 U.S.C. 10226) to establish regulations for the use of simulators within such context. The NRC is proposing to adapt the requirements of § 55.46 in § 53.815(e) to address the use of simulation facilities for training and examinations, and experience requirements, as well

as to address the maintenance of simulator fidelity. The use of full scope, plant-referenced simulators would not be mandated. The potential use of alternative simulation facilities consisting of, for example, partial scope simulators or the plant itself, would be allowed provided that all associated requirements could be demonstrated to be met using alternative approaches and methods. Additionally, in allowing for the possibility that an applicant or licensee might demonstrate compliance with training and examination requirements using the plant itself, the NRC is not allowing the initiation of transients on the actual plant. Consistent with this, aside from controlled reactivity manipulations that are conducted for the purposes of demonstrating compliance with experience requirements, actual plant components may not be operated for these purposes. Rather, the use of the plant for training and examination purposes should be restricted to techniques such as walkthroughs, job performance measures, simulated tasks, use of augmented reality technology, and similar approaches that provide training and examination value while avoiding the operation of actual plant components.

There may be situations in which GLROs have previous training and experience that justifies waiving some, or all, of the initial examination. Therefore, the NRC is proposing under § 53.815(f) to allow facility licensees to waive some, or all, portions of initial examinations provided that such waivers are consistent with a program that has been approved by the NRC.

For GLROs to safely and reliably perform their assigned duties, it is essential that they perform those duties frequently enough so as to maintain a sufficient degree of proficiency. However, the NRC recognizes that facilities that utilize GLROs may have concepts of operation that warrant unique proficiency considerations. Therefore, the NRC is proposing in § 53.815(g) to require that facility licensees develop, implement, and maintain programs to maintain and reestablish, if needed, the proficiency of GLROs.

This could occur, for example, if an individual's extended absence from watch standing has rendered proficiency requirements unmet.

The general license should remain in effect for an individual only while that individual remains employed in a position that may call for the individual to manipulate the reactivity controls of the facility. The NRC proposes under § 53.820 to require that the general license would cease to be applicable on an individual basis when an individual's employment status becomes such that this is no longer the case. However, the NRC recognizes that for some types of self-reliant-mitigation facilities, very long periods may elapse between circumstances that necessitate manual manipulation of reactivity controls. Therefore, the general license remains in effect for an individual as long as the individual's current position could potentially require that individual to manipulate reactivity controls at some point within the course of the individual's assigned job duties.

The NWPA, section 306 (42 U.S.C. 10226) authorizes and directs the NRC to, in part, issue regulations and guidance that address the training and qualifications of civilian nuclear power plant operators, supervisors, technicians, and other appropriate operating personnel. The NRC implements this in part 50 through the requirements of § 50.120, "Training and qualification of nuclear power plant personnel." The NRC is proposing under § 53.830 to adapt, with modifications, the requirements of § 50.120 for use in part 53 to provide more flexible personnel training and qualification requirements than those in § 50.120 [or part 50] and better reflect diverse concepts of operations.

The NRC recognizes that the categories of nuclear power plant personnel in § 50.120 may not be needed for the diverse concepts of operations, staffing models, and non-traditional personnel roles and responsibilities anticipated under proposed part 53; conversely, and for the same reasons, additional categories of plant personnel may

need to be covered by part 53. The NRC also recognizes that the timeframe prescribed in § 50.120 for the establishment of training programs may not be aligned with the schedules associated with the startup of certain types of commercial nuclear plant facilities. However, the NRC also recognizes that the SAT-based training required under § 50.120 remains an appropriate means by which training programs should continue to be developed and implemented. Thus, the approach taken by the NRC in addressing the training of certain plant staff under the proposed part 53 reflects greater flexibilities in personnel categories and programmatic timeframes, while still retaining the requirement that such training programs be based on SAT.

The NRC is proposing under § 53.830 to require SAT-based training programs with the timeframe for when such programs are required being based upon when the associated personnel are needed to support facility-specific needs. The training programs would cover the training and qualification of plant personnel in the general categories of supervisors, technicians, and other appropriate operating personnel. The licensee would not be required to seek NRC approval of a training program prior to usage. However, the licensee is required to accommodate NRC inspection of the training program. The NRC intends to develop guidance to facilitate the inspection of these training programs but does not intend for such guidance to preclude the potential for the training programs to be maintained by a separate, NRC-approved accreditation process.

Proposed § 53.845 would require programs to be developed, implemented, and maintained to help ensure that design features and human actions have the capabilities and reliabilities necessary to demonstrate compliance with the safety criteria in subpart B throughout the operating life of each commercial nuclear plant. The proposed programmatic requirements in subpart F would also address areas such as radiation

protection needed to control routine effluents during normal operations. The proposed §§ 53.850 through 53.880 would require programs to support specific activities needed to ensure the prevention or mitigation of unplanned events or to support normal operations for any reactor design. However, each holder of an OL or COL would be required to assess whether additional programs are needed for the specific reactor design and location of the commercial nuclear plant. Licensees would be able to combine, separate, and otherwise organize programs and related documents as appropriate for the technologies and organizations associated with the commercial nuclear plant.

Proposed § 53.850 would require a radiation protection program associated with the requirements in subparts B and C for public doses resulting from normal operations and the protection of plant workers. The proposed requirements related to doses from normal operations, including routine effluents, would be similar to those specified in § 50.36a, “Technical specifications on effluents from nuclear power reactors,” and related requirements in standard TS for offsite dose calculation manuals. While the proposed section would include requirements that are technically and programmatically similar to part 50, proposed § 53.850 would not include a requirement for effluent-related TS as is required in § 50.36a. A proposed requirement similar to that found in the administrative controls section of TS for operating reactors licensed under parts 50 and 52 would be included for programmatic controls of solid wastes to complement the design requirements in proposed § 53.425.

Proposed § 53.855 would require an emergency response plan that demonstrates compliance with the requirements in appendix E to part 50 and § 50.47. The regulations in § 50.47 state that the NRC will not issue certain licenses unless it finds that there is reasonable assurance that adequate protective measures can and will

be taken to protect public health and safety in the event of a radiological emergency. The proposed § 53.855 also relates to an ongoing rulemaking activity that would provide alternatives to certain elements of the existing regulations. The draft final rule is described in SECY-22-0001, “Final Rule: Emergency Preparedness for Small Modular Reactors and Other New Technologies,” dated January 3, 2022. If the NRC proceeds with revising its regulations as described in SECY-22-0001, the same flexibility in determining appropriate emergency preparedness measures, as directed by the Commission, would be added to part 53.

In its 2008 Advanced Reactor Policy Statement, the Commission stated their expectation that “the safety features of advanced reactor designs will be complemented by the operational program for Emergency Planning (EP). This EP operational program, in turn, must be demonstrated by inspections, tests, analyses, and acceptance criteria to ensure effective implementation of established measures.” Consistent with this policy statement, emergency plans are not used to demonstrate compliance with the safety criteria in subpart B but complement safety features in the design. In SECY-97-020, “Results of Evaluation of Emergency Planning for Evolutionary and Advanced Reactors,” dated January 27, 1997, the staff indicated that the rationale upon which EP for current reactor designs is based, that is, potential consequences from a spectrum of accidents, is appropriate for use as the basis for EP for evolutionary and passive advanced LWR designs and is consistent with the Commission's defense-in-depth safety philosophy. Also, in its Safety Goals Policy Statement the Commission stated that: “A defense-in-depth approach has been mandated in order to prevent accidents from happening and to mitigate their consequences. Siting in less populated areas is emphasized. Furthermore, emergency response capabilities are mandated to provide additional defense-in-depth protection to the surrounding population.” Consistent with this policy statement,

proposed § 53.855 contributes an additional independent layer of defense in depth for commercial nuclear plants.

Proposed § 53.860 would identify the applicable regulations for part 53 applicants under part 53 related to the programs for physical security, cyber security, FFD, AA and information security. These programs are discussed in more detail in section V, “Changes to Other Parts of 10 CFR Chapter I,” of this document.

Proposed § 53.860(a) would establish the physical protection program and present a graded approach to physical protection requirements. If a licensee can meet the proposed criterion in § 53.860(a)(2), then the requirement for a physical protection program to protect against the design-basis threat (DBT) of radiological sabotage would not be applicable because the need for such a program would be addressed by design and engineered safety features under § 53.440(f). The criterion in § 53.860(a)(2) would require a licensee to show that potential consequences resulting from a DBT initiated event would result in offsite doses below the values in § 53.210 even if licensee mitigation and recovery actions, including any operator action, are unavailable or ineffective. Where the criterion is met, the resulting physical protection requirements would be those for protection of SNM and Category 1 and Category 2 radioactive material, if applicable. This proposal would apply a new regulatory approach for certain commercial nuclear plants in which the DBT of radiological sabotage would not be applicable.

For those licensees able to meet the criterion in § 53.860(a)(2), the NRC would not conduct Force-On-Force (FOF) exercise inspections. Section 170D.a of the AEA permits the Commission to determine which licensed facilities are part of a class of licensed facilities where NRC-conducted FOF exercises are appropriate to assess the ability of a private security force of a licensed facility to defend against any applicable

DBT. For the class of licensees that meet the criterion of § 53.860(a)(2), it would not be appropriate to conduct FOF exercises to evaluate performance at commercial nuclear plants where the DBT of radiological sabotage is not applicable and the facility poses a lower risk to public health and safety from potential radiation exposure. These facilities would still have tailored security requirements and oversight consistent with their relatively low risk.

For those licensees not able to meet the criterion in § 53.860(a)(2), proposed § 53.860(a) would permit the licensee to choose one of two paths to provide physical protection: (1) the current set of requirements in § 73.55, which would include any changes resulting from the ongoing proposed rulemaking on Alternative Physical Security Requirements for Advanced Reactors[2] that provides pre-determined physical security alternatives; or (2) the performance-based requirements in proposed § 73.100. In either case, the licensee would be subject to NRC-conducted FOF inspections.

Proposed § 53.860(b) would require licensees to establish, implement, and maintain an FFD program under part 26. Section 53.860(c) would require licensees to establish, implement, and maintain an AA program in accordance with either § 73.56 or proposed § 73.120, as appropriate. Section 53.860(d) would require licensees to establish, implement, and maintain a cyber security program in accordance with either § 73.54 or proposed § 73.110. Section 53.860(e) would require licensees to establish, implement, and maintain an information protection system that complies with the requirements of §§ 73.21, 73.22, and 73.23, as applicable.

Proposed § 53.865 would establish requirements for quality assurance using appendix B to part 50. Proposed requirements related to evaluating and reporting

[2] SECY-22-0072, “Proposed Rule: Alternative Physical Security Requirements for Advanced Reactors,” dated August 2, 2022.

changes to the quality assurance program would be included in proposed subpart I and would be equivalent to those found in § 50.54.

Proposed § 53.875 would establish requirements for a fire protection program supporting operations similar to § 50.48. The proposed fire protection program during operations would work in concert with specific fire protection requirements proposed in subpart C for design and analyses and in proposed subpart E for construction and manufacturing.

Proposed § 53.880 would establish requirements for an inservice inspection (ISI) and inservice testing (IST) program, which are historically important activities conducted in accordance with ASME codes and regulations in § 50.55a. While the proposed part 53 would not incorporate specific consensus codes and standards into the regulations, § 53.880 allows for the use of generally accepted codes and standards. The proposed requirement for an ISI and IST program would reinforce the need to develop monitoring programs to be conducted during a plant's operations phase to complement the design process and address inherent uncertainties. The NRC encourages the continued use of consensus codes and standards supporting design, testing, and inspections to support integrated and performance-based approaches in demonstrating compliance with the proposed requirements in part 53.

Subpart G – Decommissioning Requirements

The proposed subpart G would provide the regulatory requirements for the decommissioning phase of the life cycle of a commercial nuclear plant. The requirements being proposed are adapted from the current regulations in § 50.75, "Reporting and recordkeeping for decommissioning planning," § 50.82, "Termination of license," and § 50.83, "Release of part of a power reactor facility or site for unrestricted use." Although the requirements from those sections of part 50 have been copied into

proposed subpart G with relatively few changes, the requirements are reorganized to fit within the part 53 structure. The few changes made were primarily to make the proposed requirements more technology-inclusive by adding alternatives within sections, whereas some requirements in part 50 were developed specifically for LWRs.

As an example, § 50.75 provides minimum amounts of decommissioning funds required to demonstrate reasonable assurance of funds for decommissioning LWRs. Such generic amounts have not been developed for all reactor technologies that may be licensed under part 53. Therefore, the Commission proposes in § 53.1020, “Cost estimates for decommissioning,” that site-specific cost estimates for decommissioning must be developed considering costs in such areas as engineering, labor, and waste disposal. The derivation of the generic cost estimates for LWRs in § 50.75 is provided in NUREG/CR-5884, “Revised Analyses of Decommissioning for the Reference Pressurized Water Reactor Power Station,” and NUREG/CR-6187, “Revised Analyses of Decommissioning for the Reference Boiling Water Reactor Power Station.” Similar to part 50, a provision for an annual adjustment of decommissioning cost estimates would be included in proposed § 53.1030..

The NRC is currently pursuing another rulemaking, “Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning,” which was published as a proposed rule for public comment on March 3, 2022 (87 FR 12254). As these rulemakings progress, the NRC will consider revisions to part 53 to align the two rulemaking efforts. For example, the proposed §§ 53.1075 could be expanded to include or reference requirements for decommissioning in areas such as EP and security in addition to the proposed decommissioning fire protection plans that would provide an equivalent to § 50.48(f).

Subpart H – Licenses, Certifications, and Approvals

Proposed subpart H would provide requirements related to applications under part 53 for NRC licenses, certifications, or approvals for commercial nuclear plants.

Proposed subpart H would specify requirements applicable to all part 53 applications as well as requirements specific to part 53 applications for LWAs, ESPs, standard design approvals, standard DCs, MLs, CPs, OLs, and COLs. Proposed subpart H would be equivalent to and include all existing licensing, certification, and approval processes currently covered under parts 50 and 52, with the exception of the process for early review of site suitability issues. Interactions with external stakeholders during the development of the proposed rule did not identify significant interest in or need for including the process for early review of site suitability issues in part 53.

Much of the proposed subpart H regulatory text is identical to the corresponding language in parts 50 and 52, with minor changes to account for cross references in part 53, to make language technology neutral, or to reflect the unique analytical approach. In these instances, this preamble discussion will describe the language as “equivalent” to the existing corresponding requirement in part 50 or part 52 and will describe any deviations, where applicable.

Because part 53 carries over the majority of the licensing options from parts 50 and 52, there are several sections in proposed subpart H that are similar to existing regulations in parts 50 and 52. Some of this text corresponds to requirements that are also being addressed in the proposed rulemaking on “Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing” (Docket ID NRC-2009-0196) for parts 50 and 52, hereafter referred to as the “parts 50/52 rulemaking.” To minimize confusion and duplicative efforts between this rulemaking and the parts 50/52 rulemaking, the NRC will reconcile similar requirements between the parts 50/52 rulemaking and the part 53 rulemaking once the parts 50/52 rulemaking is issued as a

final rule. Therefore, proposed subpart H largely reflects the current version of parts 50 and 52.

Proposed § 53.1100 would address filing of applications for licenses, certifications, or approvals under oath or affirmation and is equivalent to § 50.30. The proposed § 53.1100 does not include the current requirement in § 50.30(a)(2) that the applicant maintain the capability to generate additional copies, because it is unnecessary in the age of electronic submissions. In addition, the existing requirement on applications for OLs in § 50.30(d) is included in proposed § 53.615, “Application for operating licenses,” rather than in proposed § 53.1100. The proposed § 53.1100 includes applicants for standard design certifications within the scope of individuals required to submit applications under oath or affirmation under § 53.1100(b), pay necessary § 170.21 fees under § 53.1100(e), and submit environmental reports under § 53.1100(f). Such applicants are not within the scope of § 50.30 despite the requirements of § 51.55 for submittal of environmental reports by design certification applicants and the requirements of § 170.21 for the reimbursement of the full cost of a design certification review.

Proposed § 53.1101 would lay out activities requiring an NRC license and is equivalent to § 50.10(b). Proposed § 53.1103 would address combining applications and is equivalent to §§ 50.31, 50.52, and 52.8. Proposed § 53.1103(b) would continue the Commission’s practice of combining multiple authorizations for a facility under parts 30, 40, 50, 52, and 70 into one license based on the Commission's authority under Section 161h. of the AEA to combine NRC licenses. Proposed § 53.1106 would address elimination of repetition and is equivalent to § 50.32.

Proposed § 53.1109 would provide general information requirements for the content of applications submitted to the NRC under part 53 and is equivalent to § 50.33,

with the exception of § 50.33(f) on financial qualifications, which is covered in proposed subpart J, and § 50.33(h) on earliest and latest dates for completion of construction, which is covered in § 53.1306 of this subpart. Each application would need to include information to address the items in proposed § 53.1109 as cited in the appropriate section of this subpart for the application type. Proposed § 53.1109(g) and (i) could be updated as needed following the Commission's decision regarding the final rule on "Emergency Preparedness for Small Modular Reactors and Other New Technologies" (Docket ID NRC-2015- 0225). One change from current requirements can be found in proposed § 53.1109(i), which is not limited to electricity generation as it is currently in part 50. Some prospective NRC applicants are considering development of nuclear plants for other commercial ventures, such as process heat generation or hydrogen production. Additionally, a footnote corresponding to footnote 5 in § 50.33 regarding the incorporation by reference of previously submitted emergency response plans is not provided in § 53.1109 because incorporation by reference would be covered under § 53.1106, "Elimination of repetition."

Proposed § 53.1112 would address environmental conditions and is equivalent to § 50.36b. Proposed § 53.1115 would address requirements for agreements limiting access to classified information and is equivalent to § 50.37. Proposed § 53.1118 would address ineligibility of certain applicants and is equivalent to § 50.38. Proposed § 53.1121 would address public inspection of applications and is equivalent to § 50.39.

Proposed § 53.1124 would address the relationship between the various licenses, certifications, and approvals provided in this subpart, and the requirements are equivalent to a number of similar provisions in parts 50 and 52 including §§ 50.10, 52.13, 52.43, 52.73, 52.133, and 52.153. New provisions are provided in § 53.1124(a) that would allow an application for either a standard design approval or a standard DC under

part 53 to reference applicable licensing basis information that supported issuance of an OL or COL under part 53. These provisions are being proposed to offer additional flexibility beyond what is currently allowed under parts 50 or 52 for an applicant who may wish to license a first-of-a-kind reactor for operation prior to seeking generic approval or certification of the standard design.

Proposed § 53.1124(b) would address the limitations that a manufactured reactor may only be transported to a site with a COL and is equivalent to § 52.153 with the exception of not allowing transportation to a site under a CP. Proposed § 53.1130 would address LWAs and is equivalent to § 50.10. However, in proposed part 53, the definition of construction from § 50.10 would be included in § 53.020, “Definitions,” rather than in this section on requesting LWAs.

Proposed §§ 53.1140 through 53.1188 would govern the content of ESP applications. Proposed § 53.1140 is equivalent to § 52.12. Proposed § 53.1143 would address filing of applications and is equivalent to § 52.15. Proposed § 53.1144 would address general information requirements for the content of applications and is equivalent to § 52.16.

Proposed § 53.1146 would specify requirements for the technical contents of applications and is equivalent to § 52.17. Note that the proposed requirements in § 53.1146(b)(2) may be affected by issuance of the final rulemaking on “Emergency Preparedness for Small Modular Reactors and Other New Technologies” (Docket ID NRC-2015-0225).

Proposed § 53.1149 would address standards for review of ESP applications and administrative review of applications, including hearings, and is equivalent to §§ 52.18 and 52.21. Proposed § 53.1155 would address referral to the ACRS and is equivalent to § 52.23. Proposed § 53.1158 would address issuance of ESPs and is equivalent to

§ 52.24. Proposed § 53.1161 would address the extent of activities permitted and is equivalent to § 52.25. Proposed § 53.1164 would address the duration of an ESP and is equivalent to § 52.26. Proposed § 53.1167 would address provisions for requesting a LWA after issuance of an ESP and is equivalent to § 52.27. Proposed § 53.1170 would address transfers of ESPs and is equivalent to § 52.28. Proposed § 53.1173 would address applications for ESP renewals and is equivalent to § 52.29. Proposed § 53.1176 would address criteria for renewal of an ESP and is equivalent to § 52.31. Proposed § 53.1179 would address the duration of an ESP renewal and is equivalent to § 52.33. Proposed § 53.1182 would address the use of a site for purposes other than those described in the permit and is equivalent to § 52.35. Proposed § 53.1188 would address finality of ESP determinations and is equivalent to § 52.39.

Proposed §§ 53.1200 through 53.1221 would govern the contents of standard design approval applications. Proposed § 53.1200 is equivalent to § 52.131. Proposed § 53.1203 would address filing of applications and is equivalent to § 52.135. Proposed § 53.1206 would address general information requirements for the content of applications and is equivalent to § 52.136.

Proposed § 53.1209 would address requirements for the technical content of applications and is largely equivalent to § 52.137. In proposed § 53.1209(a), the NRC proposes text that expands the discussion of “major portion” standard design approvals. Additional discussion regarding standard design approvals for a major portion of a standard design can be found in the NRC’s "A Regulatory Review Roadmap for Non-Light Water Reactors,” which considers the Nuclear Innovation Alliance (NIA) report “Clarifying ‘Major Portions’ of a Reactor Design in Support of a Standard Design Approval.” Proposed § 53.1209(b) outlines the required content of the Final Safety Analysis Report (FSAR). Proposed requirements in § 53.1209(b)(2) for portions of the

application addressing design information state that the application must include design information equivalent to that required for a standard DC. This reference to the pertinent DC requirements (specifically, those in proposed § 53.1239(a)(2) through (27)) is an efficiency that would prevent the need to repeat many of the same requirements for the content of a standard design approval application.

Proposed § 53.1210 would address requirements for the content of a standard design approval application other than the FSAR. Proposed § 53.1210(a) would require the inclusion of a description of availability controls that are not included in the FSAR.

Proposed § 53.1212 would address standards for review of applications and is equivalent to § 52.139. Proposed § 53.1215 would address referral to the ACRS and is equivalent to § 52.141. Proposed § 53.1218 would address staff approval of designs and duration of design approvals and is equivalent to §§ 52.143 and 52.147. Proposed § 53.1221 would address finality of standard design approvals and information requests and is equivalent to § 52.145 with the exception that it extends such finality to a standard approval referenced in a DC application. Standard design approvals issued to date under part 52 have been issued during the NRC's review of the standard DC application and have relied on the same application content. However, a future scenario could arise where the DC application is not submitted until after a design approval has been granted. The NRC would apply the same finality provisions in this situation as in the situation where a standard design approval is referenced in a COL application.

Proposed §§ 53.1230 through 53.1263 would address standard DCs. Proposed § 53.1230 would address general provisions for standard DCs and is equivalent to § 52.41. Proposed § 53.1233 would address filing of applications and is equivalent to § 52.45. Proposed § 53.1236 would address general information requirements for the content of applications and is equivalent to § 52.46. Proposed § 53.1239 would address

requirements for the technical content of applications and is equivalent to § 52.47(a). The requirements in proposed § 53.1239 have been modified from the analogous requirements in § 52.47(a) to align with the technical requirements in proposed part 53.

Proposed § 53.1241 would address requirements for the content of a standard DC application other than the FSAR and is equivalent to § 52.47(b) and (d).

Proposed § 53.1242 would address review of applications and is equivalent to §§ 52.48 and 52.51. Proposed § 53.1242(c) would include a provision that would allow a DC applicant to reference applicable licensing basis information for an OL or COL issued under part 53. As explained previously, this provision is being proposed to explicitly allow flexibility for an applicant who may wish to license a first-of-a-kind reactor for operation prior to seeking certification of the generic reactor design. For NRC findings on a reactor design in an OL or COL proceeding, this proposal would provide finality in a subsequent DC application that references information on the OL or COL proceeding's docket. This finality accorded to the OL or COL findings would bind the NRC staff and the ACRS but would not bind members of the public or the Commission. (To the extent an Atomic Safety and Licensing Board (ASLB) might have a role in a DC rulemaking, the OL or COL findings would not bind the ASLB either.) Specifically, members of the public would have the opportunity to comment on a proposed DC rule under well-established NRC practice. The rationale for binding the NRC staff and ACRS is similar to the rationale for a COL applicant referencing a standard design approval under part 52.

Proposed § 53.1245 would address referral to the ACRS and is equivalent to § 52.53. Proposed § 53.1248 would address issuance of standard DCs and is equivalent to § 52.54. Proposed § 53.1251 would address referencing standard DC applications in applications for a CP or COL prior to the granting of the DC and is equivalent to

§ 52.55(c). Proposed § 53.1263 would address finality of standard DCs and is equivalent to § 52.63.

There are no equivalent sections in part 53 corresponding to § 52.55(a)-(b) or §§ 52.57 through 52.61. This reflects the Commission's determination that the imposition of a duration on its finding that the criteria of § 53.1248 have been met would be inappropriate in light of the inefficiency of requiring a further application for renewal of a granted standard DC under the same criteria that were in effect at the initial granting of the standard DC with certain allowances for modifications corresponding to those of § 52.59. Should information come to light following the granting of a standard DC that shows that modification, rescission or the imposition of new requirements on the certification information would be warranted under the finality provisions in § 53.1263, the Commission would take appropriate action based on the totality of the circumstances taking into account the cost of a rulemaking to amend the DC rule, the direct and indirect costs of addressing the circumstances on a facility-specific basis, and the safety implications of the issues. Instances where information shows that action is necessary to provide adequate protection of the public health and safety or the common defense and security at a commercial nuclear plant licensed under part 53 that referenced an effected standard DC would be required to be addressed by the Commission under proposed §§ 53.1263(a)(4) and 53.1590(a)(5).

Proposed §§ 53.1270 through 53.1295 would address MLs covering manufacturing activities at one or more licensee facilities. Proposed § 53.1270 would address the scope of these sections and is equivalent to § 52.151.

Proposed § 53.1273 would address filing of applications for an ML and is equivalent to § 52.155(a).

Proposed § 53.1276 would address general information requirements for the content of ML applications and is equivalent to § 52.156, with one exception. Proposed § 53.1276 would require each application for an ML to also include the information required by § 53.1109(e). This information includes the type of license applied for, the use to which the facility will be put, the period of time for which the license is sought, and a list of other licenses, except operator's licenses, issued or applied for in connection with the proposed facility to address the potential variations in how MLs might be formulated under the proposed part 53.

Proposed § 53.1279 would address requirements for the technical content of applications for MLs to be included in the FSAR and is equivalent to § 52.157. In addition, the requirements in proposed § 53.1279(a) and (b) have been modified from the analogous requirements in § 52.157 to align with the technical requirements in proposed part 53. Proposed § 53.1279(a)(2) outlines the required content of the application addressing design information and states that the application must include design information equivalent to that required for a standard DC. This reference to the pertinent DC requirements is an efficiency that would prevent the need to repeat the same requirements for the content of an ML application.

Proposed § 53.1279(c) would provide application requirements related to the deployment of the completed manufactured reactor. Proposed § 53.1279(c)(1) would require inclusion of information related to the procedures governing the preparation of the manufactured reactor for shipping to the site where it is to be operated, the conduct of shipping, and the verification of the condition of the shipped items upon receipt at the site. Proposed § 53.1279(c)(2) would require that the application include information on the interaction of the design, manufacture, and installation of a manufactured reactor within the applicant’s organization and the manner by which the applicant will ensure

close integration between the designer, contractors, and any licensee of a facility in which the manufactured reactor is to be installed. Finally, proposed § 53.1279(c)(3) would require that the application include a description of the measures used for the control of interfaces between the holder of the ML and the holder of the COL for the commercial nuclear plant at which the manufactured reactor is to be installed. This information is necessary for the NRC to determine whether the applicant would have appropriate controls in place to ensure coordination between parties involved in the design, manufacture, and eventual operation of any reactor manufactured under an ML.

Proposed § 53.1279(d) would provide additional considerations to allow for fueling of a manufactured reactor at the factory and its use as transportation container under part 70 prior to its installation at a site as part of a commercial nuclear plant.

Proposed § 53.1282 would provide requirements for other application content for MLs and is equivalent to § 52.158. Proposed § 53.1282(a)(1) would provide requirements to include in the ML application the ITAAC within the scope of the ML that the COL holder referencing the manufactured reactor must satisfy. Proposed § 53.1282(a)(2) would require that the ITAAC from a referenced standard design apply to the portions of the ML design within the scope of the referenced standard design. Proposed § 53.1282(a)(3) would state that the COL application may include a notification that required referenced standard DC ITAAC have been satisfied at the manufacturing facility.

Proposed § 53.1282(b)(1) would require an ML application to include an environmental report and, consistent with existing requirements, proposed § 53.1282(b)(2) would note that if the ML application references a standard DC, the environmental report need not contain a discussion of severe accident mitigation design alternatives for the manufactured reactor as used in a commercial nuclear plant.

Proposed § 53.1285 would provide standards for review of applications and administrative review of applications for MLs, including hearings, and is equivalent to §§ 52.159 and 52.163.

Proposed § 53.1286 would address referral of applications to the ACRS and is equivalent to § 52.165. Proposed § 53.1287 would address issuance of an ML and is equivalent to § 52.167.

Proposed § 53.1288 would address finality of MLs and is equivalent to § 52.171. Proposed § 53.1291 would address the duration of MLs and is equivalent to § 52.173. Proposed § 53.1293 would address the transfer of MLs and is equivalent to § 52.175. Proposed § 53.1295 would address the renewal of MLs and is equivalent to §§ 52.177, 52.179 and 52.181, with a minor exception. Proposed § 53.1295(a)(3) would state that an ML for which a timely application for renewal has been filed remains in effect until the Commission has made a final determination on the renewal application but would not include a prohibition of initiation of manufacture 3 years before the expiration of the license. Any safety concerns related to the duration of the manufacturing license are addressed by the requirement in § 53.1291 to cease the manufacture of uncompleted reactors upon expiration of the manufacturing license.

Proposed §§ 53.1300 through 53.1348 would address licensing requirements for CPs. Proposed § 53.1300 would set out general requirements for CPs and is equivalent to § 50.23. Proposed § 53.1306 would address the general information requirements for the content of applications for CPs and is equivalent to § 50.33.

Proposed § 53.1309 would address requirements for the technical content of applications for CPs and includes the requirement to submit a Preliminary Safety Analysis Report (PSAR) that describes the facility and presents a preliminary safety analysis of the facility as a whole. This is in contrast to an OL application which is

required to include an FSAR that describes the facility and presents a final safety analysis of the facility as a whole. Proposed § 53.1309 is equivalent to § 52.17(a)(1)(iv) through (x) and 52.17(b), with two exceptions. First, proposed § 53.1309 would replace the analysis of the dose criteria required by § 52.17(a)(1)(ix) with analysis to demonstrate compliance with the safety criteria defined in §§ 53.210 and 53.220. Second, proposed § 53.1309(a)(2) would add a requirement for a CP application to include several categories of detailed design information, although § 53.1309(a)(2)(ii) would allow certain relaxations of this requirement in view of aspects of a design that may not yet be fully developed. Section 53.1309 would reference the requirements for the content of an ESP application to address application requirements related to siting and would reference the requirements for the content of a DC application to address application requirements related to design of the commercial nuclear plant. Proposed § 53.1309(a)(2)(ii) would address the treatment of preliminary design information and notes that information provided in the application may include some aspects of the design that are not fully developed. This provision would require that the completed design, including any changes during construction, be described in the FSAR in an application for an OL. This would include the requirement for a description of the risk evaluation required by § 53.450(a) and its results. Risk evaluations developed for commercial nuclear plants prior to construction would be based on the design and other information available at the time of the CP application. Risk evaluations performed in early design stages or prior to construction may be inherently less detailed and may include projected information that will be subsequently verified or revised when the plant is built. Proposed § 53.1309(a)(4) would address preliminary description of the plans for coping with emergencies.

Proposed § 53.1312 would address other application content for CPs. Proposed § 53.1312(a)(1) is equivalent to § 52.80(b) but is adapted for a CP application. Proposed § 53.1312(a)(2) is equivalent to § 52.80(c) but is adapted for a CP application. Proposed § 53.1312(b)(1) is equivalent to § 52.79(b), (c), and (d) but is adapted for a CP application. Section 53.1312(b)(2) is equivalent to portions of §§ 52.63(b)(1), 52.79(b)(1) though (3), (c), and (d)(1) and (3), 52.80, and 52.93(b), but is adapted for a CP application. Guidance for equivalent requirements in parts 50 and 52 is also addressed in RG 1.206, “Applications for Nuclear Power Plants,” Revision 1, section C.1.7.

Proposed § 53.1315 would address standards for review of applications and administrative review of applications, including hearings, and is equivalent to §§ 52.81 and 52.85, but is adapted for a CP application.

Proposed § 53.1318 would address finality of NRC approvals, licenses, and certifications referenced in a CP application and is equivalent to § 52.83(a) but is adapted for a CP application.

Proposed § 53.1324 would address referral to the ACRS and is equivalent to § 50.58(a) and to § 52.87 but is adapted for a CP application.

Proposed § 53.1327 would address authorization to conduct LWA activities and is equivalent to § 52.91 but is adapted for a CP application. Proposed § 53.1327(a) is equivalent to § 52.91(a) but is adapted for a CP application. Proposed § 53.1327(b) is equivalent to § 52.91(b) but is adapted for a CP application. Proposed § 53.1330 would address exemptions, departures, and variances for CP applicants.

Proposed § 53.1333 would address issuance of CPs. Proposed § 53.1333(a) is equivalent to § 50.35(a). Proposed § 53.1333(b) is equivalent to § 50.35(b) and to § 52.97(c) but is adapted for a CP application. Proposed § 53.1336 would address the effect of CPs and is equivalent to § 50.35(b). Proposed § 53.1342 would address the

duration of CPs. Proposed § 53.1342(a) is equivalent to § 50.55(a). Proposed § 53.1342(b) is equivalent to § 50.55(b). Proposed § 53.1345 would address the transfer, assignment, and disposal of CPs and is equivalent to § 50.80. Proposed § 53.1348 would address the termination of CPs and is equivalent to §§ 52.3(b)(8) and 52.110(a)(1) but is adapted for a CP application.

Proposed §§ 53.1360 through 53.1405 address requirements for OLs.

Proposed § 53.1366 would address requirements for the general content of applications for OLs. It would refer to general content requirements in proposed § 53.1109 and would require supplemental information. Proposed § 53.1366(a) is equivalent to § 50.33(f). Proposed § 53.1366(b) is equivalent to § 50.33(k).

Proposed § 53.1369(a) would provide requirements for the technical content of applications for OLs to be included in the FSAR and is equivalent to § 50.34(b) but has been modified to align with the technical requirements in proposed part 53. It would require that the FSAR include and, as needed, update information provided in the PSAR that was submitted and reviewed to support the associated CP application.

Similar to the proposed requirements for the content of CP applications, proposed § 53.1369(a)(1) would reference the requirements for the content of an ESP application to address application requirements related to the site. Section 53.1369(a)(2) would reference the requirements for the content of a DC application to address some of the application requirements related to design of the commercial nuclear plant.

Proposed § 53.1369(a)(3) is equivalent to § 50.34(b)(7). Proposed § 53.1369(a)(4) is equivalent to § 50.34(e). Proposed § 53.1369(a)(5) would provide requirements for OL application content to support proposed § 53.730 related to the role of personnel in the operation of the commercial nuclear plant and is adapted from requirements in part 55 and § 50.34(f). Likewise, proposed § 53.1369(a)(6) would

provide requirements for OL application content related to training programs to support proposed §§ 53.730(g) and 53.830 and includes requirements equivalent to § 50.34(b)(8), § 52.79(a)(33), and part 55. Proposed § 53.1369(a)(7) would provide requirements for OL application content related to emergency plans to support proposed § 53.855 and is equivalent to § 50.34(b)(6)(v). If the NRC proceeds with revising its regulations as described in SECY-22-0001, the same flexibility in determining appropriate emergency preparedness measures, as directed by the Commission, would be added to part 53.

Proposed § 53.1369(a)(8) would provide requirements for OL application content related to the applicant's organizational structure and is equivalent to § 50.34(b)(6)(i). Proposed § 53.1369(a)(9) would provide requirements for OL application content related to the applicant’s proposed maintenance program to support proposed § 53.715 and is equivalent to § 50.34(b)(6)(iv). Proposed § 53.1369(a)(10) would provide requirements for OL application content related to the applicant's quality assurance program to support proposed § 53.865 and appendix B to part 50 and is equivalent to § 50.34(b)(6)(ii). Proposed § 53.1369(a)(11) would provide requirements for OL application content related to the applicant’s proposed radiation protection program to support proposed § 53.850 and is equivalent to § 50.34(b)(3).

Proposed § 53.1369(a)(12) through (a)(14) would provide requirements for OL application content related to the applicant’s proposed physical security program to support proposed § 53.860(a) and are equivalent to § 50.34(c) and (d). Proposed § 53.1369(a)(15) would provide requirements for OL application content related to the applicant’s proposed cyber security plan to support proposed § 53.860(d) and is equivalent to §§ 52.79(a)(36)(iv) and 73.54. Proposed § 53.1369(a)(16) would provide requirements for OL application content related to the implementation of proposed

security, safeguards, and cyber security plans to support proposed § 53.860 and is equivalent to § 52.79(a)(35)(ii) and 52.79(a)(36)(iv) and (v).

Proposed § 53.1369(a)(17) would provide requirements for OL application content related to the applicant's proposed fire protection program to support proposed § 53.875 and is equivalent to § 52.79(a)(40). Proposed § 53.1369(a)(18) would provide requirements for OL application content related to the applicant's proposed ISI and IST program to support proposed § 53.880 and is equivalent to part of § 52.79(a)(11). Proposed § 53.1369(a)(19) would provide requirements for OL application content related to the applicant's FFD program to support part 26 and is equivalent to § 52.79(a)(44). Proposed § 53.1369(a)(20) would provide requirements for OL applicant's programs to demonstrate that any safety questions identified at the CP stage have been resolved and is equivalent to § 50.34(b)(5). Proposed § 53.1369(a)(21) would provide requirements for OL applicants to describe how the performance of each safety design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof to support proposed § 53.090(d). It is largely equivalent to §§ 50.34(b)(5) and 50.43(e).

Proposed § 53.1369(b) through (d) would address content of applications; technical information requirements for OL applications referencing early site permits, design approvals, or design certifications modeled on the provisions of § 52.79(b) through (d) and § 53.1416(d) through (f) for COL applications under parts 52 and 53 similarly referencing early site permits, design approvals, or design certifications.

Proposed § 53.1372 would address requirements for the content of OL applications other than the FSAR. Proposed § 53.1372(a) would require submission of an environmental report and is equivalent to § 50.30(f) and § 51.53(b). Proposed

§ 53.1372(b) does not have a direct parallel in parts 50 and 52 and would require the inclusion of a description of availability controls that are not included in the FSAR to support proposed § 53.710(b).

Proposed § 53.1375 would address standards for review of OL applications and the administrative review of applications, including hearings, and is equivalent to §§ 52.81 and 52.85, except that the NRC has omitted 10 CFR part 54, “Requirements for Renewal of Operating Licenses for Nuclear Power Plants,” from the list of standards in the proposed § 53.1375(a). Proposed part 53 does not include detailed requirements related to renewal of licenses, although a general provision and possible placeholder for future requirements has been included as proposed § 53.1595. The NRC will decide after the part 53 final rule is published whether this future section will be retained in part 53 to address license renewal or whether the agency will take another approach to address license renewal for part 53 licensees, such as amending part 54 to address part 53 licensees.

Proposed § 53.1381 would address referral to the ACRS and is equivalent to §§ 50.58 and 52.87. Proposed § 53.1384 would address exemptions, departures, and variances for OL applicants. Section 53.1384(a) is equivalent to § 52.93 but is adapted for OLs. Proposed § 53.1384(b) is equivalent to §§ 52.39(d) (with respect to ESPs) and 52.93 but is adapted for OLs.

Proposed § 53.1387 would address issuance of OLs. Proposed § 53.1387(a)(1)(i) is equivalent to §§ 50.50 and 50.57(a)(1). Proposed § 53.1387(a)(1)(ii) addresses the requirement for notifications to have been duly made under § 50.50. Proposed § 53.1387(a)(1)(iii) is equivalent to § 50.57(a)(2). Section 53.1387(a)(1)(iv) is equivalent to § 50.57(a)(3). Proposed § 53.1387(a)(1)(v) is equivalent to § 50.57(a)(4). Proposed § 53.1387(a)(1)(vi) is equivalent to § 50.57(a)(6). Proposed

§ 53.1387(a)(1)(vii) is equivalent to § 50.57(a)(5). Proposed § 53.1387(a)(1)(viii) is equivalent to § 52.97(a)(1)(vi) but is adapted for OLs. Proposed § 53.1387(c) is equivalent to § 50.57(b). Proposed § 53.1387(d) is equivalent to §§ 50.36(b) and 50.50.

Proposed § 53.1390 would address finality of OLs and is equivalent to § 52.98(a) but adapted for an OL application. Proposed § 53.1396 would address duration of an OL and is equivalent to § 50.51(a). Proposed § 53.1399 would address transfer, assignment, and other disposition of an OL by invoking § 53.1570, which is equivalent to § 50.80. Proposed § 53.1402 would address applications for renewal of an OL and refers to the placeholder proposed in § 53.1595. Proposed § 53.1405 would address continuation of an OL and is equivalent to § 50.51(b).

Proposed §§ 53.1410 through 53.1461 would address requirements for COLs. Proposed § 53.1410 is equivalent to § 52.71. Proposed § 53.1413 would address general information requirements for the content of applications for COLs and is equivalent to § 52.77, which references § 50.33. Most of the provisions from § 50.33 are restated in proposed § 53.1109. Some requirements in § 50.33 related to financial qualifications and construction timelines are addressed in other sections of part 53.

Proposed § 53.1416 would address the technical content to be included in an FSAR for an application for a COL and is equivalent to § 52.79 except as modified to reflect the technical requirements in part 53with one addition. Proposed § 53.1416 includes the statement that the Commission will require, before issuance of a COL, that engineering documents, such as analyses, drawings, procurement specifications, or construction and installation specifications, be completed and available for audit if the more detailed information is necessary for the Commission to verify the information in the application and make its safety determination. This statement is equivalent to DC application requirements in § 52.47 and is included in proposed § 53.1416 for clarity.

Similar to the proposed requirements for the content of OL applications, proposed § 53.1416(a)(1) would reference the requirements for the content of an ESP application to address application requirements related to siting. Section 53.1416(a)(2) would reference the requirements for the content of a DC application to address some of the application requirements related to design of the commercial nuclear plant. The remaining items under proposed § 53.1416(a) are likewise similar to the required content for OL applications under proposed § 53.1369(a). Proposed § 53.1416(b) would require COL applicants to provide a report documenting the resolution of any safety questions for SSCs for which research and development was necessary to confirm the adequacy of their design and is equivalent to § 50.34(b)(5). Proposed § 53.1416(c) would provide requirements for COL applicants to describe how the performance of each safety design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof to support proposed § 53.440(a). It is largely equivalent to §§ 52.79(a)(24) and 50.43(e). Proposed § 53.1416(d) would address the content of COL applications referencing an ESP. Proposed § 53.1416(e) would address the content of COL applications referencing a standard design approval. Proposed § 53.1416(f) would address the content of COL applications referencing a standard DC. Proposed § 53.1416(g) would address the content of COL applications referencing an ML.

Proposed § 53.1419 would address other application content for COLs and is equivalent to § 52.80. Proposed § 53.1419(a)(2) is new and would require the inclusion of a description of availability controls that are not required to be included in the FSAR.

Proposed § 53.1422 would address standards for review of applications and the administrative review of applications, including hearings, and is equivalent to §§ 52.81

and 52.85. The NRC has removed part 54 from the list of standards in proposed § 53.1422(a).

Proposed § 53.1425 would address the finality of NRC approvals referenced in a COL application and is equivalent to § 52.83(a). Proposed § 53.1431 would address the referral of COL applications to the ACRS for review and is equivalent to § 52.87. Proposed § 53.1434 would address the authorization to conduct LWA activities and is equivalent to § 52.91. Proposed § 53.1437 would address exemptions, departures, and variances and is equivalent to § 52.93. Proposed § 53.1440 would address issuance of COLs and is equivalent to § 52.97. Proposed § 53.1443 would address finality of COLs and is equivalent to § 52.98.

Proposed § 53.1449 would address inspection during construction and is equivalent to § 52.99. Proposed § 53.1452 would address operation under a COL and is equivalent to § 52.103. Proposed § 53.1455 would address duration of COL and is equivalent to § 52.104. Proposed § 53.1456 would address the transfer of a COL and is equivalent to § 52.105. Proposed § 53.1458 would address application for renewal by reference to the placeholder provision in § 53.1595 and is equivalent to § 52.107. Proposed § 53.1461 would address continuation of COL and is equivalent to § 52.109.

Proposed § 53.1470 would address standardization of commercial nuclear plant designs and licenses to construct and operate commercial power reactors of identical design at multiple sites and is equivalent to appendix N of part 50 and appendix N of part 52. This section would set out the particular requirements and provisions applicable to situations in which applications for CPs and subsequent OLs, or COLs, under this part are filed by one or more applicants for licenses to construct and operate nuclear power reactors of identical design ("common design") to be located at multiple sites. Additional

information related to this proposed section is provided in the final rule to revise part 52 (72 FR 49352; August 28, 2007).

Subpart I – Maintaining and Revising Licensing Basis Information

Part 53 would establish requirements for the maintenance of licensing basis information in subpart I. Section 53.1500 would describe the purpose of the subpart in terms of the common definition of licensing basis information in subpart A. Subpart I would be closely tied to the requirements in subpart H, which would provide the requirements for contents of applications for the various types of licenses issued under part 53. Subpart I would generally be organized into sections dealing with: (1) licensing basis information that licensees are not authorized to change without NRC approval (e.g., licenses, regulations); and (2) licensing basis documents that licensees may change provided specified criteria are satisfied (e.g., FSAR, program descriptions). The subpart would also capture certain general conditions on licenses and changes to the licenses related to the transfer and termination of licenses.

Section 53.1502 would define specific terms and conditions of licenses. These terms and conditions would be equivalent to the regulations in: (1) § 50.54(h) stating that each license is subject to the provisions of the Act and requirements issued by the Commission; (2) § 50.54(s)(2)(ii) and (s)(3) stating the actions the Commission would take if it makes a finding that there is not reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency; (3) § 50.54(aa) stating that each license is subject to the specified sections of the Federal Water Pollution Control Act; and (4) § 50.54(dd) stating that a holder of an OL or COL may take reasonable actions that depart from the license in a national security emergency.

Section 53.1505(a) would serve as an introduction to and overview of the sections that follow on changes to licensing basis information requiring prior NRC

approval, namely the elements of licensing basis information defined by licenses, orders, and regulations. The related sections within subpart I would primarily deal with the process of how a licensee requests and the NRC issues an amendment to a license or issues an order that modifies a license. Another important element of licensing basis information that a part 53 licensee would not be able to change or deviate from without NRC approval would be the NRC regulations themselves. Section 53.1505(b) would refer to § 53.080 in subpart A that would provide the criteria to be used by the Commission when granting an exemption from NRC regulations when requested by an applicant or on its own initiative.

Section 53.1510 would be equivalent to § 50.90 and would require that a licensee submit an application to request an amendment to a license. The required assessments that would be included within an application to amend a license under part 53 would need to address the safety criteria and analysis requirements of subparts B and C. As with parts 50 and 52, licensees under part 53would be required to include in their applications to amend a license an analysis of whether the amendment involves no significant hazards consideration using the standards in §§ 53.1520, which would be equivalent to the standards in § 50.92. Although this rulemaking provided an opportunity to revise the terminology related to no significant hazards consideration determinations, which dates to the early 1960s when applications were supported by final hazard summary reports, the NRC is proposing to maintain the same terminology used in part 50 to minimize the need for associated changes in other regulations, guidance, and public notices.

Section 53.1515 would establish requirements for public notices and state consultations associated with the NRC’s processing of a license amendment request and is equivalent to § 50.91 for the NRC’s processes related to applications to amend an

OL or COL. Section 50.91(b) stipulates that the Commission will make available to the licensee the name of the appropriate State official designated to receive such amendments. While the Commission intends to continue following this practice, the Commission has not included this administrative matter in proposed part 53. Proposed § 53.1515(b)(3) contains some modifications compared to § 50.91(b)(3) for clarity; these revisions are not intended to revise the substance of the provisions in part 53 compared to part 50.

Section 53.1520 would be based on § 50.92 and would continue to use the criteria in § 50.92 for determining that a proposed amendment involves no significant hazards consideration. Although more specific terms such as event sequence are used throughout part 53, § 53.1520 would use the term “accident” to maintain consistency with the long history of making no significant hazards consideration determinations under part 50.

Section 53.1525 would provide requirements for holders of an OL or COL requesting to revise information from a DC rule that was referenced in the initial license application and included in or incorporated by reference into the facility FSAR. In keeping with the current requirements in part 52, the portion of the part 53 facility licensing basis information obtained from the certified design would be divided into two categories. The most significant design information and the ITAAC would be certified by rule and designated as “certification information.” The remaining information, which makes up the majority of the design information approved as part of the DC, would not be certified by rule and is not considered “certification information.” Part 52 refers to these categories of information as Tier 1 and Tier 2 information, respectively, and refers to a change made to that information on a plant-specific basis as a departure. Under part

52, a departure from Tier 1 information requires an exemption and, for information incorporated into the license, a license amendment.

Part 53 would dispense with the Tier 1 and Tier 2 terminology. Rather, § 53.1525 would use the term “certification information” in place of Tier 1, and a plant-specific departure from the certification information would require both a request for an exemption from the associated DC rule and, for information such as ITAAC incorporated into the license, a license amendment. However, as would be provided in § 53.1525(c), a plant-specific departure from the information approved by the NRC as part of the DC rule but which is not certification information (i.e., Tier 2 information under part 52) would be assessed using the process and criteria defined in § 53.1550 for changes to a FSAR. An applicant or licensee would need to identify such a change as a departure from the referenced standard design in the updated FSAR. The process for making a generic change to a certified design would be described in the associated sections in subpart H.

Section 53.1530 would not allow the holder of an ML or the holder of a COL using a manufactured reactor to make changes to the design of the manufactured reactor without requesting a license amendment from the NRC. This would provide the equivalent requirements as those in §§ 52.98 and 52.171.

Section 53.1535 would establish requirements for license amendments during construction. This would provide the equivalent options and requirements for the holders of a CP as those in § 50.35(b). The regulations would allow but do not require the holder of a CP or LWA to request an amendment under § 53.1510 if the licensee desires to obtain NRC approval of a specific design feature or specification. The requirements for obtaining an amendment to a COL to address changes during construction would also be provided in § 53.1535. The proposed process would differ from the current requirements in part 52 by adopting a requirement similar to that included in SECY-22-

0052, “Proposed Rule: Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150-AI66).” The proposed regulation would allow the holder of a COL to proceed at its own risk in making a change during the construction process and would require that licensee to submit a license amendment request no later than 45 days from the date the licensee begins to implement the change or departure requiring NRC approval.

Section 53.1540 would serve as an introduction to the sections that follow on changes to licensing basis information that are primarily under the control of a licensee but for which evaluations are made to determine if a submittal to the NRC requesting approval would be required. .

Section 53.1545 would provide the proposed requirements for updating of FSARs. While the process-related requirements proposed under § 53.1545 would be largely the same as those in § 50.71, the specifics of information to be updated would differ due to the role of risk evaluation in satisfying the requirements in subparts B and C. Additionally, the use of the risk-informed approach in subpart C would result in some but not all risk information being in the FSAR or another licensing basis document and therefore a separate update requirement similar to § 50.71(h) is not included in proposed subpart I.

Proposed § 53.1239(a)(18) in subpart H and the related references to this proposed requirement for the holders of OLs and COLs would require a description of the risk evaluation required by § 53.450(a) and its results to be included in FSARs. However, guidance documents are planned to clarify the division of risk-related information that would need to be in the FSAR, in other possible licensing basis documents, and controlled as plant records subject to inspections and audits. At a minimum, the information from the risk evaluation that would be needed to show

compliance with subpart C would be included in the FSAR (e.g., summary and analytical results for LBEs). The submittal of voluminous PRA information was initially required under part 52, but that proved to be impractical and was revised in the 2007 revision of part 52. Guidance is being developed to ensure sufficient information is submitted to the NRC to support the licensing process and the NRC's regulatory findings under part 53 or similar applications using the LMP under parts 50 or 52.

The NRC has posed a question in section VII, "Specific Requests for Comments," of this document that asks about the appropriate level of detail for risk-related information in an FSAR and whether other licensing basis documents might be more appropriate to both provide information to the NRC and ensure the risk evaluation is maintained and updated as proposed in subpart C. The program document would provide more detail than the summaries in the FSAR but still be a much-condensed source of information in comparison to the documentation of a PRA, for example.

Section 53.1545(a)(3) and (4) would be based on the inclusion of at least a summary of risk evaluation results and the related margins to safety criteria in the FSAR and would require updates to that information.

Section 53.1550 would establish requirements for evaluating changes to a facility as described in its FSAR. This would provide the equivalent of the requirements in § 50.59 for evaluating changes to an Updated Final Safety Analysis Report (UFSAR) and determining if a license amendment is required to implement a change to a facility or procedures. Given that the options provided for an applicant or licensee under part 53 allow the use of certain deterministic approaches to items such as fire protection, the protection of SR SSCs from external hazards, and the control of reactivity after a DBA, § 53.1550 would propose to use the same evaluation criteria as provided in § 50.59. Guidance would be provided on the application of the criteria in § 53.1550 that would

reflect the role of the risk evaluation in the safety analyses under part 53 that would include several measures related to the changes in plant risk resulting from a change in the plant design or plant procedures. Examples would include criteria that rely on the identification of risk-significant event sequences in accordance with the analysis requirements of § 53.450; exceeding the LBE evaluation criteria as defined in § 53.450; the consideration of potential reductions in margin between the estimated plant risks and the cumulative risk measures; changes to the safety classification of SSCs; and consideration of reductions in defense in depth.

Section 53.1550 would include a criterion related to a departure in a method of evaluation used in the safety analyses and would use the same wording as all eight criteria in § 50.59, including criterion (viii) on departing from methods of evaluation. Therefore, licensees could consider technically relevant information in existing guidance documents related to § 50.59 to support such evaluations. The NRC has not yet developed draft guidance for use in applying proposed § 53.1550 but anticipates that the NRC staff and stakeholders will assess the potential need for such guidance and that such guidance would, if needed, be developed as part of ongoing or future activities.

Section 53.1550(a)(2)(x) would require evaluating plant changes to ensure they would not prevent satisfying the design requirements in § 53.440(j) related to the impact of a large commercial aircraft. The inclusion of a proposed requirement under § 53.1550 related to design features for protecting against aircraft impact would reflect the proposed design requirement in subpart C and related proposed requirements in subpart H to address the proposed design requirement in FSARs submitted under part 53.

Sections 53.1560 through 53.1565 in subpart I would define the processes for a licensee to evaluate changes to the program documents included in the licensing basis

information submitted to the NRC and to modify such programs without NRC prior approval.

Section 53.1560 would include the proposed requirements for updating program documents included in licensing basis information and would provide the equivalent of UFSAR updates for key program documents. The proposed requirements would provide a uniform approach for updating program documents, which correspond to the programs required under subpart F.

The proposed § 53.1565 would provide a process for licensees to make changes to program documents included in licensing basis information without obtaining prior NRC approval. The proposed requirements would include several generic criteria that, if not satisfied, would prompt the need for NRC approval of a change to a program document. These generic criteria would include whether a change would comply with TS and NRC regulations. Another proposed criterion for evaluating changes to program documents would be conforming with program-specific requirements, including NRC-approved program documents with more specific criteria for a particular program, regulations, administrative controls sections of TS, and NRC-approved program documents.

Proposed § 53.1565(d) would include specific criteria for evaluating changes to several program documents that have well established change processes and guidance for licensees under parts 50 and 52. The program documents specifically addressed in the proposed section would include quality assurance programs that would be equivalent to § 50.54(a), an emergency preparedness program that would be equivalent to § 50.54(q), and the security program documents which would be equivalent to § 50.54(p).

The proposed § 53.1570 would establish requirements for the transfer of commercial nuclear plant licenses by providing the equivalent requirements of § 50.80 for the possible transfer of an ESP, CP, OL, or COL.

Section 53.1580 would establish requirements for information requests the NRC could send to the various types of licensees under part 53 and would provide requirements that would be equivalent to requirements in § 50.54(f). The proposed § 53.1585 would provide the requirements that would be equivalent to requirements in § 50.100 to address revocation, suspension, modification of licenses, and approvals for cause under part 53. Section 53.1590 would propose to address backfitting requirements by providing requirements that would be equivalent to those in § 50.109.

Proposed § 53.1595 would provide a placeholder to address license renewals under part 53. This section would be expanded through future rulemakings to more fully describe or reference the processes related to requesting and processing applications to renew ESPs, OLs, and COLs issued under part 53 (if finalized).

Subpart J – Reporting and Other Administrative Requirements

Part 53 would address various reporting and administrative requirements in subpart J.

Section 53.1600 would explain the organization of the various sections within the subpart related to providing unfettered access to NRC inspectors; maintaining certain records and reporting specified events or conditions; demonstrating compliance with financial qualification requirements and providing specified financial reports; and maintaining financial protections to address potential accidents.

Section 53.1610 would establish requirements for the provision of facilities and unfettered access for inspections. These requirements would be equivalent to § 50.70 with only minor changes proposed to provide additional flexibilities and address possible

differences related to reactors licensed under part 53 and the possibility that some commercial nuclear plants may not be assigned resident inspectors.

Section 53.1620 would provide for maintenance of records and the making of various reports to the NRC. These requirements would be largely equivalent to § 50.71. This section is not intended to reflect all provisions in § 50.71; several important requirements in § 50.71 would be captured in other sections of part 53. For example, § 53.1545 within subpart I would provide requirements that would be equivalent to § 50.71(e), updating FSARs, and § 53.1680, “Annual financial reports,” would provide the equivalent of § 50.71(b), which covers financial reports. A reporting requirement related to completion of power ascension testing would be added to § 53.1620 to support the assessment of annual fees under 10 CFR part 171, “Annual Fees for Reactor Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC,” which normally commence upon completion of those testing activities.

Section 53.1630 would establish requirements for immediate notification requirements for operating commercial nuclear plants. These requirements would be equivalent to § 50.72 with minor changes proposed to make the reporting criteria technology inclusive. The slight differences between these requirements and those of § 50.72 would reflect the differences in terminology and approaches to topics such as safety functions. Section 53.1630 would refer to the derivation of safety functions under § 53.230 as compared to a standard set of safety functions used in defining SR SSCs and organizing PDCs. In addition, a new version of NRC Form 361 (NRC Form 361S) would be created for use by part 53 licensees, but without LWR-specific terminology to ensure technology-inclusiveness. A separate rulemaking activity, “Reporting

Requirements for Nonemergency Events at Nuclear Power Plants," has been initiated to consider possible changes to the requirements in § 50.72. At a future date, the NRC may consider reconciling future changes to § 50.72 with the requirements proposed in part 53, which have been taken or derived from the current reporting requirements.

Section 53.1640 would address the licensee event report system. These requirements would be equivalent to § 50.73 with minor changes proposed to make the requirements inclusive of various reactor technologies and to reflect appropriate internal references to other sections in part 53. In addition, NRC Forms 366, 366A, and 366B would be revised to include corresponding check boxes for part 53 licensees.

Section 53.1645 would require periodic reporting of the quantity of radionuclides released to unrestricted areas in liquid and gaseous effluents. These reporting requirements would be largely equivalent to the reporting requirements in § 50.36a, "Technical specifications on effluents from nuclear power reactors." The only difference would be that a § 50.36a requirement to specifically address conditions where the dose to the maximally exposed individual could be significantly above design objectives would refer to a design objective of 10 mrem/year instead of referring to the design objectives in appendix I to part 50. The proposed section would also include an equivalent to the reporting requirement in section IV of appendix I to part 50 if the radiation exposure to a member of the public in any calendar quarter exceeds one-half of the annual design objective.

Section 53.1650 would include a reporting requirement to support safeguards agreements between the United States and IAEA and would be equivalent to § 50.78.

Sections 53.1660 through 53.1700 would address financial requirements and would be largely similar to existing regulations in parts 50 and 52. Section 53.1670 would be entitled "Financial qualifications" and would require applicants other than

electric utilities to possess or have reasonable assurance of obtaining funds for the activities for which the license is being sought. The NRC is seeking feedback on these sections and their ramifications for merchant plants[3] in section VII, “Specific Requests for Comments,” of this document. The remaining financial reports in part 53 would be equivalent to § 50.71(b) for annual financial reports, § 50.76 for a change of status, § 50.54(cc) for the filing of a petition for bankruptcy, and § 50.81 for creditor regulations.

Section 53.1720 would require insurance to stabilize and decontaminate a plant following an accident. These requirements would be taken from § 50.54(w) with the only notable change being the addition of a provision allowing plant-specific estimates of costs to stabilize and decontaminate a plant as an alternative to the $1.06 billion minimum coverage in § 50.54(w).

Subpart X – Enforcement

Subpart X would contain two provisions, § 53.9000 and § 53.9010, which are analogous to provisions contained in other parts of 10 CFR Chapter I imposing requirements on regulated entities. Section 53.9000 would provide notice of the Commission’s authority under the AEA to obtain injunctions or other court orders for the enumerated violations. Paragraph (a) of § 53.9010 would provide notice to all persons and entities subject to part 53 that they are subject to criminal sanctions for willful violations, attempted violations, or conspiracy to violate certain regulations under part 53. Criminal sanctions would not apply to the regulations listed in paragraph (b). The regulations for which criminal penalties would apply are limited to those that establish either a regulatory obligation or prohibition.

[3] A “merchant plant” is a plant licensed to a non-rate-regulated entity (e.g., a nonutility) that engages in the business of production, manufacturing, generating, buying, aggregating, marketing, or brokering electricity for sale at wholesale or for retail sale to the public.

V. Changes to Other Parts of 10 CFR Chapter I

10 CFR Part 26

Introduction

The NRC is proposing a technology-inclusive, risk-informed, and performance--based approach for the application of drug and alcohol testing and fatigue management requirements for facilities licensed under part 53. The proposed requirements applicable to these applicants, licensees, and other entities would be commensurate with the radiological consequences presented by the applicants' facilities and the operation of these facilities.[4] The proposed FFD framework would consist of a two-tiered graded approach similar to that currently in part 26 and an optional third tier for part 53 commercial nuclear plants that perform an analysis that demonstrates the facility and its operation would satisfy the criterion in proposed § 26.604(a), which matches the criterion of § 53.860(a)(2). This proposed FFD framework would be established in subpart M, "Fitness for Duty Programs for Facilities Licensed Under Part 53," of part 26.

The NRC used operating experience to provide regulatory flexibility in the proposed subpart M of part 26 framework to help support a licensee's or other entity's response to changes in societal drug use, drug testing technologies and processes, and FFD program performance. The flexibility would also help in FFD program implementation because of the wide variety of staff sizes anticipated at commercial nuclear plants licensed under part 53 and the geographically remote locations in which commercial nuclear plants may be sited.

[4] The NRC uses the term "operation" in its part 26 discussion to focus on human performance, namely the necessity of individuals to operate, maintain, surveil, and protect the facility and respond to operational transients and DBEs.

The proposed first-tier FFD program requirements would apply to part 53 licensees and other entities of commercial nuclear plants under construction who satisfy the criterion in § 26.604(a) but elect not to implement proposed § 26.604, “FFD program requirements for low consequence facilities,” or who do not satisfy the criterion in § 26.604(a), and to holders of MLs who are assembling or fueling manufactured reactors. These requirements would be provided in proposed § 26.605(a) and would be essentially equivalent to those requirements in subpart K, “FFD Program for Construction,” of part 26 as supplemented by select requirements from subparts E, “Collecting Specimens for Test,” and I, “Managing Fatigue,” of part 26, and the requirements in subparts A, “Administrative Provisions,” and O, “Inspection, Violations, and Penalties,” of part 26. The first-tier requirements would involve policies, procedures, behavioral observation, fatigue management, drug and alcohol testing, determinations of fitness, appeals, training, sanctions, auditing, change control, performance monitoring, recordkeeping, and reporting. These requirements would help deter individuals subject to this section from illicit drug and/or alcohol use and from being impaired from any cause including fatigue. These proposed requirements would also help licensees and other entities identify individuals as users of impairing substances and demonstrate compliance with § 26.23, “Performance objectives.”

The proposed second tier would include all the proposed first-tier requirements, plus the more comprehensive set of FFD program requirements in current subparts C, “Granting and Maintaining Authorization,” D, “Management Actions and Sanctions to be Imposed,” H, “Determining Fitness-for-Duty Policy Violations,” and N, “Recordkeeping and Reporting Requirements,” of part 26. These requirements would be provided in proposed § 26.605(b) and would be applicable to licensees and other entities satisfying the § 26.604(a) criterion, at their discretion. These requirements would also apply to

licensees or other entities not satisfying the § 26.604(a) criterion that implement an FFD program under subpart M of part 26, before the loading of fuel onsite into a reactor vessel; before receiving a manufactured reactor; or before operating, testing, performing maintenance of, or directing the maintenance or surveillance of security-related equipment or equipment that a risk informed evaluation process or alternative method for evaluating safety significance has shown to be significant to public health and safety.

The second-tier requirements are based on the additional risk presented by nuclear reactor assembly, testing, fueling, and operation and the necessity for human actions in certain event sequences. The inclusion of the current part 26 requirements would align proposed part 53 FFD and AA program requirements with the current FFD and AA programs required for facilities licensed under parts 50 and 52. This approach would ensure effective and consistent AA and FFD program implementation across the commercial nuclear power industry, thereby ensuring uniform requirements for individuals who may perform roles and responsibilities for multiple facilities regardless of facility licensure.

Proposed § 26.604 would offer an alternate option for an applicant implementing an FFD program under subpart M of part 26. If the applicant demonstrates that the criterion in proposed § 26.604(a) is met, then the applicant (and the subsequent licensee or other entity) must still implement an FFD program described in subpart M of part 26; however, drug and alcohol testing would not be required unless FFD performance declines or the applicant, licensee, or other entity elects to implement drug and alcohol testing. The proposed § 26.604 requirements are equivalent to those proposed in § 26.605(a) except for required drug and alcohol testing. This proposed framework would focus on the human performance of individuals while they are performing those duties and responsibilities that make them subject to the FFD program. This

performance would be verified through behavioral observation, evaluation of any FFD concerns, performance monitoring, fatigue management, and determinations of fitness. Applicants that do not satisfy the criterion in proposed § 26.604(a), or elect not to perform the analysis required to demonstrate that the criterion in § 26.604(a) is met, would be subject to an FFD program described in § 26.605, "FFD program requirements for facilities that do not implement § 26.604," or an FFD program that implements all part 26 requirements, except for those requirements in subparts K and M of part 26.

In establishing the minimum FFD program requirements in § 26.604, the NRC reviewed current advanced reactor designs against that of a non-power production or utilization facility (NPUF) that is not required to implement an FFD program for those individuals who have unescorted access to the controlled access area (and vital area for some facilities), including NRC-licensed operators.[5] This review was performed because commercial nuclear plants licensed under part 53 could be designed with similar power levels and radiological consequences as the currently licensed NPUFs. From this review, three principal considerations supported the minimum set of requirements for the § 26.604 FFD program.

First, the radiological consequences presented by a part 53 licensed facility and its operation that satisfies the criterion in § 26.604(a) may present a greater potential radiological consequence to workers and the public in the vicinity of the facility than does an NPUF. Second, the operating characteristics of a part 53 licensed facility are unlike that of an NPUF because there may be a higher reliance on individuals at the part 53 site to safely and competently operate, maintain, surveil, and secure SSCs that may not be required at an NPUF, such as systems that provide secondary heat transfer, reactor coolant flow, pressure control, and at-power core refueling. Differences in operating

[5] Controlled access area and vital area are defined in § 73.2, "Definitions."

characteristics could include, for example: long-term, full power operation with automated reactivity control systems for load-following; active and passive safety and security systems; innovative non-light water heat transfer systems; and energy storage and hazardous chemical systems. The individuals at part 53 facilities may also be required to communicate to individuals both onsite and offsite any conditions adverse to safety, security, or quality, such as electrical load dispatchers. Third, part 53 licensed facilities may be sited in geographically remote locations that may not have a physically available administrative or corporate support team to provide face-to-face oversight, engineering expertise, and maintenance support like that at NPUFs. This places a higher reliance on those individuals required at a part 53 facility being fit for duty and trustworthy and reliable because a replacement individual may not be readily available.

The NRC proposes to exclude drug and alcohol testing from the proposed § 26.604 framework for five reasons: (1) the § 26.23 performance objectives can be met through effective implementation of the defense-in-depth regulatory framework established by behavioral observation, reporting of legal actions, the proposed performance monitoring and review program (PMRP), FFD training, and requirements from the physical protection, AA, cyber protection, and licensed operator programs; (2) the PMRP would require the licensee or other entity to monitor its FFD program performance (both qualitatively and quantitatively) against its historical site performance, fleet-level performance, if applicable, and industry performance. The licensee or other entity would be required to implement corrective actions if site FFD performance meets a licensee- or other entity-established threshold or to resolve a finding resulting from a qualitative review or audit in a manner that restores performance and corrects root causes, contributing causes, or both; (3) the requirements in proposed § 26.609, “Behavioral observation,” are more robust than those in § 26.407, “Behavioral

observation," of subpart K of part 26 and are proposed to synchronize with and reinforce the AA behavioral observation requirements in § 73.56, "Personnel access authorization requirements for nuclear power plants," or the proposed requirements under § 73.120, "Access authorization program for commercial nuclear plants"; (4) a part 53 commercial nuclear plant that satisfies the § 26.604(a) criterion will be designed, operated, and secured with a radiological risk profile that is lower than that described in § 53.860(a)(2), and perhaps will approach the radiological risk profile of an NPUF (which does not implement an FFD program); and (5) the NRC is aware that a part 53 commercial nuclear plant could be designed and constructed in such a manner to reduce reliance on an onsite security force to protect SSCs, NRC-licensed materials, and sensitive information, with enhanced capabilities for the detection, assessment, and delay of a DBT adversary.

Regarding fatigue management requirements, work hour controls would be required for personnel at utilization and manufacturing facilities in accordance with the existing scoping criteria in § 26.4, "FFD program applicability to categories of individuals," as revised in this proposed rule. The amended § 26.4 also would be used to determine whether an individual would be subject to drug and alcohol testing. The applicability of these scoping criteria for certain individuals (such as operators and maintenance personnel) would be determined by the licensee or other entity through its risk-informed evaluation process (or alternative method for evaluating the safety significance) performed to assess the risk significance of the SSC upon which work is being performed or directed by the individual. These requirements also would be scaled based on the potential radiological consequences presented by the facility. However, fatigue management would be applied to all individuals subject to the FFD program, similar to FFD program implementation by the current fleet of commercial nuclear plants

because fatigue management is a proactive requirement designed to help prevent on-shift impairment through work hour scheduling and time off. The behavioral observation program (BOP) would be the principal requirement to provide reasonable assurance that individuals on shift are not mentally or physically impaired due to fatigue, which in any way could adversely affect their ability to safely and competently perform their duties.

The NRC is proposing subpart M of part 26 for facilities licensed under part 53, in lieu of subjecting all part 53 licensees to the same part 26 requirements that apply to facilities licensed under part 50 or 52, for four principal reasons. First, subpart M of part 26 would apply FFD requirements in a risk-informed manner commensurate with the radiological consequences presented by facilities licensed under part 53. This regulatory strategy is consistent with the current part 26, which provides a comprehensive set of deterministic requirements for licensees and other entities at facilities that are operating. This approach is also consistent with the current subpart K of part 26, which provides a more flexible framework for nuclear power reactors under construction, where the probabilities of serious radiological accidents are lower and consequences from such accidents are less severe than at operating plants.

Second, subpart M of part 26 would enable a part 53 licensee or other entity to implement innovative drug testing technologies and behavior observation techniques while continuing to demonstrate compliance with the part 26 performance objective in § 26.23(b) of providing reasonable assurance that individuals are not under the influence of any substance or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform assigned duties. These technologies include drug and alcohol testing using oral fluid, urine, and hair specimens; screening using point of collection testing and assessment (POCTA) devices; and monitoring using passive drug and alcohol detection instrumentation. Part of the basis to

enable the use of innovative drug and alcohol testing technologies is to maintain FFD program effectiveness should the staff size at a part 53 commercial nuclear plant be small and challenge the effective implementation of the behavioral observation and drug and alcohol testing programs. Also, a commercial nuclear plant that is sited at a geographically remote location may present additional challenges to behavioral observation and drug and alcohol testing that are not presented by traditional LWR facilities licensed under part 50 or 52, such as: efficiency of postal services for shipping and controlling biological specimens; proximity to drug and alcohol collection facilities that are reasonably equivalent to that described in subpart E of part 26; availability of internet and cellular services to enable same-time discussions among the Medical Review Officer (MRO), donor, and laboratory; accessibility to substance abuse treatment services described in subpart H, “Determining Fitness-for-Duty Violations and Determining Fitness,” of part 26; and proximity to an MRO (or management and clinical staff) to evaluate potential impairment caused by fatigue and/or substance use or abuse, for-cause and post-accident occurrences, and the individual’s potential to return to duty.

A part 53 commercial nuclear plant that is sited in a geographically remote location and has a small staff size may present implementation challenges and the potential for small group dynamics to impact FFD program effectiveness. Particularly in isolated environments, psychological phenomena known as “groupthink” may take effect and could impact the effectiveness of BOPs and the ability to effectively manage safety culture. For example, in circumstances where small staffs are drawn from the same small town and thereby have a potentially narrow experience base, it could be challenging to maintain a safety conscious work environment in which personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination, and organizations may resultingly experience groupthink-like effects.

Groupthink is particularly prevalent among cohesive and insulated groups that experience high levels of decisional stress.[6] Small staffs at part 53 commercial nuclear plants may therefore be more susceptible to groupthink if they are working in an isolated environment where decision-making pressures may be high.

Groupthink could have adverse effects on workplace safety culture, as studies show that individuals will be more hesitant to speak out against practices they deem unsafe for fear of deviating from group norms.[7] Individuals may also be unaware of systematic biases in the group decision-making process and may then be less likely to scrutinize the potential risks of the group's decision or sufficiently contemplate alternative paths of action.[8] Furthermore, the literature indicates that groups make riskier decisions than individuals acting alone due to the diffusion of responsibility among group members.[9] This phenomenon, known as "the risky shift," also runs counter to a safety culture. Accordingly, "groupthink" and "the risky shift" may lead to group behaviors that render behavioral observation less effective. As such, alternative approaches to behavior observation programs, such as the utilization of video-based surveillance by individuals separate from the onsite work unit, could serve to mitigate potential issues associated with groupthink. The incorporation of remote observation, performed by

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[6] See e.g., Irene Wærø, Ragnar Rosness, and Stine Skaufel Kilska, "Human performance and safety in Arctic environments," SINTEF (2018).

[7] See e.g., Russell Mannion and Carl Thompson, "Systematic biases in group decision-making: implications for patient safety," *International Journal for Quality I Health Care*, Vol. 26, No. 6 (2014): 606-612 (arguing that small group dynamics in healthcare teams produce systematic biases in group decision-making because healthcare professionals may be reticent to vocalize concerns they have about quality of care).

[8] See e.g., Wærø, Rosness, and Kilska (arguing that groupthink leads teams to "develop shared rationalizations that bolster a proposed choice, rather than examining alternative options and identifying the risks associated with the proposed choice"). See also David Hofmann and Adam Stetzer, "A Cross-Level Investigation of Factors Influencing Unsafe Behaviors and Accidents," *Personnel Psychology*, Vol. 49 (1996) (finding that in a study of fatal accidents involving offshore oil rigs, in the absence of standard operating procedures, workers "equated normal work methods (i.e. what everyone else does) with safe and/or ideal work methods," revealing that the groupthink phenomena will further cement modes of work that do not reflect safety protocols in small groups that lack strong norms around workplace safety and tacitly reward short-cuts that prioritize efficiency over safety).

[9] Mannion and Thompson, "Systematic biases in group decision-making: implications for patient safety," *International Journal for Quality I Health Care*, Vol. 26, No. 6 (2014): 606-612.

individuals physically separate from the site, could help to bring in independent and objective perspectives and help to break patterns of thought and communication that may result in groupthink.

Even without the influence of small group dynamics, there are other practical constraints to implementing FFD requirements, such as random drug and alcohol testing, among small staffs. Random testing is less effective when applied to small staff sizes because it may be easier for staff to communicate and predict when individuals will be subject to drug and alcohol testing. Furthermore, if a facility is sited in a remote location, program implementation could be challenged by the following factors: limited mail services to laboratories certified by the U.S. Department of Health and Human Services (HHS), availability of local clinical or medical options for treatment and determinations of fitness by an MRO or Substance Abuse Expert, and use of offsite drug and alcohol collection facilities.

The increased potential for small staff sizes to impact FFD policy compliance warrants an approach to FFD that emphasizes performance over prescriptive requirements that may be ineffective or infeasible at these facilities. Therefore, the NRC proposes the subpart M of part 26 framework to provide a performance-based approach to FFD. For example, proposed § 26.603(c) would use existing part 26 auditing requirements and the reporting requirement in § 26.717, “Fitness-for-duty program performance data,” and clarify how FFD performance data would be used to maintain or improve, if necessary, FFD program effectiveness. Specifically, § 26.603(c) would require each licensee and other entity that elects to implement subpart M of part 26 to monitor and assess their site-specific performance against the preceding year’s site performance, the licensee’s most recent fleet-level performance, and the most recent industry performance. Licensees and other entities would use these datapoints to

develop performance measures, which would be qualitative descriptions of the specific FFD program elements, and threshold values for each performance measure that, if exceeded, would indicate a performance deficiency. Each licensee and other entity would compare its site's current performance data against the performance measures and, if a threshold is exceeded, the licensee or other entity would be required to take corrective actions to restore performance. Also, the NRC proposes a change control requirement to allow a licensee or other entity to change its subpart M of part 26 FFD program while ensuring that FFD program effectiveness is maintained.

Lastly, subpart M of part 26 would consolidate the applicable FFD requirements by placing in one subpart all proposed part 26 requirements (either new requirements or cross-references to existing part 26 requirements) for part 53 licensees and other entities. This should help licensees and other entities implement the requirements because it would enable easy cross-reference to similar requirements in other subparts that are being implemented by non-part 53 licensees and entities subject to part 26. Understanding how other licensees or other entities implement similar FFD requirements may facilitate the sharing of operating experience in program implementation.

The use of innovative technologies and a risk-informed performance-based framework parallels the considerations presented in the Advanced Reactor Policy Statement. As stated in the policy statement, "simplified systems should facilitate operator comprehension, reliable system function, and more straightforward engineering analysis." Furthermore, these same attributes may reduce potential radiation exposures, help prevent the theft of nuclear materials, and use technology and design innovations. Should these components and systems be designed, implemented, and maintained to minimize reliance on human actions and leverage technology and innovation, then the robust and prescriptive FFD requirements in, for example, subparts B, "Program

Elements," and E of part 26 could be scaled to the part 53-licensed facility and its operation. This strategy would be implemented in the subpart M of part 26 framework.

Even though current subpart K of part 26, provides for FFD requirements commensurate with the radiological consequences presented by a nuclear power plant construction site, proposed subpart M of part 26 would not allow part 53 licensees and other entities to implement the requirements in subpart K. The principal reasons are that (without significant changes to subpart K that would be outside the scope of this rulemaking): (1) subpart K does not apply to holders of MLs who assemble or test a reactor; (2) subpart K only applies during construction, whereas subpart M would apply during construction, operation, and decommissioning through implementation of the insider mitigation program (IMP) required by § 73.55 or proposed § 73.100; (3) subpart K does not address training, authorization as defined in § 26.5, and MRO performance; (4) subpart K does not expressly authorize the use of innovative drug and alcohol testing technologies; (5) subpart K does not describe the use of time-dependent alcohol limits or special analysis testing of dilute urine specimens; and (6) subpart K has less rigor in the protection of worker rights and sensitive information than that proposed in subpart M.

Despite the differences between subparts K and M of part 26, the requirements in subpart M would be essentially equivalent to many in subpart K that were implemented by the licensees of Vogtle Nuclear Station and V.C. Summer Nuclear Station when they were constructing four commercial nuclear power reactors and NRC inspection and operating experience evaluation determined that the use of subpart K contributed to adequately protecting the public health and safety and the common defense and security. Further, given the risk profile posed by facilities licensed under part 53 and the proposed additional requirements in subpart M of part 26 that were developed from operating experience and other part 26 subparts (but are not included in

subpart K of part 26), the NRC concludes that if licensees and other entities effectively implement the proposed requirements in subpart M of part 26, then individuals subject to the rule should be fit for duty and trustworthy and reliable.

Proposed Changes to Part 26, Subparts A through E and I

Section 26.3(d) is the applicability paragraph for contractor/vendors (C/Vs) who implement FFD programs or program elements, to the extent that the licensees and other entities specified in § 26.3(a) through (c) rely on those C/V FFD programs or program elements to meet the requirements of part 26. Section 26.3(d) would be amended to address part 53 licensees and other entities in proposed § 26.3(f).

Proposed § 26.3(f) would place part 53 licensees or other entities within the scope of part 26. For licensees and other entities of a part 53 commercial nuclear plant, except a holder of an ML, the FFD program would be required to be implemented no later than the start of construction activities. The holder of an ML would need to implement its FFD program before commencing activities that assemble a reactor.

Current § 26.4 describes FFD program applicability to categories of individuals. These categories are based on the duties, responsibilities, and the types of access an individual may possess. The NRC proposes to amend § 26.4 to include licensees and other entities described in § 26.3(f). The NRC expects that not all categories of individuals described in current § 26.4 would be applicable to all part 53 facilities. The NRC is proposing regulatory guidance in DG-5073, “Fitness-of-Duty Programs for Commercial Nuclear Plants and Manufacturing Facilities Licensed Under 10 CFR Part 53,” and DG-5078, “Fatigue Management for Nuclear Power Plant Personnel at Commercial Nuclear Plants Licensed Under 10 CFR Part 53,” to help address program applicability to certain individuals.

Section 26.4(a)(1) and (a)(4) would be amended to account for the possibility that certain individuals may perform or direct the performance of operational and maintenance activities from a remote facility (for example, a remote-control station) for licensees or other entities licensed under part 53.

The framework of the current part 26 does not account for individuals who perform operating and maintenance duties at remote facilities. Although current § 26.4(a)(1) does not limit the operating of applicable SSCs to onsite operating, § 26.5 limits the definition of “maintenance,” for the purposes of § 26.4(a)(4), to include only “onsite maintenance activities.” In the 2008 part 26 final rule preamble, the NRC explained that the work hour requirements apply to those individuals who perform maintenance activities within the licensee’s owner-controlled area. Furthermore, regarding the direction of applicable operations and maintenance activities, current § 26.4(a)(1) and (4) address only individuals who perform “onsite direction.”

Under the proposed amendments to part 26, the limitation of “onsite” activities to those performed within the owner-controlled area would still apply to facilities licensed under part 50 or 52. However, for licensees and other entities described in § 26.3(f), the NRC would remove the “onsite” limitation to include activities performed both within the owner-controlled area as well as operations and maintenance duties performed at remote facilities where safety-significant systems and components are expected to be operated within the design basis of the commercial nuclear plant.

In the 2008 part 26 final rule, the purpose of limiting "directing" activities to those "directing" activities that are conducted onsite was to avoid requiring work hour controls for individuals performing incidental duties, consistent with § 26.205(b)(5), from an offsite location in instances where those duties might be considered to be “directive” in nature. Under the proposed amendments to part 26, the exclusion of incidental duties while

calculating work hours would still be applicable for licensees and other entities licensed under part 53. However, for these licensees and other entities, beyond instances of incidental duties, the direction of operations and maintenance activities associated with safety-significant SSCs, when performed at remote facilities, would be considered in an equivalent fashion as direction performed at non-remote facilities, for the purposes of administering work hour controls.

Section 26.4(a)(1) and (4) would also be amended to include a provision for using an alternative method of evaluating the safety significance of SSCs.

Proposed § 26.4(b) would include in an FFD program individuals who are granted unescorted access to the protected area of a facility licensed under part 53 and do not perform or direct the performance of the duties described in § 26.4(a). This requirement would contribute to the defense-in-depth regulatory framework that helps provide that individuals who have unescorted access are fit for duty, trustworthy, and reliable. For example, the NRC is proposing amendments to part 73 to require a part 53 licensee to subject individuals to a series of reviews to help determine whether those individuals are trustworthy and reliable before granting them unescorted access to the facility's protected area.

The NRC would amend § 26.4(c) to include in an FFD program individuals who are assigned to physically report to the part 53 licensee's emergency response facility (or facilities) or participate remotely in emergency response activities, and individuals without unescorted access to the part 53 facility who, remotely or otherwise, make decisions and/or direct actions regarding plant safety or security. Part 53 commercial nuclear plants may be licensed for and rely upon offsite facilities to fulfill the role of a Technical Support Center (TSC) or Emergency Operations Facility (EOF). Therefore, the proposed rule would account for such offsite facilities or remotely performed activities.

Further, the use of personnel to operate systems and components, maintain and surveil SSCs, and respond to plant conditions and security events may be different than those included in the TSC or EOF team for power reactors currently licensed under part 50 or part 52.

For the individuals whose duties for the licensees and other entities in § 26.3(c) require the individuals to have the types of access or perform the activities listed in § 26.4(e)(1) through (6) at the location where the commercial nuclear plant will be constructed and operated, current § 26.4(e) requires them to be subject to an FFD program that satisfies all the requirements of part 26 except subparts I and K. The NRC would amend § 26.4(e) to except subpart M as well as subparts I and K. The NRC would also amend § 26.4(e) to include in an FFD program the individuals whose duties for the licensees and other entities in § 26.3(f) require the individuals to have the types of access or perform the activities listed in § 26.4(e)(1) through (6) or perform construction activities as defined in § 26.5.

Section 26.4(e)(4) would be revised to include in an FFD program individuals who witness or determine inspections, tests, and analyses certifications required under part 53 because current § 26.4(e)(4) includes the individuals who perform the same duties under part 52.

The proposed rule would amend § 26.4(f) to require individuals who construct, manufacture, or direct the construction or manufacture of safety- or security-related SSCs at facilities licensed under part 53 to be subject to an FFD program under subpart M of part 26 or an FFD program that demonstrates compliance with all of the requirements of part 26 except for subparts I, K, and M of part 26.

Section 26.4(g) is the applicability paragraph for FFD program personnel (e.g., the FFD manager, MRO, and technicians) and persons who perform AA determinations

(e.g., the licensee- or other entity-designated Reviewing Official). This section would be amended to address part 53 licensed facilities. Specifically, a part 53 licensee or other entity would use FFD program personnel to implement its FFD program as well as other assigned individuals who are not involved in the day-to-day operations of the program to implement specific elements of its FFD program, such as the collection of a specimen for drug or alcohol testing. These individuals would be held accountable for program implementation, including consistent implementation of protections afforded to all individuals subject to the FFD program.

Section 26.4(h) would be amended to include subpart M of part 26.

The NRC proposes to include several new definitions in § 26.5, “Definitions,” and amend some existing definitions. The NRC is proposing to add a definition for “biological marker.” The proposed definition would be consistent with “biomarker” defined by the HHS in its Mandatory Guidelines for Federal Workplace Drug Testing (HHS Guidelines) using oral fluid as the biological specimen to be tested (84 FR 57554; October 25, 2019). However, the proposed definition for § 26.5 would add that the endogenous substance used to validate that the biological specimen “was produced by the donor” because subpart M of part 26 proposes to have the MRO evaluate any discrepant biological marker identified in a biological specimen collected from a donor.

The NRC is proposing a definition for the word “change” as used in the proposed § 26.603(e), “FFD program change control,” process. The proposed definition would be consistent with the definition of “change” for a part 50 or 52 licensee’s emergency plans in § 50.54(q)(1)(i).

The NRC proposes to revise the definition of “constructing or construction activities” to clarify that for licensees or other entities in § 26.3(f), the definition of “construction” would be that as proposed in § 53.024 or § 53.028.

The definitions of “contractor/vendor” (C/V) and “other entity” would be revised to make them applicable to part 53 licensees. A holder of an ML under part 53 could be a C/V under the proposed C/V definition.

The NRC is proposing a definition for “illicit substance” because this phrase is used in subpart M of part 26 and would address substances that cause impairment and possible addiction but are not an “illegal drug” as defined in § 26.5. This proposal is based on operating experience where individuals have admitted to using common household, non-drug substances to achieve a high or satisfy an addiction. These common household items include, but are not limited to nitrous oxide, butane, propane, glue, paint vapors, lighter fluid, nail polish remover, degreasers, permanent markers, and methyl alcohol (which is found in hand sanitizer and mouthwash).

The definition of “questionable validity” would be revised to make it applicable to an FFD program implemented under subpart M of part 26, which would include all biological specimens.

The NRC is proposing a definition for “reduction in FFD program effectiveness” because this phrase, similar to the proposed definition for “change,” is used in proposed § 26.603(e). The proposed definition is generally consistent with the definition of “reduction in effectiveness” provided for emergency plans in § 50.54(q)(1)(iv).

The proposed rule would make the current definition of “reviewing official” applicable to those licenses and other entities in § 26.3(f).

The current part 26 definition of “safety-related structures, systems, and components” would be amended to use the NRC’s proposed definition in § 53.020 for the part 53 licensees and other entities described in § 26.3(d) and (f).

The NRC would amend the definition of “security-related SSCs” in § 26.5 to make it applicable to a licensee or other entity described in § 26.3(d) and (f).

The NRC proposes a definition for “Special Nuclear Material” that would refer to the definition in § 70.4, “Definitions,” of part 70 to ensure consistency.

The NRC is proposing a revision of the definition of “unit outage” to account for the potential use of commercial nuclear plants for purposes other than electricity generation.

Section 26.21, an applicability statement for part 26 FFD programs, would be amended to include licensees and other entities described in § 26.3(f) that choose to implement an FFD program that implements all part 26 requirements, except those in subparts K and M of part 26.

Section 26.51, “Applicability,” would be amended to apply to licensees and other entities described § 26.3(f) that elect not to implement the requirements in subpart M of part 26 for the categories of individuals in § 26.4 and those licensees and other entities that elect to implement the requirements in § 26.605.

Section 26.53(e), (e)(1) and (3), and (g) through (i), which are general provisions for granting and maintaining authorization, would be amended to apply to licensees and other entities described § 26.3(f).

Section 26.63(d), a suitable inquiry requirement, would be amended to apply to licensees and other entities described § 26.3(f).

Section 26.73, the applicability statement for subpart D of part 26, would be amended to apply to licensees and other entities described § 26.3(f) that elect not to implement the requirements in subpart M of part 26 for the categories of individuals in § 26.4 and those licensees and other entities that elect to implement the requirements in § 26.605(b).

Section 26.81, the purpose and applicability statement for subpart E of part 26, would be amended to apply to licensees and other entities described in § 26.3(f) that

elect not to implement the requirements in subpart M of part 26 for the categories of individuals in § 26.4 and those licensees and other entities that implement proposed § 26.605(a) or (b). The subpart E requirements to be implemented are listed in proposed § 26.607(c)(2)(i) and (ii) and (3).

Section 26.201, the applicability statement for subpart I of part 26 would be amended to apply to licensees and other entities described in § 26.3(f). Also, the applicability statement would be divided into two paragraphs for clarity.

The NRC proposes to add § 26.202, “General provisions for facilities implementing subpart M of this part,” for licensees or other entities described in proposed § 26.3(f) that elect to implement the requirements in subpart I of part 26 in accordance with § 26.604 and § 26.605. Section 26.202 would establish requirements equivalent to those in current § 26.203, “General provisions,” which is applicable to part 50 and 52 licensees. The NRC would add the separate § 26.202 because § 26.203 refers to various requirements under subpart B of part 26, which would not be applicable to facilities licensed under part 53 that implement subpart M of part 26.

Additionally, § 26.202(c), “Training and assessments,” unlike § 26.203(c), “Training and examinations,” would not include a comprehensive examination requirement because trainee assessment is conducted as part of a SAT that would be required as proposed under the FFD program training requirements in § 26.608.

Proposed changes in §§ 26.205, 26.207, and 26.211 would add references to new requirements in subparts I and M of part 26 that would be applicable specifically to licensees and other entities in § 26.3(f). The NRC would not change the specific provisions for work hour requirements in current § 26.205(d). However, as addressed in the discussion of proposed changes to § 26.4(a), whether a licensee or other entity under part 26 would need to implement work hour controls for certain individuals or

groups would be dependent, in part, on determinations reached by that licensee's risk-informed evaluation process or alternative method of evaluating the safety significance of SSCs.

Proposed changes to §§ 26.207(a)(1)(ii) and 26.211(b) would allow licensees and other entities in § 26.3(f) to perform face-to-face assessments to support the approval of work hour control waivers and the conduct of fatigue assessments, respectively, using electronic communications. These proposals would allow supervisors to conduct such assessments from a remote location under appropriate circumstances. Such remotely conducted assessments would need to be supported by someone who is present in-person with the individual being assessed and who is trained in accordance with the requirements of either §§ 26.29 and 26.203(c) or §§ 26.608 and 26.202(c). The reasoning for these proposals and the associated need for in-person support to augment electronic communications is addressed further in the preamble discussion of proposed § 26.619.

Proposed Requirements for Part 26, Subpart M

The proposed rule would add a new subpart M to part 26 that would provide alternative FFD requirements for part 53 licensees and other entities.

Proposed § 26.601 would make subpart M of part 26 applicable to part 53 licensees and other entities, at their discretion. If a licensee or other entity in § 26.3(f) does not elect to implement an FFD program that demonstrates compliance with the requirements of subpart M, then the individuals specified in § 26.4 would be subject to an FFD program that demonstrates compliance with all part 26 requirements, except for those requirements in subparts K and M.

Proposed § 26.603(a) would require an applicant to provide a description of its FFD program and its implementation within its application for a license. This requirement

is equivalent to the existing requirements in §§ 26.401(b) and 52.79(a)(44). The entities that would be required to submit these FFD program descriptions are certain applicants that would comply with the part 53 application requirements in subpart H. In subpart H, § 53.1309(a)(6) would require an applicant for a CP to provide a description of its FFD program in its PSAR. Under §§ 53.1279(b)(4), 53.1369(x), and 53.1416(a)(24), an applicant for an ML, OL, and COL, respectively, would be required to provide a description of its FFD program in its FSAR.

Unlike an application for a license, a description of an FFD program does not receive NRC review for possible approval. The applicant provides the NRC with information about the applicant's proposed FFD program to inform the NRC's inspection program and to demonstrate that the FFD program will be effectively implemented before a licensee or other entity commences any activity making individuals at the NRC-licensed facility subject to the FFD program.

Proposed § 26.603(a)(1) would require a summary description of the analysis described in § 26.603(c), if performed. The analysis should describe the operation of the facility. This would include informing the Commission of: (1) the principal individuals assigned by job title (work category) and a summary description of the human actions (e.g., monitoring, operating, responding, surveillance, oversight, etc.) that they perform to maintain the facility in a safe operating or shutdown condition; (2) the principal individuals by job title and a summarized description of the human actions to secure and protect the facility (without providing sensitive information); (3) the estimated total population of individuals subject to the FFD program and per shift by job description; and (4) references to supporting documentation. The purpose of these descriptions is to enable an NRC assessment of the licensee's or other entity's analysis and the required human actions to operate, monitor, surveil, maintain, and secure the facility within its

design and licensing basis so that if an operational or security-related event were to occur, the facility would respond as designed and licensed and the calculated radiological dose consequences would not exceed the consequences described in § 53.860(a)(2). This is important because facilities that implement § 26.604 are expected to have very small staff sizes and may be sited in geographically remote locations, both of which could challenge effective implementation of the FFD program.

Proposed § 26.603(a)(2) would require the applicant to state what FFD program it plans to implement.

Proposed § 26.603(a)(3) would require a discussion that informs the NRC of the applicability of the applicant's FFD program to individuals who perform safety- or security-significant activities. This description should summarize any key differences between the staff at the site and any remote facility and the categories of individuals in § 26.4. The principal purpose of providing this description would be to inform the NRC of any substantial differences in the applicability of the FFD program to the categories of individuals in § 26.4.

Proposed § 26.603(a)(4) would require a description of the drug and alcohol testing and fitness determination process to be implemented through the licensee's or other entity's procedures, including the collection and testing facilities to be used, biological specimens to be collected, and sanctions to be imposed upon a confirmed FFD policy violation. This process includes how individuals who test positive for a drug or alcohol will be evaluated before being afforded unescorted access to the protected area to perform or direct those duties or responsibilities making them subject to the FFD program. The principal purpose of describing this return-to-duty process is to inform the NRC of the behavioral observation strategy (for those facilities that implement § 26.604) and/or drug screening and testing strategy.

Proposed § 26.603(a)(5) would require a summary description of the applicant's planned PMRP. This description must provide the performance measures and thresholds that the applicant intends to use.

Proposed § 26.603(b) would establish when the FFD program must be implemented and the longevity of the FFD program. This proposal is equivalent to the current § 26.3, which states, in part, when licensees and other entities must begin implementing their FFD programs. Unlike the current part 26 regulations, proposed § 26.603(b) would expressly state that an FFD program would not be applicable during decommissioning of a part 53 facility for licensees and other entities specified in § 26.3(f). However, licensees of facilities licensed to operate a reactor should be aware that the physical protection program under § 73.55, "Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage," and under proposed § 73.100 include a requirement for the implementation of an IMP, even during decommissioning.

Proposed § 26.603(b) would also require the holder of an ML to implement its FFD program no later than the start of activities that assemble a reactor. The holder of the ML should establish in its procedures when reactor assembly commences and what constitutes assembly. For example, the FFD program would not need to be implemented for the receipt, storage, inspection, and staging of components and systems used to assemble (i.e., build or fabricate) the reactor because this is not a current requirement for LWR facilities licensed under part 50 or 52. Furthermore, the NRC currently does not require that an FFD program be applied to the assembly or manufacturing of components (or basic components as defined in § 21.3), or systems that were fabricated or assembled outside the footprint of a commercial power reactor, and this regulatory position would also apply to a manufacturing facility.

Proposed § 26.603(c) would require the establishment of a PMRP. The concept of a PMRP is not new. This requirement would consolidate for part 53 the requirements in current §§ 26.41, “Audits and corrective actions”; 26.415, “Audits”; 26.717, “Fitness-for-duty program performance data”; and 26.183(c), which describes MRO responsibilities. The proposal would state that the licensee or other entity must monitor the effectiveness of its FFD program by comparing performance data against performance measures and thresholds. The development of quantitative thresholds would be new, but this is born from licensees and other entities with facilities licensed under parts 50 or 52 already collecting, reviewing, and reporting FFD performance data. Additionally, the benefit of quantitatively measuring FFD program performance against established thresholds benefits a licensee’s and other entity’s determination of whether they are maintaining FFD program performance in a manner that demonstrates compliance with the performance objectives in § 26.23.

The NRC is proposing the PMRP because the subpart M of part 26 requirements would enable a high degree of flexibility in FFD program implementation (e.g., drug testing). A licensee or other entity would not only have options in the type of FFD program they may implement under part 26, but they would have options in the types of biological specimens they may test for drugs, where to collect the biological specimens (e.g., at the NRC-licensed facility or offsite at a local hospital or clinic), and the use of collection and assessment devices to screen individuals for drugs and alcohol. These FFD program flexibilities could cause FFD programs under subpart M of part 26 to become very site-specific, necessitating performance measures to enable the licensee or other entity to maintain the effectiveness of its FFD program.

FFD program effectiveness would be determined by comparing actual performance against the performance measures and thresholds. The result of that

comparison would inform licensee or other entity decisions whether to change FFD program elements to address a performance deficiency. Also, the thresholds would have sufficient margin, based on operating experience, before conditions adverse to safety and security may occur should an individual be identified as impaired or not trustworthy and reliable. The potential of a human-related failure causing a condition adverse to safety and security is dependent on the duties and responsibilities of the individual and the defense-in-depth designed to prevent or mitigate an adverse consequence. The PMRP would account for this by requiring the review of FFD performance data, in part, by work category, C/V, and individuals employed by the licensee who are not a C/V as defined in § 26.5 (i.e., a licensee employee).

Proposed § 26.603(c)(1) would require the licensee or other entity to document and maintain its PMRP. Proposed § 26.603(c)(1)(i) would require that the performance measures be identified and designed to monitor FFD program performance. Proposed § 26.603(c)(1)(i)(A) would require the FFD program of a licensee or other entity subject to the requirements of § 26.604 to include monitoring of the BOP. The purpose of this monitoring is to help ensure that individuals subject to the FFD program are observing the behaviors of others, are being observed themselves, and are reporting FFD concerns to licensee- or other entity-designated individuals. The other performance measures would include occurrence of FFD policy violations evaluated by licensee employee, C/V, and labor category, and occurrence of individuals with potentially disqualifying information or who possessed an FFD prohibited item.

Proposed § 26.603(c)(1)(i)(B) would require the FFD program of a licensee or other entity that is either subject to the requirements of § 26.604 and has implemented a drug testing program at its discretion, or is subject to the requirements of § 26.605, to include the performance measures identified in § 26.603(c)(1)(i)(A) and those necessary

to monitor the effectiveness of the drug and alcohol testing program. The drug and alcohol measures would include the monitoring of FFD performance data for pre-access and random testing and subversion attempts by the categories of licensee employee, C/V, and labor category.

Proposed § 26.603(c)(1)(ii) would require the licensee or other entity to establish thresholds for each performance measure. Initial thresholds must be based on FFD performance data from comparable facilities subject to part 26, the licensee's or other entity's fleet-level program performance if applicable, and industry FFD performance data. This provision introduces the requirement to "maintain FFD program effectiveness." This terminology describes a performance-based regulatory strategy in which the licensee or other entity must initially establish a level of performance that is representative of other facilities in the licensee's fleet of facilities subject to part 26, if applicable, and the FFD performance of comparable facilities subject to part 26.

Proposed § 26.603(c)(1)(iii) would require that the licensee or other entity evaluate FFD data as it is received to determine whether a threshold has been exceeded. Historical FFD performance data for the current LWR fleet indicates that, for particular work categories and employment types, few FFD policy violations occur per year. Therefore, for work categories that may be significant to worker safety (e.g., radiation protection technicians), physical protection (i.e., security personnel), or safety (i.e., NRC-licensed operators and individuals who perform or direct the performance of activities that a risk-informed evaluation process or alternative method for evaluating safety significance has shown to be significant to public health and safety), a single FFD policy violation could be a significant occurrence and warrant corrective actions. Based on licensee-submitted FFD-related reports under §§ 26.417, 26.419, 26.717, and 26.719, licensees and other entities with facilities licensed under parts 50 or 52

implement some form of corrective action that is typically scaled to the significance of the violation. These corrective actions have included counseling, follow-up drug and/or alcohol testing, remedial training, generic announcements to the workforce, and reviews of recently performed or directed work by the individual suspected of being impaired. Proposed § 26.603(c)(1)(iii) would require that the PMRP include a year-to-year comparison of FFD performance data to help provide assurance that an adverse trend in FFD program performance would be identified if occurring. This proposed requirement was developed from the annual FFD performance data reporting requirements in §§ 26.417(b)(2) and 26.717. In particular, the proposed year-to-year comparison of FFD performance data is equivalent to § 26.717(c), which requires, in part, licensees and other entities to analyze their performance data at least annually and take appropriate actions to correct any identified program weaknesses.

Proposed § 26.603(c)(1)(iv) would require the licensee or other entity to perform and document quantitative and qualitative reviews. These reviews would be performed in three program areas: protections afforded to individuals subject to the FFD program, laboratory test results and MRO performance, and change control. The purpose of these reviews would be to specifically target performance within the three program areas to assess whether the outcomes resulting from the implementation of procedure requirements are contributing to FFD program effectiveness. The proposed reviews would not require the establishment of measures and thresholds because the reviews are expected to result in qualitative findings regarding program effectiveness. Qualitative findings and observations could still result in the consideration of corrective actions in the targeted program areas.

Proposed § 26.603(c)(1)(iv)(A) would require the licensee or other entity to monitor whether its FFD program is affording appropriate protections to individuals

subject to the FFD program. The review of these protections would include, in part, assessing the licensee's or other entity's protection of the following: privacy during the specimen collection process; specimen integrity, custody, and control; information gathered from FFD program implementation; and due process during appeals of FFD policy violations.

Proposed § 26.603(c)(1)(iv)(B) would require, in part, a review of laboratory test results and MRO performance. Effective performance by the laboratory (e.g., obtaining and communicating accurate test results) and MRO (e.g., correct evaluation of the laboratory test results based on § 26.185 or HHS Guidelines) would result in three significant outcomes: (1) protection of the donor from an inaccurate FFD policy violation determination; (2) protection of the donor, other individuals, and the facility from potential harm should the donor be impaired or not trustworthy and reliable; and (3) a performance-based assessment of both the laboratory and MRO. This last outcome could facilitate actions to improve laboratory performance, MRO training under § 26.607(m), or both. Proposed § 26.603(c)(1)(iv)(B) would also require a comparative analysis between the POCTA screening result(s) and the corresponding specimen test results obtained from the HHS-certified laboratory if the POCTA indicated a positive, adulterated, substituted, or invalid screening result or discrepant biological marker, to assess the effectiveness of the POCTA and to inform MRO decisions under § 26.185 or § 26.607(m)(6). The results of this biennial review could also inform the conduct of laboratory audits.

Proposed § 26.603(c)(1)(iv)(C) would require that the change control requirement in proposed § 26.603(e) be included in the biennial program review to help ensure that changes implemented over the life of the facility do not result in a reduction in program effectiveness even if a mitigating action was implemented for the specific change. This

requirement was developed from §§ 26.137(f) and 26.713(d). This part of the review would require an assessment of all changes since the last review and their potential aggregated impact on FFD program effectiveness. For example, if last year the licensee elected to contract with a different MRO and this year the licensee implemented a new type of POCTA device, each of those program changes probably would not have resulted in a recognizable reduction in FFD program effectiveness. But, if the drug testing positivity rate (or FFD policy violations) for C/Vs decreased markedly during a future maintenance outage that required many C/Vs, then the reduction could indicate, for example, that the POCTA device was not as effective as determined by a forensic toxicologist review under §§ 26.603(e) and 26.607(h) or that the new MRO was improperly crediting prescription medication for laboratory-confirmed positive test results.

Proposed § 26.603(c)(2) would state when the licensee or other entity must implement corrective actions. This requirement would be equivalent to the requirement in current § 26.415(b) and was developed from requirements contained in §§ 26.41(a) and (f), 26.127(e), 26.129(b)(1)(i), 26.137(f)(3) through (5), 26.155(a)(6), 26.157(e), 26.159(b)(1)(i), and 26.203(e)(2). Corrective actions must be implemented to correct root causes, contributing causes, or both. There is margin built into the FFD performance thresholds and qualitative factors (e.g., to account for potential changes in drug and alcohol testing performance data when there is a large influx of C/Vs to perform maintenance) that may influence a licensee or other entity's causal determination for an occurrence. Thus, generalized or qualitative corrective actions may be implemented like informing management and placing a sufficiently descriptive summary of the occurrence in a corrective action program for future monitoring to assess recurrence.

However, should the occurrence challenge safety or security or significantly exceed a performance threshold even when considering qualitative factors and margin,

the licensee or other entity should implement more robust corrective actions to resolve the cause. An example of a challenge to safety or security would be the situation when an NRC-licensed operator or maintenance professional had operated, surveilled, or maintained safety-significant SSCs and was determined to have been impaired by behavioral observation or potentially under the influence of a narcotic as determined by an alcohol or drug test or screening result. Immediate corrective actions could include, but would not be limited to, a licensee or other entity assessment of the duties and responsibilities recently performed by the individual. Operating experience within the LWR operating reactor community demonstrates few FFD policy violations per year per site have been caused by individuals who perform or direct the performance of safety or security-significant activities. Therefore, any such violations of the FFD policy in a particular work category in one year could be a significant performance deficiency. These violations could be even more significant at part 53 facilities that have a very small workforce subject to part 26.

Proposed § 26.603(c)(3) would require the licensee or other entity to biennially assess and document its FFD performance monitoring program; this requirement was developed from § 26.41(b). This documented review would demonstrate that the performance measures and thresholds are appropriate based on site- and licensee's fleet-level program performance, if applicable, and industry performance and adjusted to maintain FFD program effectiveness. Also, as a result of this effort, the licensee or other entity would be in possession of lessons learned from fleet-level performance, if applicable, and industry performance that could contribute to their own performance assessment to maintain program effectiveness.

Under proposed § 26.603(c)(3)(i), the identified program weaknesses and corrective actions resulting from the biennial review would be required to be summarized

in the licensee's or other entity's annual report to the NRC in compliance with either § 26.417(b)(2) or § 26.717, as applicable. This information would inform the NRC of FFD program weaknesses to facilitate regulatory oversight and enable the NRC to aggregate industry data for use in a licensee or other entity PMRP.

Proposed § 26.603(c)(3)(ii) would establish when the biennial PMRP review must be completed and when corrective actions from the review must be implemented. The NRC selected the May 15th date of odd-numbered years to help ensure that all FFD programs will maintain their previously determined performance measures and thresholds or reset them based on FFD program performance early in the year in which the biennial review was conducted. This would assist in obtaining quality FFD performance data over two annual reporting cycles and evaluating whether previous corrective actions were effective.

In proposed § 26.603(d), the NRC proposes a change control requirement for subpart M of part 26 FFD programs. Requiring licensees and other entities to demonstrate compliance with certain requirements before implementing changes to their FFD programs would be necessary for two primary reasons. First, proposed changes to a licensee's or other entity's FFD program could affect the analysis performed by the licensee or other entity under proposed § 26.604(a), which helps determine the FFD program requirements that must be implemented. If this analysis changes, then the licensee's or other entity's FFD program requirements might change. Second, the requirements in subpart M of part 26 are performance based. Therefore, FFD program implementation may change periodically in response to societal changes in substance abuse or from PMRP implementation. Change control therefore relies on the licensee or other entity maintaining its procedures in a manner that details how its FFD program is

to be implemented while incorporating changes, with documentation that justifies the changes to support the PMRP, audits, and NRC inspection.

Proposed § 26.603(d)(1) would permit the licensee or other entity to implement changes to its FFD program if it performs and retains an analysis demonstrating that the change does not reduce the effectiveness of the FFD program or the change was necessitated or justified by a change to part 26, laboratory processes, or guidance issued by the HHS or NRC. The proposed change control requirement would enable flexibility in program implementation should the NRC or HHS change its drug testing procedures (as implemented by the licensee or other entity through its procedures) in response to changes in societal substance abuse or drug testing technologies.

The proposed change control requirement was developed from the change control requirements in § 50.54(p) and (q)—the change control requirements for security and emergency plans, respectively. However, unlike these two requirements, the NRC does not review and approve a licensee's or other entity's FFD program or its implementing procedures, and the FFD program is not licensing basis information as described in § 53.1300 or § 53.4900.

Proposed § 26.603(d)(2) would require that if a change reduces FFD program effectiveness, then the licensee must implement a mitigating strategy so the FFD program, as revised, will continue to demonstrate compliance with the performance objectives in § 26.23 and not result in a reduction in program effectiveness.

Proposed § 26.603(d)(3) would prohibit, with one exception, the use of the change control process to reduce the minimum panel of drugs to be tested and would reference the drugs listed in proposed § 26.607(c)(1). Proposed § 26.607(c)(1) would reference current § 26.31(d)(1), which states that, at a minimum, licensees and other entities shall test for marijuana metabolite, cocaine metabolite, opiates (codeine,

morphine, 6-acetylmorphine), amphetamines (amphetamine, methamphetamine), phencyclidine, adulterants, and alcohol. The testing of these drugs and drug metabolites, except phencyclidine, and alcohol is necessary for the FFD program to remain effective. Also, there is no proposed subpart M of part 26 requirement stating that this panel of drugs and drug metabolites needs to consist of only scheduled drugs.[10] This flexibility would account for the situation where an impairing substance becomes prevalent in society and a licensee or other entity elects to add the substance to their panel of substances to be tested prior to it being scheduled by the Drug Enforcement Administration.

The exception in proposed § 26.603(d)(3) would be that, should HHS elect to remove phencyclidine from the panel of drugs and drug metabolites to be tested, a licensee or other entity could make this change in its FFD program without resulting in a reduction in FFD program effectiveness. This outcome would be justified based on the very infrequent occurrence rate of FFD policy violations due to phencyclidine use since 2010. However, if HHS proposes to remove a class of drugs from the panel of drugs to be tested that is listed in § 26.31(d)(1), except for phencyclidine, then a licensee or other entity may not make a similar change to its panel of drugs to be tested, because this change would be a reduction in FFD program effectiveness even with a mitigative strategy implemented.

[10] The Drug Enforcement Administration classifies drugs, substances, and certain chemicals used to make drugs into five (5) distinct categories, depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. These categories appear as Schedules I through V of section 202 of the Controlled Substances Act (21 U.S.C. 812). Schedule I drugs have a high potential for abuse, have no currently accepted medical uses in treatment in the United States, and lack accepted safety for use under medical supervision. At the other end of the classification scheme, Schedule V drugs have the least potential for abuse among the five categories of drugs, have a currently accepted medical use in treatment in the United States, and abuse of the drug may lead to limited physical dependence or psychological dependence. For more information, see https://www.dea.gov/drug-information/drug-scheduling.

Changes in the HHS panel of drugs and drug metabolites to be tested may also shift from one metabolite to a different metabolite for the same drug class (e.g., amphetamines, opioids) to be tested. Should HHS issue such a change to its panel, this would not be expected to result in a reduction in FFD program effectiveness because HHS would be targeting a more prevalent or effective metabolite in its drug testing program. This situation could occur as HHS gathers more operating experience from Federal Government implementation of its HHS Guidelines, or data generated by drug testing laboratories and Federally mandated drug testing programs required by Federal agencies such as the NRC or U.S. Departments of Transportation, Energy, or Defense.

Proposed § 26.603(d)(4) would require that change control records be maintained for a 5-year record retention period based on the current NRC practice to conduct triennial inspections of licensees' and other entities' FFD programs. This would afford the NRC an opportunity to review the licensee's or other entity's determination that FFD program changes have not reduced the effectiveness of their FFD program. Licensees and other entities would also be required to summarize each change made under proposed § 26.603(e) in their annual FFD performance reports required by § 26.617(b)(2) or § 26.717, as applicable.

Proposed § 26.604 would establish the minimum set of FFD program requirements for licensees and other entities who have a documented analysis that demonstrates that the facility and its operation satisfy the criterion in § 26.604(a). For these licensees, compliance with the performance objectives in § 26.23 would be ensured through the BOP; defense-in-depth measures proposed in subpart M of part 26 like the PMRP, change control, and audits; and other requirements, such as those for AA, physical protection, and licensed operators. The adequacy of these measures in satisfying the performance objectives is supported by operating experience, which

demonstrates margin between an FFD-related occurrence and a condition adverse to safety or security, as illustrated by for-cause, post-event, and random testing data. A facility that satisfies the criterion in proposed § 26.604(a) would present a smaller potential radiological consequence than a facility that does not satisfy the criterion, so the requirements in proposed § 26.604 are scaled to the lower risk presented consistent with the Commission's Advanced Reactor Policy Statement.

The disadvantages of implementing the FFD program described in proposed § 26.604 would be few. Since drug and alcohol testing would not be required, behavioral observation would be the keystone requirement in this performance-based framework to provide that individuals are fit for duty, trustworthy, and reliable, and can safely and competently perform the duties and responsibilities making them subject to the FFD program. If not, the individuals would be assessed in accordance with the licensee's or other entity's procedures similar in manner to that required by subpart K of part 26, and the proposed PMRP would require corrective actions should a threshold be exceeded.

If a licensee or other entity elects not to perform the analysis in proposed § 26.604(a) to determine whether it satisfies the criterion; performs the analysis and finds that the facility and its operation does not satisfy the criterion; or is a holder of an ML, the licensee or other entity could not implement the FFD program described in § 26.604. Instead, the licensee or other entity would implement either the program described in proposed § 26.605 or an FFD program that demonstrates compliance with all the requirements in current subparts A through I, N, and O of part 26.

Proposed § 26.605 would establish requirements in a graded manner similar to the regulatory framework established by the requirements in subparts A through I, N, O, and K of part 26. This existing graded approach consists of an FFD program for construction of a commercial nuclear plant and a more robust program that must be

implemented before reactor operation. The former is the FFD program in proposed § 26.605(a), and the latter is proposed § 26.605(b). Like that for an FFD program under § 26.604, the FFD program under § 26.605 would include FFD program elements similar to those in subpart B of part 26, but the proposed requirements are less prescriptive, enabling more flexibility in program implementation like that offered in subpart K of part 26. For example, the requirements in subpart B of part 26 are explicit requirements for, in part, the collection and analysis of urine specimens. Subpart B of part 26 does not enable the use of oral fluid for drug testing or screening, except under very limited situations as described in subpart E of part 26, or the use of hair specimens, unlike proposed § 26.605. Proposed § 26.605 would require drug and alcohol testing based on either the requirements in part 26 or the HHS Guidelines. The principal benefit of the proposed § 26.605 FFD program is that it would provide a regulatory framework that is consistent with the radiological consequences for a facility that does not satisfy the criteria in proposed § 26.604(a) while affording flexibilities in the conduct of drug and alcohol testing.

Proposed § 26.605(a) would apply to licensees and other entities who perform the § 26.604(a) analysis and satisfy the criterion but decide not to implement the FFD program described in proposed § 26.604, licensees and other entities who do not perform the § 26.604(a) analysis, and licensees and other entities who perform the analysis but their analysis does not demonstrate that their facility and its operation satisfy the criterion in § 26.604(a). These entities must establish, implement, and maintain an FFD program under § 26.605(a) either during construction activities as defined in § 26.5, or during activities performed under an ML that allows the assembly, testing, or both, of a manufactured reactor. This FFD program implements all the FFD program requirements in § 26.604 plus drug and alcohol testing.

The timing element of the proposed applicability statement of § 26.605(a) is equivalent to that for an LWR licensee or other entity who is performing those same activities at a facility licensed under part 50 or 52 and helps provide assurance that those individuals who assemble, test, or perform construction activities as defined in § 26.5 or direct these activities are fit for duty and trustworthy and reliable. This is important because assembly and testing a manufactured reactor and the construction and testing of SSCs required for facility operation require, in part, adherence to procedures, possible implementation of unique and precise assembly techniques, and quality assurance and controls. Additionally, SSCs within a manufactured reactor may not be accessible, testable, or available for quality assurance and verification after the reactor is assembled. This requirement is also proposed to address solo-assembly activities that may cause latent failures and passive SSCs located internal to a reactor (for example, a fusible link designed to melt at a particular temperature to trigger an actuation mechanism) that are relied upon for safe operation but cannot be inspected or tested for proper installation, configuration, or operation after installation. A § 26.605(a) FFD program for these types of activities is equivalent to the FFD program applicable to the assembly of the reactor vessel internals and testing of the SSCs internal to the reactor at an LWR licensed under part 50 or 52.

Proposed § 26.605(b) would apply to the same licensees and other entities as in proposed § 26.605(a) but before the loading of fuel onsite into a reactor vessel; before receiving a manufactured reactor; or before individuals subject to part 26 operate, test, perform maintenance of, or direct the maintenance or surveillance of security-related equipment or equipment that a risk-informed evaluation process or alternative method for evaluating safety significance has shown to be significant to public health and safety. These entities must establish, implement, and maintain an FFD program that

implements all the requirements in § 26.605(a), except proposed §§ 26.610, “Sanctions”; 26.617, “Recordkeeping and reporting”; and 26.619, “Suitability and fitness determinations”; plus additional requirements due to the increased radiological consequences presented by a part 53 commercial nuclear plant as the licensee readies it for operation. These additional requirements include those in subparts C, D, H, and N of part 26, some of which would replace §§ 26.610, 26.617, and 26.619.

Proposed § 26.605(b) would also enable the licensee or other entity to better integrate its facility into the LWR fleet and Category I fuel cycle facilities because subparts C, D, and H of part 26 would be required. These subparts would be required, in part, because it is expected that: (1) individuals will be able to work at any part 50, 52, or 53 commercial nuclear plant and will possess a nuclear safety culture and desirable qualifications, skills, expertise, or services; and (2) licensees and other entities of facilities licensed under parts 50, 52, and 70 may venture to construct or operate a facility licensed under part 53. Therefore, the implementation of these subparts would help ensure that all individuals subject to part 26, except those individuals subject to an FFD program under § 26.604, § 26.605(a), or subpart K of part 26, would be subject to FFD programs that provide reasonable assurance that the individuals are fit for duty, trustworthy, and reliable.

Proposed § 26.606, “Written policy and procedures,” would require licensees and other entities to implement and maintain an FFD policy and procedures for their FFD programs. This section would establish requirements equivalent to those in current § 26.403, “Written policy and procedures,” of subpart K. However, a principal difference is that proposed § 26.606 is written to enable the use of urine, oral fluid, and hair for drug testing and screening.

Proposed § 26.606(a)(1) would require each licensee and other entity to provide a written FFD policy statement to individuals subject to the FFD program before the individuals are subjected to behavioral observation and any FFD program drug and alcohol test. This would be a protection measure afforded to individuals subject to the FFD program to help ensure that they know what is expected of them before being subject to the FFD program and potential consequences should they violate the FFD policy or procedures. This requirement would also contribute to safety and security because understanding FFD program responsibilities may enhance an individual's safety culture or the individual may self-select out of the licensee's or other entity's hiring process.

Proposed § 26.606(a)(2) would require that the FFD policy statement describe the performance objectives in § 26.23, which are the same FFD program performance objectives required for facilities licensed under parts 50, 52, or 70. Having a standard performance outcome based on a licensee or other entity satisfying the § 26.23 performance objectives would enhance consistency in FFD program implementation across all entities subject to part 26. It would also generate confidence that individuals subject to part 26 will safely and competently perform their duties and responsibilities and use NRC-licensed materials in a manner that will protect the public health and safety and common defense and security.

Proposed § 26.606(a)(3) would require that the FFD policy statement describe the minimum days off requirements in § 26.205(d)(3) or maximum average work hours requirements in § 26.205(d)(7), if applicable.

Proposed § 26.606(a)(4) would require the FFD policy statement be written in sufficient detail to provide affected individuals with information on what is expected of them and what consequences may result from a lack of adherence to the policy,

including those elements described in § 26.603(b), part 26-required sanctions, and required medical/clinical treatment and follow-up testing for FFD policy violations. This requirement is equivalent to § 26.403(a) of subpart K but includes an additional description of what the policy statement must include. For example, the policy would describe the NRC-required sanctions to help deter substance abuse and required medical/clinical treatment and follow-up testing for FFD policy violations. This provision would provide a protection measure by helping the individual get the assistance they need and help ensure that the individual refrains from substance abuse.

Proposed § 26.606(a)(5) would require that the FFD policy statement describes the individual's responsibilities to report for work in a physiological and psychological condition that enables the safe and competent performance of assigned duties and responsibilities and inform a licensee- or other entity-designated representative when the individual determines that this cannot be accomplished.

Proposed § 26.606(b) would require licensees and other entities implementing a FFD program in accordance with subpart M of part 26 to establish, implement, and maintain written procedures for their FFD programs. This requirement would be equivalent to that in § 26.403(b) of subpart K.

Proposed § 26.606(b)(1) would establish requirements for a subpart M of part 26 FFD program in which the licensee or other entity implements a drug and alcohol testing program. This provision would be equivalent to the requirements in current § 26.403(b)(1) of subpart K, but § 26.606(b)(1)(i) through (iv) proposes additional clarity and specificity that licensees and other entities must detail in their procedures to address new testing methods in subpart M of part 26 that are not permitted under the current part 26 framework. Clarity and specificity in procedural instructions would support consistent program implementation, which protects all individuals subject to the program.

Proposed § 26.606(b)(1)(iv) would require that if the licensee or other entity elects to use the HHS Guidelines for the conduct of drug testing, the FFD program procedures must include the name of the specific HHS Guideline and revision being implemented by the licensee or other entity and a description of the specific sections in the guideline that are being implemented, including specimen collections, drug testing, laboratory procedures, and evaluation of test results. This requirement would help ensure the following: the validity and accuracy of drug testing because the specimens would be subject to laboratory testing that has been certified by the HHS; protection of worker rights equivalent to the privacy, information, and due process protections afforded to Federal workers under the HHS Guidelines because the HHS Guidelines are used in the Federally mandated drug testing programs; consistency in program implementation because all individuals subject to the FFD program would be subject to the same collection, testing, and evaluation processes; and FFD program effectiveness because the effectiveness of the HHS Guidelines have been verified by HHS's National Laboratory Certification Program (NLCP). Detailed procedures would enhance MRO and FFD program personnel reviews of individual test results because instructions would be provided for, in part, the evaluation of specific test results (e.g., positive, negative, biological markers), the conduct of additional testing for invalid or dilute specimens, and the assessment of subversion attempts (e.g., adulterated or substituted). This would benefit FFD program effectiveness and help prevent misunderstanding of program requirements and processes.

Proposed § 26.606(b)(2) would require licensees and other entities to include in their written procedures the immediate and follow-up actions that would be taken, and the procedures that would be used, in certain situations specified in proposed § 26.606(b)(2)(i) through (vi). Proposed § 26.606(b)(2) would be equivalent to the

requirements in current § 26.403(b)(2), which provides the same requirement under an FFD program for construction for part 50 or 52 licensees and other entities. This would help ensure the effectiveness of the FFD program and its consistent implementation, because part 53 licensed facilities would be implementing procedures to address the same requirements and with individuals who would understand what is expected of them no matter what part 53 facility they were assigned.

The situation specified in proposed § 26.606(b)(2)(i) would arise when individuals subject to the FFD program have been involved in the use, sale, or possession of illegal substances, illegal drugs, or illicit substances. This provision would be equivalent to current § 26.403(b)(2)(i), except that the phrase “illegal drugs” would be replaced with “illegal substances, illegal drugs, or illicit substances.” Illegal substances would include legal substances used in a manner inconsistent with Federal or State law.

The situation specified in proposed § 26.606(b)(2)(ii) would arise when individuals who are subject to the FFD program are impaired by any substance or the consumption of alcohol as determined by behavioral observation or a test that measures blood alcohol concentration, as defined in § 26.5. Except for a few differences, this provision would be equivalent to current § 26.403(b)(2)(ii) of subpart K. The NRC would not include the phrases “to excess” and “accurately” in proposed § 26.606(b)(2)(ii). Subpart M of part 26 is a performance-based framework that focuses on impaired human performance, and for alcohol, impairment is determined by behavioral observation or by blood alcohol concentrations exceeding the limits in § 26.103, “Determining a confirmed positive test result for alcohol,” using an evidentiary breath testing (EBT) device for alcohol (not whether an individual drank “to excess”). If impairment is determined by an individual’s behavior, it must be based on physiological indications of alcohol impairment. These indications are well established in medical,

clinical, and law enforcement organizations, and could be used by the licensee or other entity through its procedures and training.[11]

The NRC would include the phrase “illegal substances, illegal drugs, and illicit substances” in proposed § 26.606(b)(2)(ii) based on operating experience and the terminology in current § 26.23(b). There are far more substances that may cause impairment than just drugs, drug metabolites, and alcohol. The phrase “before or while constructing or directing construction of safety- or security-related SSCs” in current § 26.403(b)(2)(ii) would not be included in proposed § 26.606(b)(2)(ii) because proposed § 26.606 would apply during construction, operation, and decommissioning, if applicable. The NRC would include the term “behavioral observation” in proposed § 26.606(b)(2)(ii) because impairment can be visibly or audibly observed in an individual, and individuals subject to subpart M of part 26 would be trained in behavioral observation under proposed § 26.608.

The situation specified in proposed § 26.606(b)(2)(iii) would arise when individuals who are subject to an FFD program that includes drug and alcohol testing attempt to subvert the testing process by adulterating or diluting specimens (*in vivo* or *in vitro*), substituting specimens, or by any other means. Except for one difference, this provision would be equivalent to current § 26.403(b)(2)(iii). The NRC would include the phrase “if drug and alcohol testing is conducted” to address the licensee or other entity who implements § 26.604, which does not require drug and alcohol testing. The purpose underlying this requirement has increased in significance since issuance of the 2008 part

[11] By “well established” the NRC means that there are Federal, State, and non-governmental organizations with reputable and scientifically based resources available for a licensee or other entity to use in its procedures or training to inform individuals of the physiological indications of alcohol impairment or intoxication.

26 final rule because subversion attempts have accounted for about one-third of all FFD policy violations every year since 2016.

The situation specified in proposed § 26.606(b)(2)(iv) would arise when individuals, who are subject to an FFD program that includes drug and alcohol testing, refuse to provide a specimen for analysis or refuse to follow instructions provided by FFD program personnel. Except for two differences, this provision would be equivalent to current § 26.403(b)(2)(iv). As with proposed § 26.606(b)(2)(iii), the NRC would include the phrase, "If drug or alcohol testing is conducted," to account for an FFD program implemented under § 26.604. The NRC would include the phrase "or follow the instructions provided by FFD program personnel" based on an existing requirement in § 26.89(c) that the collector must inform the donor that if the donor refuses to cooperate in the specimen collection process, then such refusal will be considered a refusal to test and sanctions for subverting the testing process will be imposed.

The situation specified in proposed § 26.606(b)(2)(v) would arise when individuals who are subject to an FFD program had legal action taken relating to drug or alcohol use. This requirement would be equivalent to current § 26.403(b)(2)(v).

The situation specified in proposed § 26.606(b)(2)(vi) would be when individuals subject to an FFD program demonstrated character or actions indicating that the individual cannot be trusted or relied upon to perform those duties and responsibilities or maintain access to NRC-licensed facilities, SNM, or sensitive information. This includes character traits beyond those attributed to drug or alcohol use. This proposal would help ensure that the licensee or other entity will implement an FFD program designed to demonstrate compliance with the § 26.23(c) performance objective that FFD programs must provide "reasonable measures for the early detection of individuals who are not fit to perform the duties that require them to be subject to the FFD program." An individual

who is not trustworthy and reliable is not fit to perform or direct the performance of those duties and responsibilities or be afforded those types of access that make the individual subject to an FFD program.

This proposed requirement also would help to align the subpart M of part 26 BOP with the BOP implemented under § 73.56(f) and proposed § 73.120 and the purpose of the IMP as described in § 73.55(b)(9) and proposed § 73.100(b)(9).[12] The demonstrated character and actions of an individual can indicate whether the individual can be trusted and relied upon to safely and competently perform assigned duties and responsibilities or be afforded those types of access making the individual subject to the FFD program. This holds true for any demonstrated adverse character indication or action on- or offsite.

The phrase “character or actions” would be used in proposed § 26.606(b)(2)(vi) to focus on observed examples that indicate an individual subject to subpart M of part 26 may not be fit for duty or trustworthy and reliable. Character traits include but are not limited to personality, temperament, honesty, carelessness, apathy, psychosis, and commitment to safety culture. Assessment of an individual’s character should consider the potential for changes in these traits when compared to a previous baseline. Actions would include a physical or verbal demonstration of a character trait that could call into question an individual’s fitness, trustworthiness, or reliability. For example, the individual does something physically, verbally, or in writing (e.g., falsifying records, driving while impaired, or harming or threatening to harm oneself, others, or property) that compels another individual to conclude that the observed individual cannot be trusted or relied

[12] The IMP must monitor the initial and continuing trustworthiness and reliability of individuals granted or retaining unescorted AA to a protected or vital area and implement defense-in-depth methodologies to minimize the potential for an insider to adversely affect, either directly or indirectly, the licensee’s capability to protect against radiological sabotage.

upon. Unlike the background investigation and reviews of “character and reputation” in § 73.56(d)(6) and (k)(1)(v) and proposed § 73.120, which are principally retrospective reviews of an individual and may be based on third-party information (i.e., information from individuals not subject to NRC requirements), the “character or action” focus of proposed § 26.606(b)(2)(vi) would be a present observation of an individual subject to the FFD program and performed by an individual who is also subject to the FFD program. Whether the information would be received from an individual subject to the FFD program or someone who is not subject to the FFD program, the licensee or other entity would need to review this information (i.e., determine if the information and its source are credible) to determine whether the individual should maintain authorization.

Proposed § 26.606(b)(3) would require licensees and other entities to address in their procedures the process, including the duties and responsibilities of FFD program personnel, to be followed if an individual’s behavior or condition raises an FFD concern. This provision would also require a process to be conducted when credible information is received by the licensee or other entity that the individual is not fit for duty, trustworthy, and reliable.

With a few exceptions, proposed § 26.606(b)(3) would be equivalent to current § 26.403(b)(3). Instead of the phrase “while constructing or directing the construction of safety- or security-related SSCs” in current § 26.403(b)(3), the NRC would use “on the NRC-licensed facility” in proposed § 26.606(b)(3) because this provision would apply during commercial nuclear plant construction, operation, and decommissioning, if applicable, in addition to holders of an ML as described in § 26.3(f). The requirement that the roles and responsibilities of FFD program personnel be described was developed from current §§ 26.4(g) and 26.31(b) and operating experience, which has demonstrated that clear job descriptions help ensure that individuals know who is

designated by the licensee or other entity to make decisions regarding FFD program implementation and who can be approached when physiological or psychological help is needed. This is principally a protection consideration afforded to individuals subject to the FFD program.

The proposed requirement would also include two conditions not found in current § 26.403(b) that would clarify the initiation of the fitness determination process should an individual's behavior or condition raise an FFD concern. The phrase, "impairment from any cause that in any way could adversely affect the individual's ability to safely and competently perform the individual's duties," would reflect the § 26.23(b) performance objective. The condition, "the receipt of credible information indicating that the individual cannot be trusted or relied on to perform those duties and responsibilities making the individual subject to this part," would reflect the § 26.23(a) performance objective. In either case, as required by § 26.23(c), the FFD program must provide reasonable measures for the early detection of individuals who are not fit to perform the duties that require them to be subject to the FFD program.

Proposed § 26.606(b)(4) would require licensees and other entities to have written procedures that address the operation and oversight of an onsite or offsite collection facility. This requirement would be equivalent to current §§ 26.403(b) and 26.405(e) and is developed from § 26.41(b), which states that each licensee and other entity who is subject to subpart B of part 26, shall ensure that the entire FFD program is audited, which is part of a licensee's or other entity's oversight of the facility, and § 26.87(a), which states that each FFD program must have one or more designated collection sites that have all necessary personnel, materials, equipment, facilities, and supervision to collect specimens for drug testing and to perform alcohol testing. Having procedures for the operation and oversight of the onsite or offsite collection facility would

enhance consistency in program implementation, protect individuals subject to testing, and account for the flexibilities afforded in the types of biological specimens than may be collected under an FFD program subject to subpart M of part 26. Section 26.606(b)(4), when used with the PMRP described in § 26.603(d) and the proposed audit requirement in § 26.605(a), would help maintain FFD program effectiveness and prevent subversion attempts at facilities that may not be under the direct day-to-day oversight of FFD program personnel.

Proposed § 26.606(b)(5) would require licensees and other entities to have written procedures that address the fatigue management requirements in §§ 26.202(b), "Procedures"; 26.205(d)(3); and 26.205(d)(7), if applicable.

Proposed § 26.606(b)(6) would require licensees and other entities to have written procedures that provide measures to prevent subversion of drug and alcohol tests conducted onsite and offsite. This proposal was developed from § 26.27(c)(1).

Proposed § 26.607, "Drug and alcohol testing," would establish drug and alcohol testing requirements for licensees and other entities implementing proposed § 26.604, at their discretion, and licensees and other entities implementing proposed § 26.605. Except for a few differences, proposed § 26.607 would be equivalent to current § 26.405, which requires licenses and other entities implementing an FFD program under subpart K of part 26 to have a drug and alcohol testing program that demonstrates compliance with the requirements in § 26.405(b) through (g). The differences are commensurate with the risk consequences presented by a part 53-licensed facility as compared to a part 50 or 52 nuclear power plant. These proposed requirements would improve flexibility in the conduct of drug and alcohol testing while maintaining protections afforded to individuals subject to the FFD program.

Proposed § 26.607(a) would require licensees and other entities to obtain a split specimen for all drug tests using oral fluid or urine for all test conditions in § 26.607(b), (h) and (j). Neither current subpart K nor current subparts B or E of part 26 require a split specimen. However, the majority of the LWR fleet uses split specimens for drug testing and commercially available drug screening products use a split specimen technique. Since publication of the 2008 part 26 final rule, the HHS has issued guidelines for urine and oral fluid that require split specimens, and the draft proposed HHS Guidelines for hair requires split specimens, as well.

The required use of a split specimen process would protect the individual because, upon a donor-alleged discrepant or questionable test result, the donor may provide permission to test the split specimen (specimen B) in an effort to refute the laboratory test results for specimen A. The requirement also would enable the MRO to direct laboratory testing of specimen B if specimen A were invalid; though the NRC expects specimens becoming invalid at the laboratory to be a rare occurrence as testing would be conducted in HHS-certified laboratories with trained collectors. In the event that a specimen is determined to be invalid, then the occurrence would likely warrant further investigation by the MRO and laboratory to identify the cause. This protocol would be equivalent to the special analysis testing in current § 26.163(a)(2) for dilute specimens in that additional laboratory analysis is performed because of a questionable test result.

If a split specimen is tested by an HHS-certified laboratory, then the test result from specimen B must be used as part of the determination for an FFD policy violation as required by § 26.185(n), “Evaluating results from a second laboratory.” However, this is not to say that the test results from specimen A should be discarded. Since the HHS-certified laboratory should report all test results from all specimens tested to the MRO,

like the information described in § 26.169, “Reporting results,” test result differences between specimens A and B can be used to inform the MRO as to what should be reported to the licensee or other entity to either facilitate medical or clinical assistance for the individual, inform an FFD-policy violation determination, or both.

The proposed § 26.607(a) requirement would also state that if the licensee or other entity elects to use a POCTA device for screening during random testing or portal area monitoring (e.g., pre-access screening), a split specimen would not need to be taken. The reason for this exception would be that the requirements in § 26.607(h)(4) establish the process to be implemented when a screening test indicates a presumptive positive, adulterant, or a discrepant biological marker, if applicable. This process includes collecting and testing a specimen for analysis at an HHS-certified laboratory.

Proposed § 26.607(b) would require the licensee or other entity to subject individuals identified in § 26.202 to drug and alcohol testing under the five conditions listed in § 26.607(b)(1) through (5). Proposed § 26.607(b) would be equivalent to current § 26.405(c).

Proposed § 26.607(b)(1) would require pre-access testing similar to current § 26.405(c)(1), which requires testing before assignment to construct or direct the construction of safety- or security-related SSCs. Unlike current § 26.405(c)(1), the proposed requirement would not include the phrase, “construct or direct the construction of safety- or security-related SSCs,” because, for licensees or other entities under part 53, the pre-access test condition applies to construction, operation, and decommissioning, if applicable, to help inform a licensee’s or other entity’s authorization determination. The proposal also would use “pre-access” instead of “pre-assignment,” which is used in current § 26.405(c)(1).

A pre-access test would require the collection of an oral fluid or a urine specimen no more than 14 days before the individual is granted unescorted access. Although this change has roots in the 2008 part 26 final rule, which reduced the period within which pre-access testing must be performed from 60 days to 30 days or less, the 14-day proposal is based on three lessons learned from operating experience.

First, the 14-day period would be a large enough window of time to collect the specimen and evaluate test results because licensees or other entities typically receive laboratory test results within 5 business days of laboratory receipt of the biological specimen. At the same time, the 14-day period would be small enough to help ensure that the test results are representative of the individual's forensic toxicology before being granted authorization.

Second, the 14-day window would enable the licensee or other entity to conduct an unannounced pre-access drug and alcohol screening using a hair specimen or a POCTA. This would help prevent an individual from attempting to subvert the drug and alcohol test by temporarily abstaining from drug or alcohol abuse or adulterating or substituting their specimen to obtain a non-positive test result.

Third, the NRC does not expect licensees and other entities licensed under part 53 to have the large and periodic influxes of individuals (either licensee employees or C/Vs) that LWRs have to support facility operation, maintenance, engineering design changes, or nuclear refueling. Therefore, these licensees or other entities would not be periodically challenged to in-take a large workforce within the proposed 14-day pre-access testing window.

Proposed § 26.607(b)(2) would require the licensee or other entity to conduct random drug and alcohol testing of all individuals subject to the FFD program. With one exception, this proposed requirement would be equivalent to current § 26.405(b).

Section 26.405(b) gives licensees and other entities that implement an FFD program subject to subpart K of part 26 the option to impose random drug and alcohol testing. Proposed § 26.607(b)(2) would not offer that option because subpart M of part 26, unlike subpart K, would not allow a licensee or other entity to implement a fitness monitoring program under current § 26.406 instead of a random testing program. The principal reasons for not allowing this flexibility would be that no licensee or other entity has ever implemented a fitness monitoring program (i.e., there is no operating or regulatory experience on which to judge the effectiveness of a fitness monitoring program) and the proposed subpart M framework already uses behavioral observation to help ensure FFD program effectiveness. Supplementing the proposed § 26.609 BOP with an additional observation technique (i.e., the fitness monitoring program) would not result in a level of deterrence or detection equivalent to that which would be obtained through behavioral observation and random drug and alcohol testing.

Proposed § 26.607(b)(2)(i) through (v) would provide specific requirements for the conduct of a random testing program. These paragraphs would be equivalent to § 26.405(b)(1) through (4), although with a few differences. The similar provisions would be proposed in §§ 26.607(b)(2)(i), 26.607(b)(2)(iii), and 26.607(b)(2)(iv).

The differing provisions would include proposed § 26.607(b)(2)(ii), which would refer to an “FFD program procedure” instead of the reference to an “FFD program policy” in § 26.405(b)(2) because procedures contain the instructions that implement FFD program requirements, but the FFD policy need not contain specific instructions. Section 26.607(b)(2)(ii) would also require individuals who are selected for random testing to report to the onsite collection site, as opposed to the collection site in § 26.405(b)(2) because alcohol metabolism necessitates a relatively timely alcohol test. This change is also proposed because the NRC expects that part 53 licensees and other

entities may use a combination of onsite (for random, for-cause, and post-accident testing) and offsite (for pre-access, post-accident, and follow-up testing) collection facilities for drug and alcohol testing and may have to afford reasonable accommodation to certain individuals, which would add complexity in the licensee's or other entity's procedurally determined time period in which an individual must report to the collection facility.

Another difference from § 26.405(b) would be proposed § 26.607(b)(2)(v), which would establish the random testing rate for the population of individuals subject to testing. Subpart K of part 26 does not establish a random testing rate. The proposed requirement would be equivalent to current § 26.31(d)(2)(vii), which requires that the sampling process used to select individuals for random testing provides that the number of random tests performed annually is equal to at least 50 percent of the population that is subject to the FFD program. The NRC would revise that slightly for proposed § 26.607(b)(2)(v) to require a 50 percent random testing rate for the licensee employee population and a 50 percent random testing rate for the C/V population. The NRC proposes this change for two reasons.

First, although operating experience has demonstrated that § 26.31(d)(2)(vii) helps provide reasonable assurance that individuals are fit for duty and trustworthy and reliable through the detection and deterrence of substance abuse, this same operating experience demonstrates that, on many occasions, the C/V population has been tested at a rate lower than 50 percent, even though this population results in the majority of all FFD policy violations. This bias occurs because C/Vs are available for testing only during short periods of time or periodically throughout the year, whereas licensee employees are essentially always available for a test.

A second reason why the NRC is proposing a different 50 percent random testing protocol than in the current part 26 requirements is that the flexibilities afforded to part 53 licensees or other entities in subpart M of part 26 are not afforded to licensees or other entities that must implement an FFD program under subparts A through I, N, and O of part 26. These flexibilities include enabling the use of a POCTA device to screen individuals during the random testing process and the use of offsite collection facilities for pre-access testing. The potential reduction in FFD program effectiveness caused by licensee or other entity implementation of these options would be offset by subpart M requirements that mitigate possible challenges to the FFD program, such as the 50 percent random testing rate for the licensee employee population and 50 percent random testing rate for the C/V population.

Proposed § 26.607(b)(3) would require for-cause testing equivalent to that used in current FFD programs implementing § 26.405(c)(2). The NRC would require for-cause testing, like random testing, to be conducted onsite to ensure that the test is conducted as soon as reasonably practicable. This is an important consideration when for-cause testing for alcohol or using oral fluid for drug screening or testing because human metabolism continually lowers the concentrations of the drugs, drug metabolites, and alcohol perhaps to concentrations lower than the initial or confirmatory testing cutoffs. Additionally, for facilities that are sited in geographically remote locations, an offsite collection facility might be too far away or not readily accessible.

Proposed § 26.607(b)(4) would require post-event testing in a manner equivalent to current § 26.405(c)(3) with a few adjustments. For part 53 licensees or other entities, the NRC proposes post-event testing under two conditions: events involving human errors that may have caused or contributed to the events (proposed § 26.607(b)(4)(i)), and events not involving human error that result in adverse health consequences or

damage to any safety- or security-related SSC (proposed § 26.607(b)(4)(ii)). The word "significant" would not be used in § 26.607(b)(4)(ii)(A) to describe the "illness or personal injury" as used in § 26.405(c)(3)(i) because § 26.607(b)(4)(ii)(A) would describe which illnesses or injuries are covered. Proposed § 26.607(b)(4)(ii)(B), unlike § 26.405(c)(3)(ii), would not use the word "significant" to describe the damage to safety- or security-related SSCs because any damage to safety- or security-related SSCs would require testing within four hours of the event unless immediate medical intervention precludes the conduct of the test on the individual(s) who caused or contributed to the event. Proposed § 26.607(b)(4)(ii)(B) also would not use the word "construction" as in § 26.405(c)(3)(ii) because § 26.607(b)(4) would apply to construction, operation, and decommissioning, if applicable.

Proposed § 26.607(b)(4)(i) would require the licensee or other entity to define in its procedures the terms "human error" and "event." These terms may take on various meanings and they are not defined in the current or proposed rule, so the licensee or other entity would be required to describe or define these terms to help ensure consistent implementation of subpart M of part 26 and that the post-event test condition would be consistently applied to all individuals subject to the FFD program. The § 26.405(c)(3)(i) requirement that "the event is recordable under the Department of Labor standards contained in 29 CFR 1904.7, and subsequent amendments thereto," would not be carried over to proposed § 26.607(b)(4). The clarification based upon the wording of 29 CFR 1904.7 was included in § 26.405(c)(3)(i) in order to reduce the number of unnecessary post-event tests performed for minor injuries and illnesses and to improve the efficiency of FFD programs. (73 FR 16966, 17019; March 31, 2008) Consistent with the Principle of Good Regulation of Reliability that regulations should not be unjustifiably in a state of transition, the NRC proposes to prescribe the post-accident

test conditions in § 26.607(b)(4) and eliminate the citation to 29 CFR 1904.7 to avoid changes unless the NRC amends the requirement.

Proposed § 26.607(b)(5) would require follow-up testing. This requirement would be equivalent to current § 26.405(c)(4), although the proposed § 26.607(b)(5) would further describe follow-up testing. The NRC proposes to describe follow-up testing as part of a series of tests for drugs, alcohol, or both, which are performed after an individual subject to part 26 has violated the FFD policy on substance use or abuse, or the sale, use, or possession of illegal drugs. Follow-up testing would be used to verify an individual's continued abstinence from substance abuse. The NRC would not include a reference to a follow-up plan as in § 26.405(c)(4) because the intent of a follow-up plan is to conduct a series of drug tests, alcohol tests, or both, to verify continuing abstinence from substance abuse. Nevertheless, individuals who violate an FFD policy on substance use or abuse, or the sale, use, or possession of illegal drugs, should have a follow-up plan that includes a definition of "abstinence" from the medical professional prescribing the plan.

Proposed § 26.607(c) would provide additional testing requirements. This proposed requirement would be equivalent to § 26.405(d) and would require implementation of select requirements from current subpart E of part 26. The proposed requirements would govern directly observed collections, shy bladder situations, special analysis testing, and alcohol testing. These requirements would be necessary to maintain FFD program effectiveness equivalent to that currently implemented by the LWR fleet.

Proposed § 26.607(c)(1) would require validity testing and establish the minimum panel of drugs and drug metabolites to be tested. This panel would be the same as those in §§ 26.31(d)(1) and 26.405(d) because, based on operating experience from

LWR FFD program implementation, this panel has been determined to contribute to a licensee or other entity satisfying the FFD performance objectives in § 26.23(a) through (d).

Proposed § 26.607(c)(1) would differ from § 26.405(d) because it would require testing of oral fluid and urine specimens for validity, including at least one biological marker (developed from an HHS Guidelines provision) and one adulterant (equivalent to current validity testing for urine specimens in part 26). Section 26.405(d) requires that urine specimens collected for drug testing be subject to validity testing. The addition of oral fluid validity testing is important because, just as there are publicly available kits to subvert a urine drug test, kits that may be used to subvert a drug test that uses oral fluid as a biological specimen are also readily available.

Proposed § 26.607(c)(2) would include requirements that already exist in the part 26 framework that provide protections for individuals subject to the FFD program and contribute to testing effectiveness when collecting and assessing a urine specimen. Specifically, current § 26.115, “Collecting a urine specimen under direct observation,” describes the exclusive grounds for performing a directly observed collection and the process to be followed to protect the privacy of the individual. Section 26.119, “Determining ‘shy’ bladder,” establishes the process to be followed when a donor is not able to produce a sufficient amount of urine for testing, and § 26.163(a)(2) requires special analysis testing when a specimen is dilute to help prevent a subversion attempt.

Proposed § 26.607(c)(3) would require implementation of all the current alcohol testing requirements in § 26.91, “Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use,” through § 26.103, “Determining a confirmed positive test result for alcohol.” Using the same alcohol testing framework for parts 50, 52, 70, and 53 licensees and other entities would provide for regulatory

consistency, protections for individuals subject to the FFD program (e.g., the quality controls and verification applied to the EBT device), and FFD program effectiveness (e.g., accuracy of test results). For alcohol testing, unlike drug testing, there is a preponderance of evidence that correlates blood alcohol concentrations to impairment and intoxication. Furthermore, FFD performance data has demonstrated that the time-dependent alcohol cutoffs in § 26.103 have increased the detection of individuals who are under the influence of alcohol. For these reasons, the current alcohol requirements in part 26 are proposed for FFD programs under subpart M.

Proposed § 26.607(c)(4) would establish additional testing requirements. This proposal would be equivalent to current § 26.405(f) for facilities licensed under part 53 for the conduct of drug testing. Unlike § 26.405(f), proposed § 26.607(c)(4) would not reference validity screening and initial drug and validity tests at licensee testing facilities as this would be required in proposed § 26.607(c)(1). Another minor difference between § 26.405(f) and proposed § 26.607(c)(4) would reflect the requirement in subpart M of part 26 to use an HHS-certified laboratory for all biological specimens collected and not just for urine specimens.

Consistent with § 26.405(f), proposed § 26.607(c)(4) would require the use of an HHS-certified laboratory for all test conditions listed in § 26.607(b), MRO-directed tests, and the testing of a split specimen. Further, HHS-certified laboratory test results using urine or oral fluid would be required for the issuance of an FFD policy violation and part 26-required sanction.

All drug testing would need to be performed at an HHS-certified laboratory to help ensure FFD program effectiveness and to protect the donor from a false positive test result and an unwarranted FFD policy violation. The donor would be protected because laboratory procedures for specimen accessioning, testing, custody and control,

and evaluation of test results and the training and qualification of laboratory personnel are evaluated by HHS as part of the NLCP. This provides assurance that the drug testing results are accurate and attributed to the donor. Urine, oral fluid, and hair specimens may also be screened and tested for drugs and alcohol as described in § 26.607. Drug and alcohol screening results obtained from urine and oral fluid specimens collected and analyzed using a POCTA device and screening results obtained from a hair specimen or a portal monitor may only be used as potentially disqualifying information for a licensee's or other entity's authorization determination (i.e., used to assess the fitness, trustworthiness, and reliability of the individual). These screening results may not be used for the administration of an FFD policy violation and sanction, except as proposed §§ 26.607(i)(3) and 26.610 for subversions, as defined in § 26.5, of the drug and alcohol screening process.

There are three phrases or requirements in § 26.405(f) that the NRC does not propose to use in § 26.607(c)(4). The first is the phrase, "consistent with its standards and procedures for certification," regarding the operation of an HHS-certified laboratory, because the laboratory would not be HHS-certified if it were not following "its standards and procedures for certification." The second is the requirement that urine specimens that yield positive, adulterated, substituted, or invalid initial validity or drug test results must be subject to confirmatory testing by the HHS-certified laboratory, except for invalid specimens that cannot be tested. This requirement would not be used because, under subpart M of part 26, licensees or other entities would be required to use an HHS-certified laboratory. For a laboratory to be HHS-certified, it must follow the HHS Guidelines and include procedures that describe when a specimen cannot be tested. Lastly, the § 26.405(f) requirement that other specimens that yield positive initial drug test results must be subject to confirmatory testing by a laboratory that demonstrates

compliance with stringent quality control requirements that are comparable to those required for certification by the HHS, would not be used because subpart M of part 26 would require the use of an HHS-certified laboratory.

Proposed § 26.607(c)(4) would require the licensee or other entity to contract with a primary and backup HHS-certified laboratory. This provision would help ensure that specimens are processed and tested to maintain FFD program effectiveness should the primary laboratory be unable to perform specimen testing. This would help maintain protections afforded to individuals subject to the FFD program (e.g., should the donor or MRO request testing of the split specimen, a different laboratory could be used). This requirement also would state that the primary and backup laboratories must have a different certifying scientist. Having a back-up HHS-certified laboratory and a different certifying scientist would benefit the program and donor because the drug testing instruments, technicians, and certifying scientist would be independent of the primary laboratory testing and review process. The back-up HHS-certified laboratory may be of the same corporate entity as the primary laboratory.

Proposed § 26.607(c)(4) would also state that the laboratory would be subject to inspection or audit by the licensee or other entity and that records and documents must be provided and/or able to be photocopied and removed from the premises to support the inspection or audit. This requirement would be equivalent to current § 26.41(d) except that laboratories would not be able to limit the use and dissemination of documents copied or taken from the laboratory by a licensee or other entity. This is necessary to ensure the continuing effectiveness of FFD programs, because NLCP findings and audit results could adversely impact FFD program effectiveness. Pertinent information includes and should not be limited to NLCP-identified weaknesses (e.g., custody and control, accessioning, instrumentation, procedures, training, supervision,

review of test results, and resolution of previously identified corrective actions) that may impact the effectiveness of FFD programs.

Proposed § 26.607(d) would help protect the donor from mistakes made during the drug and alcohol testing processes and help ensure FFD program effectiveness. The rule would require the licensee or other entity to protect the individual's privacy and the integrity of the specimen and to implement quality controls to ensure that test results are valid and attributable to the correct individual. This requirement would be equivalent to the first sentence of current § 26.405(e), except that the word "stringent" was removed from the phrase "stringent quality controls," because the word "stringent" is not defined.

Proposed § 26.607(e) would describe the requirements for licensees and other entities that use offsite collection facilities. Consistent with current § 26.405(e), a licensee or other entity would be able to conduct specimen collections and alcohol testing at a local hospital or other facility. Unlike § 26.405(e), proposed § 26.607(e) would not restrict licensees and other entities to use hospitals and other facilities that meet the requirements in 49 CFR part 40, "Procedures for Transportation Workplace Drug and Alcohol Testing Programs," because subpart M of part 26 is intended to provide flexibilities beyond those in the current part 26 framework. Licensees and other entities may use these DOT requirements to inform their procedures under § 26.606(b)(1) as long as the procedures do not conflict with the requirements in part 26 or the HHS Guidelines.

Proposed § 26.607(e) would also require licensees and other entities to audit offsite collection facilities before their use and biennially to confirm that the facility procedures are comparable to those described in subpart E of part 26 or the HHS Guidelines for urine and oral fluid. This proposed requirement is based on current § 26.41(a) and (b). The § 26.607(e) audit requirement would be a program effectiveness

consideration because offsite collection facilities may not require vigilance of their collectors (e.g., identification of subversion attempts), diligence in the protection of worker rights (e.g., privacy and specimen custody and control), or procedural compliance.

The offsite facility used by a licensee or other entity under proposed § 26.607(e) would have to be licensed to conduct specimen collections and perform alcohol testing, and be audited, by the State or a State-designated entity. This requirement would help provide assurance of adequate collection facility performance and may help reduce the burden on the licensee or other entity and the collection facility. Crediting a State audit (or State licensure, oversight, or regulation) is established in §§ 26.4(i)(4) and (j), 26.91(e)(5), 26.153(f)(1), and 26.183(a).

Proposed § 26.607(f) would provide the requirements for initial drug testing. This provision would be equivalent to § 26.405(f) except to account for the alternative biological specimens that may be tested under subpart M of part 26. For the testing of all biological specimens, the licensee or other entity under part 53 would be required to use a device that employs an immunoassay screening technique, or an alternative technology that the licensee or other entity has incorporated into its FFD program through the § 26.603(e) change control process, that demonstrates compliance with the requirements of the U.S. Food and Drug Administration (FDA) for commercial distribution. Examples of alternative technologies include liquid or gas chromatography and mass spectrometry. Licensees and other entities would use the § 26.603(e) change control process to evaluate and document a change to their collection and analysis procedures to enable the use of a better or perhaps more cost-effective collection and/or testing technology. Another difference from § 26.405(f) would be changing the word “urine” in § 26.405(f) to “biological specimens” in § 26.607(f). Lastly, proposed

§ 26.607(f) would include the phrase “discrepant biological marker” as a drug screening result that must be analyzed by an HHS-certified laboratory and evaluated by the MRO to help inform the MRO’s determination of a subversion attempt.

Proposed § 26.607(g) would enable a part 53 licensee to use oral fluid as a biological specimen for testing. This requirement would be equivalent to § 26.31(d)(5), which enables the MRO to conduct drug and alcohol testing using alternative methods, and § 26.405, which does not preclude the use of oral fluid specimens for FFD programs that implement subpart K of part 26 requirements. In order to provide assurance that drug testing is effective and protects the worker, § 26.607(g) would require that the licensee's or other entity’s procedures incorporate the HHS Guidelines or the requirements in part 26 for the conduct of urine or oral fluid testing.

The proposed § 26.607(g) requires that the oral fluid collection device must have received premarket approval from the FDA and must not expire before laboratory testing. Also, the drugs, drug metabolites, initial and confirmatory testing cutoffs, and biological markers, if applicable, must be those established by HHS for oral fluid drug testing and the alcohol cutoffs in part 26. If they are not established by HHS or the NRC for the paneled drugs and drug metabolites, then they would be determined and documented by a forensic toxicologist review. This forensic toxicologist review would help ensure that the device accurately tests for the drug, drug metabolite, biological markers, adulterants, and/or alcohol and that the results from the device are comparable to those established in the HHS Guidelines for oral fluid testing.

Proposed § 26.607(h)(1) and (2) would enable the use of a POCTA device during the random and pre-access testing processes. These requirements are adopted from § 26.97, “Conducting an initial test for alcohol using a specimen of oral fluids,” and § 26.405(f), which does not preclude the use of oral fluid testing. To use a POCTA

device for urine, oral fluid, or other biological indicators (breath, sweat, etc.), a forensic toxicology review would be required to ensure that the device is forensically effective. If the POCTA device is forensically effective, then the donor would be reasonably protected from a false positive test result, the licensee or other entity would be reasonably protected from false negative test results, and the FFD program would remain effective. For a POCTA device to be forensically effective, the forensic toxicologist would need to document an evaluation that the performance of the POCTA device must be comparable to the requirements in § 26.161(b) for a urine specimen or the procedures in the HHS Guidelines for urine or oral fluid, as implemented by the licensee or other entity through its procedures.

The use of POCTA for oral fluid and urine specimens for the pre-access and random testing processes would be acceptable because individuals in the pre-access process would be subject to an oral fluid or urine specimen collection and possible drug screening using a hair specimen, which are both required to be sent to an HHS-certified laboratory. For random testing, the individual would have also been granted authorization under the AA and FFD requirements and have been subject to behavioral observation and physical protection screening (e.g., verification of identify, and screening for explosives and contraband).

Proposed § 26.607(h)(3) would require that procedures be developed that ensure the effectiveness of the POCTA collection process, assessment of the screening results, and prevention of subversion attempts. This requirement would be equivalent to current § 26.403(b)(1) and would help ensure protections afforded to individuals subject to the FFD program and program effectiveness. The subpart M of part 26 framework enables the use of POCTA for random screening of individuals for any part 53 facility, so the licensee or other entity should exercise due diligence and implement risk management

strategies to ensure the efficacy of random screening and its contribution to an effective FFD program.

Proposed § 26.607(h)(4) would provide that an individual donor who screens positive (or whose specimen is invalid or indicates a discrepant biological marker or adulterant) is removed from all duties and responsibilities making the donor subject to subpart M of part 26. Under proposed § 26.607(h)(4)(i), the donor then would be immediately subject to a drug and alcohol test that provides quantified confirmatory test results from which an FFD policy violation may be issued. Similar to other requirements for specimen collections, except for biological specimens analyzed by a passive detection system, the licensee or other entity would be required to implement procedures that ensure that all specimens collected are uniquely assigned to the donor (i.e., procedures that provide for custody and control of the specimen). If the individual shows signs of impairment during the POCTA process, proposed § 26.607(h)(4)(ii) would require the temporary removal of the individual's authorization until the MRO reviews the laboratory test result(s), and interviews the individual, and a determination of fitness finds that authorization may be restored. Section 26.607(h)(4) is equivalent to § 26.77(b) and was informed by the requirements in §§ 26.419, 26.75(c) and (d), and 26.185(c).

Proposed § 26.607(i) would enable the collection of hair specimens for drug testing to supplement pre-access testing that uses urine or oral fluid specimens. Hair testing would be a new feature in the part 26 framework. The NRC proposes to permit the use of hair testing for only Schedule I or II drugs or their metabolites to inform a licensee's or other entity's determination whether the individual is trustworthy and reliable. For example, if an individual stated no prior use of illegal drugs or potentially addictive habits, a hair screening test could be performed during the pre-access process

to ascertain the validity of the individual's statement. However, if the HHS-certified laboratory communicates a laboratory-confirmed positive test result, an FFD policy violation may not be administered. This laboratory information must be treated as potentially disqualifying FFD information, unless the individual subverts the screening process, in which case a permanent denial of authorization must be issued under proposed § 26.610. To provide assurance of testing effectiveness and protections afforded to individuals subject to the FFD program, proposed § 26.607(i) would require that an HHS-certified laboratory must be used to analyze the hair specimen, a forensic toxicologist must review the licensee's or other entity's hair screening process, the test kit must be cleared by the FDA, and hair screening must be conducted in accordance with the HHS Guidelines. The forensic toxicologist review would be necessary if the panel of drug or drug metabolites to be tested and their cutoffs are not established by HHS or the NRC for hair.

Proposed § 26.607(j) would allow the use of portal area screening for drugs, alcohol, or both. This provision would result in a substantial contribution to a licensee or other entity satisfying the § 26.23 performance objectives by helping ensure that 100 percent of all individuals who arrive at the NRC-licensed facility to perform or direct those duties and responsibilities or maintain those types of access making them subject to the FFD program are fit for duty and deterred from arriving onsite in a physiological condition that may be adverse to safety and security. Additionally, screening could be conducted when an individual exits the NRC-licensed facility to provide assurance that substance abuse had not occurred on the site (see § 26.23(d)). The screening device could be electronically linked to temporarily prevent ingress or egress and could automatically inform licensee- or other entity-designated officials of the portal area alarm. The proposed requirement would enable the licensee or other entity to use

innovative technologies to maintain FFD program effectiveness when their PMRP compels the licensee or other entity to implement mitigative strategies to maintain program effectiveness. The use of portal screening technologies may also represent cost savings because, for NRC-licensed facilities that have small staff sizes or are geographically remote, passive drug and alcohol screening technologies could be an innovative alternative to a random testing program, although the license or other entity would need to request and receive an exemption.

Proposed § 26.607(j) would also provide that if the portal area screening instrument detects a substance that exceeds the instrument's established setpoint, the individual would be tested with either a collection kit that must be analyzed by an HHS-certified laboratory or a POCTA. This situational screening would be equivalent to a for-cause test. The requirements would not allow an individual to be rescreened by the portal area screening instrument following an initial screening detection that exceeded an established setpoint in order to prevent a subversion attempt. Similar to other drug and alcohol testing technologies enabled for use by subpart M of part 26, a forensic toxicology review would be required before using passive screening technology to help ensure the effectiveness of the instrument by protecting against false positive or negative screening results, which would place an unwarranted burden on the individual, licensee, or other entity. These instruments and alcohol screening devices, already in the marketplace, may also be used to determine true identity to facilitate implementation of the FFD BOP, which may be very practicable at facilities that operate with small staff sizes.

Proposed § 26.607(k) would enable the use of a blood specimen for drug, alcohol, or other testing for certain medical conditions as determined by the licensee- or other entity-designated MRO. This requirement would be equivalent to current

§ 26.31(d)(5). The use of a licensee- or other entity-designated MRO and not one designated by a third party, such as an MRO employed by an offsite specimen collection facility, is important because the MRO must be familiar with the subpart M of part 26 requirements. To help ensure testing effectiveness and protect the worker, the blood test would need to be conducted by a laboratory that demonstrates compliance with quality control requirements that are comparable to those required for certification by the HHS, such as a hospital or clinic certified by the State, Commonwealth, or territory.

Proposed § 26.607(l) would require licensee and other entities to use a Federal custody-and-control form (CCF) approved by the OMB for the collection and packaging of a hair, oral fluid, or urine specimen. This proposed requirement is based on the CCF documentation requirements in current subpart E of part 26 because subpart K of part 26 does not require the use of a CCF under § 26.117(e). Additionally, when using a POCTA device, the licensee or other entity would be required to implement a licensee- or other entity-approved and -maintained procedure that ensures the reliability of the tracking, handling, and storage of a specimen from the point of specimen collection to final disposition of the specimen and the reliability of an identification system to uniquely assign the specimen to the donor. Both requirements would help protect the worker by helping ensure chain of custody and by contributing to program effectiveness.

Proposed § 26.607(m) would establish requirements for the licensee- or other entity-designated MRO. Section 26.607(m)(1) would be equivalent to § 26.405(g), however, the word “designated” would be added to the first sentence to clarify that the MRO would be designated by the licensee or other entity, and not by a third party. As stated with regard to proposed § 26.607(k), this change would clarify that it is the licensee’s or other entity’s responsibility, through their designated MRO, to determine whether an individual is fit for duty and trustworthy and reliable. This would be consistent

with the description of FFD program personnel in current § 26.31(b) and help provide FFD program effectiveness and protections to individuals subject to the FFD program. The paragraph was also modified from § 26.405(g) to address the determinations of FFD policy violations and fitness required by subpart H for a part 53 licensee or other entity that implements the FFD program described in § 26.605(b).

Proposed § 26.607(m)(2) would help ensure that MRO reviews are consistent with those MRO reviews conducted at other NRC-licensed facilities subject to part 26 and that the MRO maintains knowledge of drug collection, testing processes and procedures, and evaluation of testing results.

The NRC also proposes that if an MRO performed the duties and responsibilities in §§ 26.185 and 26.187 for at least three continuous years in the last 10 years prior to being hired or contracted by the licensee or other entity, then the MRO would not need to repeat the initial training and examination requirements. The basis for 3 years is that the MRO would have experienced three annual cycles of evaluating drug and alcohol test results, contributed to the FFD annual report to the NRC, experienced a refueling or maintenance outage, understood the duties and responsibilities of individuals subject to the FFD program to make informed determinations of fitness, demonstrated a safety culture that helps ensure FFD program effectiveness, and been subject to NRC inspection. The basis for 10 years is the relatively long periods between significant changes to part 26 and the HHS Guidelines.

Proposed § 26.607(m)(3) would require that the MRO attend a medical- or clinical-based training session on a triennial basis. This proposal was developed from Section 13.1 of the HHS Guidelines for urine and oral fluid with two substantial differences: the HHS Guidelines state that “requalification training,” including an exam, must be conducted “at least every 5 years from initial certification,” whereas the

proposed § 26.607(m)(3) would require a training session every three years. The proposed requirements are justified because changes in societal drug use or forensic toxicology could occur more frequently than every 5 years, which could compel MROs to attend training in areas of forensic toxicology, determinations of fitness, or other part 26 technical areas on a more frequent periodicity than every 5 years to improve their knowledge and expertise.

Proposed § 26.607(m)(4) would require the MRO to evaluate drug testing results by implementing the requirements in § 26.185 or the HHS Guidelines through the licensee's or other entity's procedures. This requirement would help ensure FFD program effectiveness and enhance consistency across the commercial nuclear industry for the evaluation of drug testing results. This also would help protect individuals because they would be subject to the same evaluation criteria. If § 26.185 provides insufficient information for an MRO to make a determination on a drug testing result (including adulterant and discrepant biological markers), the guidance issued by a State agency in the state in which the NRC-licensed facility is located, Federal agency, or nationally recognized MRO training and certification organization may be used to inform an MRO determination. This provision would ensure that the MRO has the flexibility to inform their evaluation of the drug testing results and fitness determination, if necessary, considering the drug- and alcohol-related flexibilities afforded in subpart M of part 26.

The proposed requirement would also state that an MRO need not review a confirmed alcohol positive test result determined by an EBT device under § 26.607(c)(3)(vi) and (vii), which are equivalent to the current requirements in §§ 26.101 and 26.103, respectively. The results of an EBT device are precise and accurate enough to support the issuance of an FFD policy violation without an MRO review of an EBT test result if the instrument demonstrates compliance with the requirements in § 26.91. The

NRC acknowledges that there are physiological conditions that may cause an abnormally high blood alcohol concentration, such as diabetes, acid reflux, gastroesophageal reflux disease, and perhaps certain diets (high protein and low carbohydrates). However, operating experience has not demonstrated a compelling need to require an MRO review of all EBT test results. For consistency, a licensee or other entity may elect to require its MRO to review all EBT test results when a donor communicates a testing concern or physiological condition. If the donor has a testing concern, the occurrence could be appealed under the proposed § 26.613. If the donor presents a physical condition to the MRO that may have caused an elevated EBT test result, the MRO may direct an alternative testing process (see § 26.607(m)(5)) should it be medically necessary.

Proposed § 26.607(m)(5) would require the licensee- or other entity-designated MRO to determine and approve the use of oral fluid or urine as an alternative biological specimen when the donor cannot provide a requested specimen for testing. This proposed requirement is equivalent to § 26.31(d)(5), which enables the use of an alternative specimen collection if a medical condition makes the collection of the biological specimen difficult. This determination and the retest must be completed as soon as reasonably practicable and documented to support recordkeeping, auditing, and NRC inspection.

Proposed § 26.607(m)(6) would require that the MRO review all specimens screened or tested associated with a drug-related FFD policy violation. This includes POCTA, split specimens, and all specimens taken to resolve a discrepant condition, such as a possible subversion attempt, impairment without a known cause, or a donor-requested or MRO-directed retest. To resolve a discrepant condition, the MRO is authorized to test a specimen for a biological marker, adulterants, or additional drugs.

The broad scope of this MRO evaluation would be necessary because of the variety of different screening and testing methods that may have been associated with the FFD policy violation. All information learned from the conduct of part 26 drug and alcohol screening and testing should be used in the evaluation of an individual's trustworthiness and reliability, issuance of a sanction, and development of a follow-up treatment and testing plan, if administered.

Proposed § 26.607(n) is equivalent to current § 26.31(d)(6) and would establish limits on the screening and testing of biological specimens. This is a protection consideration afforded to individuals subject to the FFD program and was not provided in subpart K of part 26. This requirement states that specimens collected under NRC regulations may only be designated or approved for screening and testing as described in this part and may not be used to conduct any other analysis or test without the written permission of the donor. Analyses and tests that may not be conducted include, but are not limited to, deoxyribonucleic acid (i.e., DNA) testing, serological typing, or any other medical or genetic test used for diagnostic or specimen identification purposes.

The NRC proposes to require that no biological specimens may be passively sampled and analyzed in a manner different than described in subpart M of part 26 to ensure workers are protected from non-consensual passive screening. The subpart M framework enables passive detection of drugs and alcohol, whereas passive detection is not afforded in subparts A through I, N, and O of part 26.

Proposed § 26.607(o) is equivalent to current §§ 26.31(b)(1)(iii)(A) and 26.89 and would require that all specimen collections be conducted by a licensee- or other entity-designated and -trained individual. For subpart M of part 26, this would include onsite specimen collections, except a collection by a portal area screening instrument in § 26.607(j),

Proposed § 26.608 would require licensees and other entities to provide FFD program training to individuals subject to the FFD program. The proposed performance-based § 26.608 requirement was developed from the prescriptive training requirements in current § 26.29 and modeled on current § 50.120 and the proposed requirements in §§ 53.725 and 53.830 because there is no training requirement in subpart K of part 26.

Proposed § 26.608(a)(1) would require an FFD training program that includes the licensee's or other entity's FFD policies and procedures, including fatigue management, and the individuals' FFD program responsibilities. Individuals who collect specimens for testing or screening must also be trained in specimen collector duties and responsibilities, including, at a minimum, specimen collection, custody and control, identification and response to subversion attempts, and privacy. The fatigue management training must include the knowledge and abilities described in § 26.202(c). For individuals specified in § 26.4, a licensee or other entity of a commercial nuclear plant would be required to use a SAT as defined in proposed in § 53.725. These requirements are based on requirements in § 26.29(a)(2), (3), (9), and (10).

Proposed § 26.608(a)(2) would require training on the BOP. This requirement would be based on §§ 26.29(a)(8), (9), and (10) and 26.33. The proposal would require individuals to be trained in the detection of behaviors or conditions related to not only illegal drugs, as in the current § 26.33 BOP requirements, but also illicit drugs and substance abuse onsite and offsite. Also, in reference to impairment from fatigue or any cause if left unattended, the phrase in § 26.33, "may constitute a risk to public health and safety or the common defense and security," would be replaced in § 26.608(a)(2)(iii) with "could result in inattentiveness or human errors," because subpart M of part 26 is focused, in part, on ensuring individuals are fit for duty to safely and competently perform or direct the performance of assigned duties and responsibilities.

Proposed § 26.608(a)(2)(iv) focuses on training to inform individuals that they are responsible for their own conduct, as well as observing others. Specifically, individuals would be trained to recognize when they feel unable to safely and competently perform assigned duties and responsibilities or act in a trustworthy and reliable manner. The proposed training requirement and the proposed reporting requirement in § 26.606(a)(5) are in the interest of safety and security because the individual is proactively announcing that assistance may be necessary. This would be consistent with the performance objectives in § 26.23(b) and (c) where certain behavior or stress conditions may be indicative of an individual not being fit for duty, trustworthy, and reliable.

Proposed § 26.608(a)(3) would help ensure that individuals subject to the FFD program understand that FFD policy violations would result in an FFD program sanction and that program information learned or generated by FFD program implementation would be used to aide licensee or other entity authorization determinations and be shared, as requested, with other licensees or other entities subject to parts 26, 53, and 73. This proposed requirement is equivalent to § 26.29(a)(1). Proposed § 26.608(a)(3) would be a protection measure afforded to individuals subject to the FFD program because they would understand that licensees and other entities subject to parts 26, 53, and 73 would be informed of, in part, an individual's character, reputation, and ability to follow policies, procedures, and instructions to safely and competently perform assigned duties and responsibilities in a trustworthy and reliable manner. FFD-related information would include drug and alcohol testing results (not quantitative testing values), issuance of any sanctions, FFD-determinations regarding trustworthiness and reliability, testing programs, treatment, and other remedial or corrective action.

Proposed § 26.608(b) would require individuals be trained and receive a trainee assessment before pre-access testing and that refresher training and trainee

assessments be conducted periodically thereafter. These requirements would be equivalent to § 26.29(c)(1). However, § 26.608(b) was developed from the SAT-based training requirements in § 50.120 and training elements from the annual training requirements in § 26.29(c)(2). The term “systems approach to training” would have the meaning in proposed § 53.020. A trainee assessment would be the same as in currently required SAT-based training programs.

Proposed § 26.608(c) would require licensees and other entities to periodically evaluate their FFD training programs and revise them as appropriate. This training focus is not required by subpart K of part 26 or § 26.29 but is proposed to address the flexibilities afforded in subpart M of part 26. This section would be equivalent to § 50.120(b)(3).

Proposed § 26.609 would require the implementation of a BOP. The proposed requirement would be equivalent to that in §§ 26.33 and 26.407, “Behavioral observation,” and would apply during construction, operation, and decommissioning, if applicable. Because subpart M of part 26 would apply during decommissioning through a licensee’s IMP, proposed § 26.609(a) and (b) were developed, in part, from proposed § 73.100(b)(9) and current §§ 73.55(b)(9) and 73.56(f) to help ensure consistency in the conduct of behavioral observation whether conducted for FFD or security purposes.

Under the FFD program, the purpose of the BOP would be to help ensure that individuals subject to the FFD program are fit for duty and trustworthy and reliable to perform or direct those duties and responsibilities and maintain those types of access that make the individual subject to the FFD program. This assurance is accomplished by requiring each individual subject to subpart M of part 26 to be subject to behavioral observation, and by requiring all individuals to perform behavioral observation of others and report FFD concerns to the licensee- or other entity-designated representative(s).

The intent of the BOP requirement is not to require that all individuals be observed at all times by others; NRC-licensed operators, maintenance professionals, security officers, and others routinely perform solo operations periodically throughout the day. However, individuals must be subject to observation while they are performing or directing the performance of duties and responsibilities or maintaining the types of access making them subject to the FFD program. Observing behavior only at the beginning of a work shift is not sufficient to ascertain whether an individual is fit for duty, trustworthy, and reliable. Controlled substances may have a delayed effect between use (e.g., ingestion) and the onset of physiological or psychological effects, and fatigue accumulates with time. Behavior must be continually observed throughout the work shift to detect any changes from baseline human performance characteristics, including mental or physical health and mannerisms, or any activities that may indicate that the individual is not trustworthy and reliable.

Proposed § 26.609(a) would differ from §§ 26.33 and 26.407 in that it would place the responsibility for performing behavioral observation on “all individuals subject to this subpart,” rather than only those “individuals specified in § 26.4(f) [who] are constructing or directing the construction of safety- or security-related SSCs” in § 26.407 or “individuals who are trained under § 26.29 to detect behaviors” in § 26.33 to improve clarity.

Proposed § 26.609(b) would require all individuals subject to the FFD program to report to the licensee- or other entity-designated representative any onsite or offsite behaviors or activities by individuals subject to this part that may constitute an unreasonable risk to the safety or security of the NRC-licensed facility or SNM, or may cause harm to others. The NRC proposes this description of reportable conduct because an individual’s activities (e.g., use of illegal substances) and communications (e.g., hate

speech or threats of violence) offsite are a direct indication of the individual's fitness, trustworthiness, and reliability and must be evaluated as to whether authorization should be granted or maintained. Proposed § 26.609(b) would include a description of this conduct instead of the § 26.33 undefined phrase, "FFD concerns," to enhance the clarity of the requirement. This proposed BOP reporting requirement would include any information relating to character or reputation of the individual indicating that the individual cannot be trusted or relied upon to perform those duties and responsibilities or maintain access to NRC-licensed facilities, SNM, or sensitive information. This would better align with the proposed § 73.120 BOP requirement, which states that each person subject to behavioral observation must communicate to the licensee or applicant observed behaviors or activities of individuals that may constitute an unreasonable risk to the health and safety of the public and common defense and security. Proposed § 26.609(a) and (b) were written broadly to include offsite conduct that the reporting individual considers serious enough to call into question the character or reputation of the subject individual.

Proposed § 26.609(c) would require that licensees and other entities perform behavioral observation visually, in-person, and, when necessary, remotely by live video and audible streaming and capture. This requirement was developed from the security observation requirements in § 73.55(e)(7)(i)(B) and (C), (h)(2)(v), and (i)(2) and (5)(ii). Conducting an in-person observation of another individual is the preferred method to ascertain whether the observed individual can safely and competently perform assigned duties and responsibilities. When in-person observations are not feasible (e.g., during solo operations), the proposed requirement would enable the use of video monitoring. This is addressed, for example, in proposed § 26.609(d) regarding NRC-licensed operator manipulation of reactor controls. Additionally, certain duties (such as

maintenance activities performed by a single worker outside of a control room) may not present an opportunity for video monitoring; in these situations, behavioral observation should be conducted on a sampling basis (i.e., a planned observation of the work activity) as outlined in a licensee's or other entity's FFD program.

In situations involving small staff sizes, facilities sited in geographically remote locations, or both, additional observers would enhance the effectiveness of a BOP. Technological developments in automated safety and security systems may enable licensees or other entities to reduce staff sizes to 10 to 40 percent of the staff size of an LWR facility licensed under part 50 or 52. Smaller staff sizes may translate into more solo operations, less teamwork, fewer peer checks, or infrequent management oversight of field activities, leading to fewer behavioral observations. Therefore, a licensee or other entity would have fewer opportunities to observe whether individuals are fit for duty. Enabling video and audible streaming and capture to enhance the BOP would be consistent with the security-related behavioral observation requirement in proposed § 73.120(c)(2)(ii), which would also enable video conferencing or other acceptable electronic means promoting face-to-face interaction for those individuals working remotely.

Proposed § 26.609(d) would require that licensees or other entities perform behavioral observation of NRC-licensed operators who manipulate the controls of any utilization facility licensed under part 53, remotely by live video and audible streaming capture for those part 53 utilization facilities where individual task loading does not allow for the effective conduct of behavior observation in addition to assigned operational tasks. The purpose of this paragraph would be similar to that of proposed § 26.609(c), where the possibility of in-person observation is significantly diminished because of solo operations or because the facility may only require a minimum staff size onsite.

Proposed § 26.610 would be equivalent to § 26.409, “Sanctions,” and would require the licensee or other entity to establish sanctions for FFD policy violations that, at a minimum, prohibit the individuals specified in § 26.4 from being assigned to perform or direct those duties and responsibilities or maintaining authorization making them subject to subpart M of part 26. To be consistent with § 26.75, “Sanctions,” the severity of the sanction as described in § 26.610 would escalate with the number of occurrences and severity of the FFD policy violation. The sanction would be long enough to help deter future FFD policy violations and facilitate counseling and treatment before the licensee reinstates the individual’s access to the facility. The NRC proposes this requirement because the 14-day denial described in § 26.75 may not allow sufficient time for counseling and treatment based on the particular FFD policy violation.

Equivalent to § 26.75(c), proposed § 26.610 would also require a minimum 5-year denial of access to the NRC-licensed facility for certain violations of the FFD policy within the protected area of a commercial nuclear plant and by an individual or individuals who are the operators of the conveyance to transport or use formula quantities of strategic SNM. Equivalent to § 26.75(b), proposed § 26.610 would require a permanent denial of authorization be issued for any subversion attempt.

Proposed § 26.611 would protect information collected from FFD program implementation and would be equivalent to current § 26.411, “Protection of information.” The protected information would include, but not be limited to, privacy and medical information. Section 26.611 would not include the § 26.411 requirement that FFD programs must maintain and use the personal information with the highest regard for individual privacy because such a requirement would be unnecessary in light of the proposed § 26.611(a) requirement that licensees and other entities must establish and maintain a system of files and procedures to prevent unauthorized disclosure.

Proposed § 26.611(b), although equivalent to § 26.411(b), would require licensees and other entities to have all individuals sign a consent to be subject to the FFD program before subjecting the individual to the FFD program (e.g., before being subject to a pre-access test in § 26.607(b)(1), unlike § 26.411(b)). The purpose of this proposal would be to enhance protections afforded to individuals subject to the FFD program and their knowledge of, in part, why they are subject to drug and alcohol testing, behavioral observation, information collection, MRO reviews, and other FFD program elements. Like the consent required by § 26.411(b), the consent would authorize disclosure of the collected information. Consent would not be needed for disclosures to the individuals and entities specified in § 26.37(b)(1) through (b)(6), (b)(8), and persons deciding matters under review in proposed § 26.613, “Appeals process.”

Proposed § 26.613 would be equivalent to § 26.413, “Review process.” The proposed title was changed to an appeal process to clarify that § 26.613 would be the process implemented when an individual elects to appeal a licensee or other entity determination that the individual had violated the FFD policy. The proposal would also require that the process include a schedule for the completion of the review of the determination that the individual had violated the FFD policy. The NRC proposes this requirement because operating experience demonstrates that workers may not be protected from a continuous review process that does not result in an outcome.

Proposed § 26.615 would require licensees and other entities to perform audits of the FFD program. The proposed section would be equivalent to § 26.415, “Audits.” Under proposed § 26.615(a), audits would be performed at a frequency that ensures the FFD program’s continuing effectiveness. This would be particularly important for FFD program elements that are not part of the FFD PMRP required by § 26.603(d). Corrective actions would be taken as soon as reasonably practicable to resolve any

problems identified and preclude recurrence. Proposed § 26.615(b) would require the subject matter, scope, and frequency of audits be revised as necessary to improve or maintain program performance based on findings resulting from licensee or other entity implementation of its FFD PMRP. These requirements were developed from appendix B to part 50, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants”; criterion X, “Inspection”; and criterion XVIII, “Audits.”

Proposed § 26.615(c) would be equivalent to § 26.415(b) and would enable licensees and other entities to conduct joint audits or accept audits of C/Vs so long as the audit addresses the relevant services of the C/Vs.

Proposed § 26.615(d) would be equivalent to § 26.415(c) by establishing requirements for the auditing of HHS-certified laboratories. Unlike § 26.415(c), the proposal would not contain a reference to DOT drug and alcohol testing requirements. This would broaden the regulatory flexibility afforded to a licensee or other entity in that they may use an offsite collection or testing facility that does not meet the DOT requirements.

Proposed § 26.615(d) would state that licensees and other entities need not audit an HHS-certified laboratory if the licensee’s or other entity’s panel of drugs and drug metabolites to be tested is equivalent to the panel by which the laboratory is certified by HHS or is subject to the standards and procedures for drug testing and evaluation used by the laboratory under the HHS Guidelines. The NRC would afford this flexibility because the NRC is aware that HHS desires to streamline changes in its guidelines to its panel of drugs and drug metabolites to be tested. Therefore, if a licensee or other entity elects to implement the HHS Guidelines in its procedures and maintains the minimum panel of drugs and drug metabolites to be tested as required by subpart M of part 26, a licensee or other entity may still use (and not audit) the HHS-certified

laboratory because the § 26.603(e) change control process would maintain FFD program effectiveness.

To help ensure FFD program effectiveness, § 26.615(d) would also require that collection facility procedures are comparable to those required in subpart E of part 26, including a proposed requirement that the offsite facility's specimen collection and testing procedures are audited on a biennial basis, which is also a protection consideration afforded to individuals subject to the FFD program. Conducting this audit on a biennial basis would be equivalent to that required in § 26.41(b) and would help ensure that the specimen collection process at the facility remains effective.

Proposed § 26.617 would establish recordkeeping and reporting requirements equivalent to those in current § 26.417. However, § 26.617 would require retention of records pertaining to administration of the FFD program and FFD performance data required by § 26.717 until license termination, which is based on current § 26.711(a) because § 26.417 does not provide for a retention period.

Proposed § 26.617(b)(1) would be identical to the reporting requirements in § 26.417(b)(1) regarding the licensee's or other entity's FFD program.

Proposed § 26.617(b)(2) would require the reporting of annual (i.e., January through December) program performance information to the NRC before March 1 of the following year. This reporting would be equivalent to the annual program performance requirement in § 26.417(b)(1), and the March 1 due date is based on the reporting deadline in § 26.717(e). Licensees and other entities would be required to report FFD performance information using new NRC Forms 893, "Single FFD Policy Violation Form," and 894, "10 CFR Part 26, Subpart M, Annual Reporting Form for FFD Performance Information."

Proposed § 26.617(c) would require that FFD-related information be shared within the commercial nuclear industry when requested to support authorization determinations. This requirement would help individuals seeking employment by another NRC-licensed facility subject to subpart C of part 26, complete their NRC-required sanctions and licensee-administered or -directed drug and/or alcohol abuse treatment plans before the restoration of authorization by a licensee or other entity. Information sharing may also enhance FFD program effectiveness because FFD-related lessons learned from, for example, substance testing, subversion attempts, and laboratory and MRO performance must be shared when requested.

Proposed § 26.619 would require licensees or other entities to establish a process to evaluate individuals when their fitness or trustworthiness and reliability are in question. Section 26.619 would be equivalent to § 26.419, “Suitability and fitness determinations,” but, unlike § 26.419, would apply during the construction and operation phases. Also, proposed § 26.619 would require that a suitability or fitness determination conducted for cause be conducted face-to-face. This proposed requirement is based on current § 26.189(c); however, unlike § 26.189(c), proposed § 26.619 would not prohibit augmenting determinations via electronic means of communication. Instead, § 26.619 would explicitly permit determinations to be performed via electronic means, so long as those determinations are supported by an appropriately trained individual who is present in-person with the individual being assessed.

In considering the current restriction on the use of electronic means of communication for determinations of fitness conducted for cause, the NRC finds that since publication of the 2008 part 26 final rule, there have been developments in using electronic means of communication (i.e., “videoconferencing”) as an alternative to conducting face-to-face interactions. To address these considerations, the NRC

contracted the Pacific Northwest National Laboratory (PNNL), DOE, to study whether a medical and mental health assessment via electronic communication could be an acceptable alternative to an in-person, face-to-face assessment.[13] Based on this study, if electronic means were to be used to conduct a face-to-face assessment, an in-person element would still be integral to the assessment process. However, under certain circumstances, face-to-face determinations and assessments conducted as part of an FFD program for an entity licensed under part 53 (i.e., those determinations and assessments performed in accordance with § 26.619, § 26.207, or § 26.211) may be augmented via electronic communications. Such remotely conducted determinations and assessments would be required to be conducted with someone who is present in-person with the individual being assessed and who is trained in accordance with the requirements of either §§ 26.29 and 26.203(c) or §§ 26.608 and 26.202(c). Permitting the use of electronic communications would help ensure FFD program effectiveness, especially in instances where the part 53 commercial nuclear plant is sited in a geographically remote location or when the facility has a small staff size.

Proposed Changes to Part 26, Subpart N

Proposed § 26.709 would make the recordkeeping and reporting requirements in subpart N of part 26 applicable to licensees and other entities of facilities licensed under part 53 that elect not to implement the requirements in subpart M of part 26 or elect to implement the requirements in § 26.605(b).

Proposed § 26.711(c) and (d) would be amended to make these requirements applicable to licensees or other entities described in § 26.3(f). Section 26.711(c) provides protection to individuals subject to part 26 by enabling an individual's right to

[13] PNNL, Technical Letter Report, "The Use of Electronic Communications to Perform Determinations of Fitness," dated August 2017.

review FFD-related information and correct any inaccurate or incomplete information. Section 26.711(d) requires, in part, that any FFD-related information shared with other licensees or other entities is correct and complete.

Proposed Changes to Part 26, Subpart O

The vast majority of the proposed changes to part 26 would be new or revised substantive provisions that would establish a regulatory obligation or prohibition or would be conforming edits to reflect the addition of part 53. The only new provision that would not be substantive, such that violation of it would not result in a criminal penalty, would be proposed § 26.601. Therefore, the NRC proposes to add § 26.601 to the list of regulations in § 26.825(b) to which criminal sanctions do not apply.

10 CFR Part 73

Section 73.100: Technology-inclusive requirements for physical protection of licensed activities at commercial nuclear plants against radiological sabotage.

Proposed § 73.100 would provide a performance-based regulatory framework for the design, implementation, and maintenance of a physical protection program and security organization for certain commercial nuclear plants licensed under part 53. The current § 73.55 physical security requirements for nuclear power reactors licensed under part 50 and part 52 use a combination of performance criteria (e.g., § 73.55(b)(1) through (3)) and numerous prescriptive requirements developed to achieve performance objectives (e.g., § 73.55(k)(5)(ii)). By contrast, in the proposed performance-based approach to physical security for part 53, performance objectives and requirements would be the primary bases for regulatory decision-making, giving the licensee the flexibility to determine how to demonstrate compliance with the established performance criteria for an effective physical protection program. This proposed physical protection program would provide an optional pathway for licensees that elect not to demonstrate

compliance with the provisions in § 73.55 and do not satisfy the criterion as described in proposed § 53.860(a)(2). This proposed physical protection program would provide that activities involving SNM are not inimical to the common defense and security and do not constitute an unreasonable risk to the public health and safety.

Section 73.100(a) would require each part 53 licensee that elects to demonstrate compliance with this section rather than § 73.55 to implement the requirements therein through its physical security plan, training and qualification plan, safeguards contingency plan, and cyber security plan (referred to collectively hereafter as ‘‘security plans”) prior to initial fuel load into the reactor. The security plans would need to identify, describe, and account for site-specific conditions that affect the licensee’s capability to satisfy the requirements of § 73.100. Based on experience from recent new reactor licensing reviews, the NRC recognizes that licensees may seek to receive unirradiated fuel onsite before carrying out the security requirements in § 73.100. However, these security requirements would have to be implemented at some point before fuel load to address the increased risk arising from irradiated fuel onsite. This proposed rule would make clear that part 53 applicants and licensees using § 73.100 may bring unirradiated nuclear fuel onsite and protect it in accordance with the NRC’s requirements for physical protection of SNM of moderate and low strategic significance under § 73.67 until initial fuel load into the reactor.

Section 73.100(b) would outline the general performance objective and design requirements of the licensee physical protection program. A licensee’s program would be required to provide protection against any deliberate act within the DBT of radiological sabotage, including spent fuel sabotage, which could directly or indirectly endanger the public health and safety by exposure to radiation. The physical protection

program is supported by the AA program, cyber security program, and IMP to demonstrate compliance with the general performance objective of § 73.100(b).

Section 73.100(b)(2) was developed, in part, from § 73.55(b)(3). To satisfy the general performance objective of § 73.100(b)(1), the physical protection program would need to protect against the DBT of radiological sabotage. The existing fleet of LWR satisfies this objective by preventing significant core damage and spent fuel sabotage. Some non-LWR reactor licensees' physical protection programs may be designed to prevent a significant release of radionuclides from any source. Therefore, the proposed performance objective would focus on radiological sabotage in general, rather than a specific focus on core damage or spent fuel sabotage, to be technology inclusive and allow for flexibility for different reactor technologies.

Under the proposed § 73.100(b)(2)(ii), licensees must provide defense in depth in achieving performance requirements through the integration of engineered systems, administrative controls, and management measures. This requirement would apply defense-in-depth concepts as part of the physical protection program to ensure the capability to demonstrate compliance with the performance objective of the proposed § 73.100(b)(1) is maintained in the changing threat environment. The defense-in-depth philosophy applies to measures against intentional acts as required by § 73.100(b), and the designs of physical security systems should employ defense in depth through systems diversity, independence, and separation under § 73.100(b)(2). The most common defense-in-depth measures apply concepts of redundancy, diversity, independence, and safety margin to ensure systems reliability and availability. The defense-in-depth philosophy applies to the design of a physical protection program, which integrates engineered controls and administrative controls, to provide protection against the DBT for radiological sabotage.

Section 73.100(b)(3) would require the physical protection program to be designed and implemented to achieve and maintain the reliability and availability of SSCs required for demonstrating compliance with specified performance requirements. These physical protection performance requirements were informed by § 73.55(b) and the Commission's Advanced Reactor Policy Statement.

The performance objective of protecting against the DBT of radiological sabotage is achieved by the design and implementation of the physical protection program, maintained at all times, with the following required performance capabilities proposed in the provisions in § 73.100(b)(3): intrusion detection, intrusion assessment, security communication, security response, protecting against land and waterborne vehicle bomb assaults, and access control portals. The physical protection program must maintain the reliability and availability of SSCs relied upon for demonstrating compliance with the performance requirements. The terms ‘‘reliability and availability’’ are intended to describe defense in depth in a performance-based manner and would be critical elements for demonstrating compliance with the proposed requirement for protection against the DBT of radiological sabotage as described in the proposed § 73.100(b)(2).

The first element, “intrusion detection,” would be provided through the use of detection equipment, patrols, access controls, and other program elements and would provide notification to the licensee that a potential threat is present and where the threat is located.

The second element, ‘‘intrusion assessment,” would provide a mechanism through which the licensee would identify the nature of the threat detected. This would be accomplished through the use of video equipment, patrols, and other program elements that would provide the licensee with timely information about the threat for use in determining how to respond.

The third element, “security communication,” would provide a mechanism through which the licensee would communicate the necessary information to the response force to ensure effectiveness of the physical protection program. This would be accomplished through the redundant, independent, and diverse design of physical security and/or plant SSCs relied on for onsite and offsite security communications. The continuity and integrity of communications should account for the DBT’s ability to affect the reliability and availability of communications.

The fourth element, “security response,” would provide a mechanism through which the licensee would be capable of timely security response to interdict and neutralize threats up to and including the DBT of radiological sabotage. The security response may include the use of onsite armed responders, law enforcement responders (local, State, or Federal), or other offsite armed responders (e.g., licensee proprietary or contract security personnel who are positioned offsite), or a combination thereof, as appropriate.[14] The licensee must provide protection against any element of the DBT, to include those that do not rise to the full capability of the DBT. SSCs relied on to provide delay functions must be designed to provide for timely response to adversary attacks with adequate defense in depth. Delay would allow the licensee to take necessary actions to counter any attempt by the threat to advance towards the protected target or target set element. The overall response objective would be to place the threat in a

[14] The proposed rule would permit advanced power reactor licensees to use any interdiction and neutralization method for threats up to and including the DBT of radiological sabotage, which would be an extension of the Commission’s position in SRM-SECY-17-0100, “Security Baseline Inspection Program Assessment Results and Recommendations for Program Efficiencies,” dated October 8, 2018 and the staff’s commitment in SECY-20-0070, “(Redacted) Technical Evaluation of the Security Bounding Time Concept for Operating Nuclear Power Plants,” dated November 8, 2021. Under the proposed rule, a licensee would retain the responsibility to detect, assess, interdict, and neutralize threats up to and including the DBT of radiological sabotage, but would be able to rely on law enforcement or other offsite armed responders as a method for fulfilling the required interdiction and neutralization capabilities. For licensees that choose to rely on law enforcement to fulfill these capabilities, the proposed rule would not create any NRC regulatory jurisdiction over, or requirements for, law enforcement.

condition from which the threat no longer has the potential for, or capability of, doing harm to the protected target.

The fifth element, “protecting against land and waterborne vehicle bomb assaults,” would provide a mechanism through which the licensee would be capable of protecting the plant against the DBT vehicle bomb assault. The methods that are relied on to protect against a DBT land vehicle and waterborne vehicle bomb assault must be designed to protect the reactor building, structures containing safety or security related systems, and components from explosive effects.

The sixth element, “access control portals,” would provide a mechanism through which the licensee would be capable of detecting and denying unauthorized access to persons and pass-through of contraband materials (e.g., weapons, incendiaries, explosives) to protected areas. Integrity of the access control system is maintained through licensee oversight and ensures that attempts to circumvent or bypass the established process will be detected and access denied.

The proposed performance requirements would permit the applicant or licensee to determine how to design the physical protection program to protect the plant against the DBT of radiological sabotage without prescriptive requirements such as those currently found in § 73.55. DG-5076, “Guidance for Technology Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants,” has been developed by the NRC to describe one acceptable approach to demonstrate compliance with requirements proposed in § 73.100.

Section 73.100(b)(4) would require the licensee to identify target sets in accordance with § 73.55(f). For non-LWR and SMRs, target sets would be defined in DG-5071, “Target Set Identification and Development for Nuclear Power Plants,” as the minimum combination of equipment, operator actions, and/or structures that, if all are

prevented from performing their intended safety function or prevented from being accomplished, barring extraordinary actions by plant operations, would likely result in a significant release of radionuclides from any source (e.g., a release to the environment exceeding that analyzed in the DBA licensing basis).

Section 73.100(b)(5) would require that each licensee perform a site-specific analysis for the purpose of identifying and analyzing site-specific conditions that affect the design of the onsite physical protection program.

Section 73.100(b)(6) would require licensees to implement a performance evaluation program, which would ensure that a licensee will periodically test and evaluate the effectiveness of the physical protection program to protect against the DBT. This program would ensure that licensees are able to demonstrate that the physical protection program satisfies the response requirements of § 73.100 and that the site's protective strategy effectively protects against the DBT. Licensee performance evaluations would include methods to assess, test, and challenge the integration of the physical protection programs functions and demonstrate the effectiveness of security plans, licensee protective strategy, and implementing procedures in accordance with § 73.100(g).

Section 73.100(b)(7) would require licensees to implement an AA program in accordance with § 73.56. Section 73.100(b)(8) would require licensees to establish, maintain, and implement protection against a cyberattack based on either the proposed cyber security program described in § 73.110 or the program described in existing § 73.54.

Section 73.100(b)(9) would require an IMP that monitors the initial and continuing trustworthiness and reliability of individuals granted or retaining unescorted access or unescorted AA to a protected or vital area. The IMP must also implement defense-in-

depth methodologies to minimize the potential for an insider (active, passive, or both) to adversely affect the licensee's capability to protect against radiological sabotage. Because no one element of the AA program, FFD program, cyber security program, or physical protection program, would, by itself, provide the level of protection against the insider necessary to demonstrate compliance with the performance objective of the proposed § 73.100(b), the effective integration of these programs is a necessary requirement to achieve defense in depth against the potential insider.

Section 73.100(b)(10) would require that the licensee have the capability to track, trend, correct, and prevent recurrence of failures and deficiencies in the implementation of the requirements of this section. Section 73.100(b)(11) would require the coordination of the security plans and associated procedures with other onsite plans to manage the safety and security interface during normal or emergency operations.

Section 73.100(c) was developed from § 73.55(c)(7), "Security implementing procedures," and § 73.55(d), "Security organization," and would outline the requirements for the composition, equipping, and training of the security organization. The purpose of the security organization is to effectively implement the physical protection program. Individuals assigned to perform physical protection or contingency response duties must be trained, equipped, and qualified to perform assigned duties and responsibilities.

Section 73.100(d) would establish a performance requirement for searches of personnel, vehicles, and materials for the protection against radiological sabotage. The requirement describes broad categories of material (explosives, firearms, incendiary devices, etc.) to be detected and prevented from entry into the protected area; specific items that will be prohibited would not be prescribed in the regulation but will be stated in the licensee security plans with detailed descriptions being identified in implementation procedures.

Section 73.100(e) would require a training and qualification program, described in the training and qualification plan, that ensures personnel are able to effectively perform their assigned security-related job duties. This high-level requirement would allow flexibility in how the licensee chooses to train its security personnel. One method for accomplishing this requirement would be to provide a training and qualification program that would be equivalent to appendix B to part 73.

Section 73.100(f) would require periodic security reviews of the physical protection program to ensure effective implementation of the program by independent individuals. The evaluation process would provide a systematized approach for assessing the physical protection program as a basis for further development and improvement. Program reviews should be designed to ensure that the physical protection program maintains effectiveness and demonstrates compliance with NRC requirements. Section 73.100(f)(1) was developed from § 73.55(m) and would require review of each element of the physical protection program. Section 73.100(f)(2) would require licensees to perform self-assessments of physical protection program functions to ensure that the capability to detect, assess, interdict, and neutralize the DBT of radiological sabotage is maintained. Section 73.100(f)(3) would require an audit of the effectiveness of the physical protection program; security plans; implementing procedures; cyber security programs; management of the safety/security interface activities; the testing, maintenance, and calibration program; and response commitments by local, State, and Federal law enforcement authorities. Section 73.100(f)(4) would require that results and recommendations, management findings, and any actions taken be documented and maintained to be available for inspection by the NRC. These reviews are independent of the ongoing performance evaluations described in § 73.100(b)(6) and 73.100(g).

Section 73.100(g) would require that licensee performance evaluations, described in § 73.100(b)(6), include methods appropriate and necessary to assess, test, and challenge the integration of the physical protection program's functions to protect against the DBT. The performance evaluations must also address the licensee's measures to protect against cyberattacks, in accordance with the required cyber security plan, and engineered systems designed to protect against the DBT standalone ground vehicle bomb attack.

Section 73.100(h) would establish performance requirements for maintaining security SSCs relied on to perform security functions to protect against the DBT. It would require that corrective actions and compensatory measures be taken by a licensee in response to a degradation of security equipment or failure of the equipment to perform its intended functions. The licensee would be required to maintain the SSCs described in its design and licensing basis to ensure that they are reliable and available.

Section 73.100(i) would establish requirements for the suspension of security measures in response to emergency and extraordinary conditions. The requirements of this paragraph, which were developed from § 73.55(p), would be intended to provide flexibility to a licensee for taking reasonable actions that depart from a security plan in an emergency when such actions are immediately needed to protect the public health and safety and no action consistent with license conditions and TS that can provide adequate or equivalent protection is immediately apparent in accordance with proposed § 53.740(h).

Section 73.100(j) would establish requirements regarding the inspection, retention and maintenance of records required to be kept by the NRC regulations, orders, or license conditions. These proposed requirements are developed from § 73.55(q).

Section 73.110: Technology-inclusive requirements for protection of digital computer and communication systems and networks.

Section 53.860 would require that a licensee establish, implement, and maintain a cyber security program in accordance with § 73.54 or § 73.110. Section 73.110 would establish requirements for the development and maintenance of a cyber security program for commercial nuclear plants licensed under part 53. This proposed section would implement a graded approach to determine the level of cyber security protection required for digital computers, communication systems, and networks. The proposed new section is informed by: (1) the operating experience from power reactors and fuel cycle facilities; and (2) the existing § 73.54 framework, which addresses some of the basic issues for cyber security regardless of the type of reactor. Differences between the § 73.54 requirements and those proposed in § 73.110 are primarily based on the implementation of a consequence-based approach to cyber security to accommodate the wide range of reactor technologies to be assessed by the NRC. A graded approach based on consequences is intended to account for the differing risk levels among reactor technologies. Specifically, the proposed new section would require licensees to demonstrate protection against cyberattacks in a manner that is commensurate with the potential consequences from those attacks.

Under proposed § 73.110(a), licensees would need to ensure that digital computer and communications systems are adequately protected against a potential cyberattack that would result in: (1) a scenario where the cyberattack leads to offsite radiation doses that would endanger public health and safety (i.e., the resulting consequence exceeds the reference dose values in § 53.210); or (2) a scenario where the cyberattack adversely impacts the physical security digital assets used by the licensee to prevent unauthorized removal of material or radiological sabotage. Security

digital assets would include those used for nuclear material control and accounting (MC&A).

The proposed § 73.110(b) would require licensees to protect the communication system and networks associated with the functions described in § 73.110(a)(1) and (a)(2) from cyberattacks. To accomplish this, the licensee would establish, implement, and maintain a cyber security program for protecting digital assets within the scope of § 73.110 that would make use of risk insights, including threat information, and would consider the resulting level of consequences of the threats. If the outcome of the assessment by the licensee under § 73.110(b)(1) revealed that a potential cyberattack would not compromise any digital assets that support safety and security functions, and thus would not result in the consequences listed in § 73.110(a) (e.g., would not exceed the reference dose values), then only a narrow set of the cyber security program requirements in § 73.110(d) and (e) would apply. For example, the licensee would only need to develop a cyber security program that implements the requirements dealing with:

- Analyzing modifications of any asset before implementation to see if they demonstrate compliance with the potential consequences in § 73.110(a);
- Ensuring employees and contractors are aware of cyber security requirements and have some level of cyber security training;
- Evaluating and managing cyber security risks to the plant;
- Reviewing the cyber security plan for any required changes; and,
- Retaining records of the cyber security plan along with any plan changes.

Sections 73.110(c) through (e) of § 73.110 were developed from § 73.54(a)(2), (c) through (h), respectively.

The proposed requirements would address the need for the licensee to develop a

cyber security program that implements a defense-in-depth protective strategy as required by proposed section § 73.110(d)(2). A defense-in-depth protective strategy for cyber security is represented by collections of complementary and redundant security controls that establish multiple layers of protection to safeguard critical digital assets. Under a defense-in-depth protective strategy, the failure of a single protective strategy or security control should not result in the compromise of safety and security functions.

Section 73.120: Access authorization program for commercial nuclear plants.

Section 73.120 would address AA for certain commercial nuclear plants licensed under part 53. The proposed language in § 73.120 would provide an alternate approach to the existing framework for AA under §§ 73.55, 73.56, and 73.57, commensurate with risk and consequences to public health and safety. It would be available to part 53 applicants and licensees who demonstrate in an analysis that the offsite consequences of a DBE satisfy the criterion defined in § 53.860(a)(2) (i.e., would not exceed the offsite dose values in § 53.210(b)). The proposed requirements in § 73.120 would be similar to the existing AA program elements for those NRC licensed facilities issued additional security measures (ASM) orders and for materials licensees under § 37.21. Applicants not satisfying the criterion would need to establish, implement, and maintain a full AA program, including an IMP, in accordance with § 73.56.

Proposed § 73.120(a) would be based on an applicant satisfying the eligibility criterion in § 53.860(a)(2). Section 73.120(b) would identify the categories of individuals who would be subject to an AA program in accordance with this section. The applicability statement in § 73.120(b)(1)(i) would encompass individuals whom the licensee intends to grant unescorted access to the facilities' most sensitive areas, consistent with § 73.56(b)(1)(i) for power reactors and the ASM orders and license conditions issued to any NRC licensed facility or material licensee. Sections 73.120(b)(1)(ii) through (iv)

would be consistent with § 73.56(b)(1)(ii) through (iv), respectively. The program would include individuals who may be onsite or offsite (e.g., remote operators or information technology staff) and have virtual access to important plant operational and communication systems based upon assigned duties and responsibilities. An individual who has remote access to plant equipment and communication systems may have trusted privileges greater than the personnel at the plant site. Section 73.120(b)(1)(iii) would state that offsite law enforcement personnel on official duty would not be subject to the licensee AA program.

Section 73.120(c) would provide general performance objectives and requirements largely consistent with the AA program requirements for nuclear power reactors under § 73.56 and would provide licensees and applicants the flexibility in establishing their AA program to demonstrate compliance with various performance objectives.

Section 73.120(c)(1) would include background investigation requirements consistent with § 37.25, as well as ASMs and license conditions that are applied to non-power reactor licensees. Background investigations include important elements to establish the trustworthiness and reliability of an individual, such that they do not constitute an unreasonable risk to public health and safety or the common defense and security. These include the following: (1) personal history disclosure, (2) verification of true identity, (3) employment history evaluation, (4) unemployment/military service/education, (5) credit history evaluation, (6) character and reputation evaluation, and (7) Federal Bureau of Investigation criminal history record check.

Section § 73.120(c)(2) would establish behavioral observation requirements, which are an awareness initiative for recognizing behaviors adverse to the safe operation and security of the facility through observing the behavior of others in the

workplace and reporting aberrant behavior or changes in behavior that might reflect negatively on an individual's trustworthiness or reliability. Maintaining behavioral observation would assist and/or improve worker safety and reduce the risk of an insider threat. This proposed requirement in § 73.120(c)(2) would be a scaled version of the full BOP required under § 73.56(f).

Section § 73.120(c)(2) would provide licensees greater flexibility to implement behavioral observation options for individuals granted unescorted access to the commercial nuclear plant's protected area. Such options on reporting questionable behavior may include a program similar to the Department of Homeland Security's program, "If you see something, say something," or to a corporate behavioral awareness program. Commensurate with the potential lower safety and security risks of a commercial nuclear plant that meets the criterion in § 53.860(a)(2), § 73.120(c)(2) would not require the establishment of a comprehensive training program for behavioral observation (i.e., initial and refresher training including knowledge checks) as required for power reactors under § 73.56 and part 26. Under § 73.120(c)(2)(ii), behavioral observation would be able to be performed in-person or remotely by video, and identified behavior of concern would need to be reported to plant supervision. The remote access alternative to face-to-face interactions provides substantial flexibility for licensees and applicants. Any video conferencing or other acceptable electronic means promoting face-to-face interaction for those individuals working remotely would demonstrate compliance with this regulation.

Section 73.120(c)(3) captures and maintains the self-reporting of legal actions as an essential performance element to enhance the licensee's behavioral observation initiative similar to the current requirements under § 73.56(g), assuring that personnel who are granted and who maintain unescorted access are trustworthy and reliable.

Section 73.120(c)(4) would provide a scalable approach for granting and maintaining unescorted access. One component not included from § 73.56 is the need for a psychological assessment and reassessment under § 73.56(e) for granting unescorted access and § 73.56(i)(v)(B) for individuals who perform one or more of the job functions described in § 73.120(b)(1)(ii) for maintaining unescorted access. Moreover, the requirement would permit criminal history updates to be completed within 10 years of the last review, compared to the three- or five-year reinvestigation periodicity for personnel at an operating commercial nuclear plant. In addition, no credit check re-evaluation would be required for these individuals.

The continued need to maintain unescorted access would be evaluated on an annual basis by the reviewing official. Guidance in DG-5074, “Access Authorization Program for Commercial Nuclear Plants,” would specify that this evaluation should be based on a compilation of personnel interactions as described in the licensee’s or applicant’s policy and procedures for behavioral observation and the maintenance of an approved AA list.

Section 73.120(c)(5) would require licensees and applicants to determine when a person no longer requires the need for unescorted access or no longer satisfies the AA requirement found within this section. Guidance in DG-5074 would further explain that licensees have the flexibility to terminate unescorted access to specific areas of the site if individuals lack the continued need for that access to perform their duties and responsibilities.

Section 73.120(c)(6) would be consistent with the purpose of § 37.23(e) and would include the individual’s right to correct and complete information as required under § 37.23(g). The section would include a requirement for designating a reviewing official. The language would provide clarity regarding the roles and responsibility of a reviewing

official, who would be the only individual authorized to make unescorted access determinations.

Section 73.120(c)(7) would align with the corresponding requirements under § 37.23(f), and § 73.120(c)(8) would align with the corresponding requirements under § 37.31. These requirements would encompass the roles and responsibilities for licensees, applicants, and if applicable, the contractor/vendors to establish, implement, and maintain a system of files and records to ensure personal information is not disclosed to unauthorized persons.

Section 73.120(c)(9) would align with the requirements of § 37.33. Section 73.120(c)(10) would require licensees, applicants, and contractors or vendors to maintain the records that are required by the regulations in this section and retain them for a period of 3 years after the record is superseded or no longer needed. The record retention period of three years would be consistent with § 37.23(h), contrasting with the five-year retention period under § 73.56(o). Records maintained in any database(s) would need to be available for NRC review, consistent with the requirements found under § 73.56(o)(6)(ii).

VI. Specific Requests for Comments

The NRC is seeking advice and recommendations from the public on the proposed rule. We are particularly interested in comments and supporting rationale from the public on the following:

Part 26 – Fitness for Duty Program

1. The proposed rule under § 26.604(a) would enable a licensee or other entity to implement an FFD program under proposed § 26.604, “FFD program requirements for low consequence facilities,” if the licensee or other entity performs a site-specific

analysis to demonstrate that the facility and its operation satisfy the criterion in § 26.604(a).

Should the NRC consider replacing its proposed § 26.604(a) criterion with an alternative requirement that if the commercial nuclear plant is of the class described in § 53.800, “Self-reliant-mitigation facilities,” then drug and alcohol testing would not be required? This proposal would align the § 26.603(c) criterion with that proposed in the NRC-licensed operator regulatory framework of part 53. Please provide your considerations and rationale for your recommendation.

Should the NRC also consider making a conforming change to the proposed § 73.120 criterion used for the AA program? Please provide your considerations and rationale for your recommendation.

Part 26 – Technology-Inclusive Approaches to Fatigue Management Requirements Applicable to Unit Outages

In establishing the outage minimum days off requirement of § 26.205(d)(4), the NRC’s objective was to ensure that individuals performing the duties described in § 26.4(a)(1) through (a)(4) have sufficient periodic long-duration breaks to prevent cumulative fatigue from degrading their ability to safely and competently perform their duties. In addition to the science of fatigue management, the NRC considered several factors in establishing the existing requirements. These additional factors were practical and safety considerations associated with the management of refueling outages for large LWRs, including the following: (1) the typical duration and frequency of outages; (2) the availability of contract personnel to perform the work; (3) the risk presented by the outage work while the reactor is shut down; and (4) the controls applied to the work that may limit the potential for latent errors to challenge reactor safety when the reactor is returned to power. The details of such considerations may differ for new reactor

technologies or designs. Such considerations may not be relevant for some reactor designs (e.g., reactors capable of on-line refueling) and there may be additional, more pertinent factors to consider for other designs.

The NRC is seeking stakeholder input on whether alternative fatigue management requirements applicable to outages should be adopted to support technology--inclusive approaches that would be appropriate to support the licensing and regulation of future commercial nuclear plants. Please provide your considerations and rationale for your recommendation.

Part 26 – Draft Regulatory Guidance Approach for Fatigue Management

In support of this proposed rule, the NRC has issued DG-5078, "Fatigue Management for Nuclear Power Plant Personnel at Commercial Nuclear Plants Licensed Under 10 CFR Part 53." This DG describes methods the NRC staff considers acceptable for addressing certain aspects of FFD programs at commercial nuclear facilities licensed under part 53.

The NRC staff also intends to eventually transition this draft guide into an update to RG 5.73, "Fatigue Management for Nuclear Power Plant Personnel," or the development of a new RG. At this point, NRC staff is considering four options for future RG development:

- *Option 1: Amend the existing RG.* The NRC may develop an updated version of RG 5.73 that continues to endorse (with clarifications, additions, and exceptions) the guidance contained in NEI 06-11, "Managing Personnel Fatigue at Nuclear Power Reactor Sites," Revision 1, and incorporates the topics discussed within DG-5078 as new NRC staff positions in section C of RG 5.73.
- *Option 2: Issue a new RG specific to part 53 licensees.* The NRC may develop an entirely new RG applicable specifically to facilities licensed under part 53. This new

RG would capture the guidance contained in DG-5078 and incorporate existing guidance (e.g., selected guidance in RG 5.73 and NEI 06-11) that is considered to be technology inclusive in nature. The existing guidance (i.e., RG 5.73) would remain in place as the guidance for facilities licensed under parts 50 and 52.

- *Option 3: Review and potentially endorse new or revised industry-developed guidance*. The NRC may engage with the industry regarding a potential update to industry guidance document NEI 06-11 or the development of new, separate industry-developed guidance specific to facilities licensed under part 53. The NRC would then review the new or revised industry-developed guidance within the NRC's RG process, which includes opportunities for public participation. New or revised industry-developed guidance could incorporate DG-5078 or propose alternatives for the NRC to consider.
- *Option 4: Develop a comprehensive revision of the existing RG*. The NRC may develop a more comprehensive revision of RG 5.73 that would explicitly detail all NRC positions reflected in the existing RG (including those endorsed positions currently contained in NEI 06-11, Revision 1), along with the guidance of DG-5078. Such a revision would thereby be a "stand-alone" document, without reference to or explicit endorsement of separate, industry-developed guidance.

The NRC is seeking stakeholder input regarding which of the four options listed above would be optimal (or whether there are other options that the NRC should consider). Please provide your considerations and rationale for your recommendation.

Part 53, Subpart B – Defense in Depth

Proposed § 53.250 would establish requirements based on the longstanding NRC philosophy of providing defense in depth to address uncertainties concerning the design, operation, and performance of commercial nuclear plants during LBEs.

The NRC is seeking comment on the inclusion of the proposed requirements to assess and provide defense in depth. The NRC is also seeking comment on whether to include specific provisions in § 53.250 and subpart B to more explicitly address the possible role of inherent characteristics of some SSCs in preventing or mitigating unplanned events. The proposed § 53.250 is worded to preclude relying on a single engineered design feature to address the range of LBEs other than DBAs, which could possibly allow crediting inherent characteristics without further lines of defense. How could possible inherent characteristics of SSCs be considered in the proposed requirements in § 53.250 or in any alternative requirements for defense in depth provided in response to this item? Please provide your considerations and rationale for your recommendation.

Part 53, Subparts C and D – Earthquake Engineering

Proposed § 53.480 would establish requirements related to seismic design considerations. This is intended to provide a clear connection between siting activities and seismic design activities and to support various approaches to presenting seismic hazards and addressing those hazards in designs and provide sufficient flexibility to allow approaches like those currently in parts 50 and 100 or approaches that might be endorsed by the NRC in the future that could incorporate more risk insights.

The NRC is seeking comment on whether the proposed requirements for earthquake engineering provide appropriate flexibility in addressing seismic risks while also ensuring that the regulations continue to adequately address seismic hazards. Please provide your considerations and rationale for your recommendation.

Part 53, Subpart E – Construction and Manufacturing

1. Proposed § 53.610(b)(1)(iii) would require procedures that describe how construction will be controlled so as not to impact other features important to the design (e.g., dewatering, slope stability, backfill, compaction, and seepage).

The NRC is seeking comment on whether such specific requirements are useful or whether these requirements could be met through other existing requirements such as quality assurance requirements under appendix B to part 50.

Part 53, Subparts E and H– Manufacturing Licenses

1. The proposed regulations in subpart H allow holders of or applicants for a COL to reference an ML but do not include such a provision for the holder of a CP. This proposed change from the current relationship between subparts in part 52 and the part 50 licensing process was made to simplify the provisions in the proposed part 53 for licensing and deploying manufactured reactors.

The NRC seeks comment on whether the possible references to an ML by holders of a CP is a relationship that should be included in part 53 and, if so, how it would be used.

2. Proposed § 53.1288 provides the finality provisions for MLs and include, as does existing § 52.171, limitations on the NRC's imposition of new requirements on either the design or the requirements for the manufacture of a manufactured reactor. No MLs have been issued under part 52 and there is no practical experience with the proposed finality sections. While the implications of the finality provisions related to the design of a manufactured reactor can reasonably be inferred from experience with DCs and COLs, there is no experience or available guidance regarding finality for "requirements for the manufacture of the manufactured reactor."

The NRC is seeking comment on the proposed finality provisions for MLs and specifically if and how finality for manufacturing processes might be requested and used.

3. The Atomic Energy Commission developed requirements for MLs in part 50 as part of a broader effort to encourage standardization of plant designs. The requirements were subsequently moved to part 52 by rulemakings undertaken by the NRC. Although the NRC and some developers have explored the potential uses of MLs, the concept has never been fully exercised through issuance and implementation of such a license. This rulemaking includes proposals to align MLs with possible adoption of a factory-style model for building and deploying transportable microreactors. The proposed rule would include provisions for loading of fuel into manufactured reactors at a manufacturing facility as suggested by some stakeholders. The NRC has historically viewed operation as including fuel load and existing NRC regulations reflect this view. While the AEA authorizes the NRC to issue licenses to manufacture production or utilization facilities, it does not contain specific provisions on fueling or operating facilities licensed under an ML.

The NRC is considering whether one way to allow fuel to be loaded into a manufactured reactor could be to require the ML holder to modify the manufactured reactor to include certain design features to preclude criticality. These design features could be two independent mechanisms, each of which could be sufficient to prevent criticality assuming that maximum reactivity of the fissile material would be attained from possible fuel configurations, neutron moderation, and neutron reflection from the manufactured reactor and surrounding materials. The NRC is considering whether such a fueled manufactured reactor would be a utilization facility as defined under the AEA, and if not, whether fuel load could be governed by part 70 and the ML, and not a COL. If the fueled manufactured reactor is not considered a utilization facility, the NRC is considering when it might become, or should be considered, a utilization facility. For example, should a fueled manufactured reactor be considered a utilization facility after

installation at the site specified in the COL, completion of corresponding ITAAC, and after all requirements necessary for operation are met, at which point it would be subject to all applicable COL provisions and regulations. Further, the NRC is considering whether such a regulatory approach should include requirements for the ML holder to establish and install certain programs and equipment prior to receipt of SNM. For example, should the following be in place prior to receipt of SNM: (1) radiation monitoring instrumentation and alarms; (2) measures to prevent and detect criticality accidents in accordance with §§ 70.61 and 70.64; (3) procedures, equipment, and personnel qualified to handle and load fresh fuel, monitor reactivity, and secure the fuel and manufactured reactor for shipment; (4) a physical security program in accordance with § 73.61; and (5) an MC&A program in accordance with part 74? Also, the NRC is contemplating whether any loading or unloading of fresh fuel into a manufactured reactor and any changes to the configuration of reactivity-related systems would need to be performed by a certified fuel handler demonstrating compliance with the requirements in subpart F.

As an additional matter, the NRC is considering whether the FSAR for an ML applicant proposing to load fuel in the factory would need to include things like a description of the safety program and integrated analysis required by subpart H of part 70, including the procedures used for receipt, storage, and loading of the fuel into the manufactured reactor; and procedures for transferring the authority and responsibility for the manufactured reactor to the COL holder at the installation site. Also, the NRC is considering whether other programs required by proposed § 53.620 should be modified to account for fuel loading including the Radiation Protection Program under § 53.620(a)(4), the FFD program under § 53.620(a)(5), the information security program

under § 53.620(a)(8), the fire protection program under § 53.620(c)(2), the emergency plan under § 53.620(c)(3), and the physical security program under § 53.620(c)(5).

Finally, the NRC is considering how to best define operations and fuel load at a manufacturing facility, and whether changes to NRC's policies and practices may be needed to accommodate fuel load without a COL. For example, the NRC has historically defined operation to begin at fuel load, and the AEA contemplates that all ITAAC will be closed prior to operation. In light of the potential use of mechanisms to prevent criticality, the NRC is considering the possibility that the Commission could determine that fuel load into a manufactured reactor at a manufacturing facility does not constitute operation in the circumstances described above, and operation could be deemed to begin at a later date when the fueled manufactured reactor is installed at the site specified in the site-specific COL, all corresponding ITAAC have been met, and all other requirements necessary for operation have been met.

The NRC is seeking comments on the desirability of redefining operation, fuel load, or some other term to facilitate ML factory fuel loading, and if so, what other points in the regulatory process would be reasonable places to conclude that operations have commenced or that fuel load has occurred. The NRC is also seeking comment on how the hearing process would be conducted if fuel load were allowed at the ML facility without a COL. Further the NRC is seeking comment on whether it would be desirable or feasible to issue a certificate of compliance for fueled manufactured reactors under these circumstances under 10 CFR part 71, "Packaging and Transportation of Radioactive Material," and whether technical features of a fueled manufactured reactor would require further changes to that part of 10 CFR Chapter I. Finally, the NRC is seeking comments on technical and policy concerns that allowing fuel load at the ML

facility without a COL would raise with respect to the transportation, storage, and disposal of the fuel and module after use.

6. In addition to the considerations in question 5, the NRC is also seeking comment on whether provisions supporting the low power nuclear physics testing of fueled manufactured reactors in the manufacturing facility should be included in part 53 and, if so, what would be reasonable in terms of being practical for the holder of an ML while also ensuring the activity poses no undue risks to public health and safety. One possibility could be COLs that would be issued to the holders of an ML to support low power (e.g., <1% rated thermal power) nuclear physics testing of fueled manufactured reactors within the manufacturing facility prior to the fueled manufactured reactors being transported to and incorporated into a commercial nuclear plant for the purpose of energy production. The NRC recognizes configuration changes are needed to perform nuclear physics testing and is considering what requirements should apply to the fueled manufactured reactors and the manufacturing facility during such testing.

While an ML holder could accomplish low power nuclear physics testing by applying for a COL under subpart H, stakeholders have indicated that many of the subpart H requirements would likely be unnecessary, given the reduced risk profile posed by such activities. Therefore, NRC is considering what requirements in subparts H should apply to applicants for a COL to support low power nuclear physics testing of fueled manufactured reactors. Examples of proposed requirements that might be relaxed or modified to support applications for low power testing at ML facilities include those related to selection of licensing basis events to reflect limited inventory of radionuclides and decay heat, aircraft impact assessments, and earthquake engineering.

Additionally, the NRC is considering whether several other requirements in part 53 could be modified for applications for a low power testing COL at a

manufacturing facility. For example, the NRC is considering whether § 53.610 (construction) should apply to all portions of the ML facility used to support low power testing; whether §§ 53.710 and 53.715 (SSC configuration control) must be implemented to ensure portions of the ML facility relied on to limit potential radiological consequences from licensing basis events are available to perform their safety functions; and whether the requirements of § 53.730 could be modified to reflect low power physics testing.

Moreover, the licensing mechanism for the facility could present unique challenges. One option could be to issue a low power testing COL for each fueled manufactured reactor to be tested. This would comport with the agency's practice of issuing one license per reactor but could prove prohibitive from a cost standpoint and may provide very little safety benefit if all modules are the same. Alternatively, one low power testing COL could be issued for the portions of the ML facility used to test the fueled manufactured reactors. However, the manufactured reactors themselves would be completed over the course of the ML licenses. For this reason, any ITAAC related to physics testing of the manufactured reactors would need to be closed after they were manufactured but prior to testing. This may introduce unwarranted delays in the manufacturing process.

The NRC is particularly interested in comments on whether specific COL provisions in subpart H should not apply to or be modified for low power testing. Also, the NRC is interested in comments on using one COL to support testing for all or a group of fueled manufactured reactors at an ML facility and the process for closing ITAAC for those modules as they are manufactured.

Part 53, Subpart F – Staffing and Generally Licensed Reactor Operators

Under AEA Sections 106 and 107, the NRC is proposing to group commercial reactors into classes upon the basis of the similarity of operating and technical

characteristics of the facilities, and then to prescribe uniform conditions for licensing individuals as operators of any of the various classes; determine the qualifications of such individuals; and, for certain classes of commercial reactors, issue general licenses (i.e., licenses for which no application is needed) to such individuals allowing the individuals to operate the commercial reactor.

1. *Categories of Individuals Who May Manipulate Facility Controls*: The NRC is proposing requirements that would allow the manipulation of the controls of certain facilities by GLROs in lieu of specifically licensed reactor operators and senior reactor operators. Reactor operators and senior reactor operators are the only categories of individuals currently allowed to be licensed to manipulate the controls of utilization facilities under part 55.

The NRC is interested in public perspectives on this proposed addition of the GLRO category, particularly in light of new reactor technologies and concepts of operations.

2. *Criteria for GLRO Staffing*: The NRC is proposing criteria under which facilities would be staffed by GLROs in lieu of specifically licensed reactor operators and senior reactor operators. These criteria, establish a new class of self-reliant-mitigation facilities, as defined in part 53, for which distinct GLRO licensing and staffing requirements would apply.

The NRC is soliciting public feedback regarding whether these proposed criteria are appropriate and what, if any, alternative criteria should be considered. Please provide your considerations and rationale for your answer.

3. *Medical Requirements for GLROs*: Based on the proposed criteria that a self-reliant-mitigation facility, as defined in part 53, must meet, the NRC is proposing not to subject GLROs to requirements for medical fitness and medical examination. This is in

contrast with the proposed requirements associated with specifically licensed reactor operators and senior reactor operators, as well as the existing requirements for reactor operators and senior reactor operators under part 55.

The NRC is soliciting public feedback regarding whether GLROs should be subject to medical fitness and/or medical examination requirements like reactor operators and senior reactor operators. Please provide your considerations and rationale for your answer.

4. *Onshift Engineering Expertise*: The NRC is proposing to require that engineering expertise be accounted for within facility staffing plans. This proposed requirement would be in lieu of the traditional position of the Shift Technical Advisor. The NRC is further proposing that individuals providing such engineering expertise would need, among other things, to possess either a qualifying 4-year degree or licensure as a Professional Engineer.

The NRC is interested in feedback from the public regarding the appropriateness of this requirement, including any alternatives that should be considered. Please provide your considerations and rationale for your answer.

5. *Use of Simulation Facilities as HFE Testbeds*: The NRC is proposing to establish regulations pertaining to the use of simulation facilities within the context of the licensing programs both for specifically licensed reactor operators and senior reactor operators as well as for GLROs. However, these regulations, as currently proposed, do not address the use of simulation facilities within the context of serving as testbeds HFE-related analyses and assessments. Rather, the NRC currently envisions that the use of simulation facilities as HFE testbeds is more appropriately addressed via guidance documents.

The NRC is soliciting public feedback regarding whether simulation facility requirements should also address the use of simulation facilities as HFE testbeds. Please provide your considerations and rationale for your answer.

Part 53, Subpart G – Decommissioning

1. On March 3, 2022, the NRC published the proposed rule entitled “Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning” (87 FR 12254). This rulemaking would amend the NRC’s current regulations to provide an appropriate regulatory framework for nuclear power reactors transitioning from operations to decommissioning. The rulemaking would address lessons learned from licensees that have completed or are currently in the decommissioning process.

What aspects of this proposed rule, if any, should be incorporated in a part 53 final rule and why?

2. Proposed § 53.1060(b) in subpart G would require that, “No later than 30 days after the Commission publishes notice in the *Federal Register* under § 53.1452(a), the licensee must submit an updated decommissioning report, including a copy of the financial instrument obtained to satisfy § 53.1040.” This is similar to the current requirement in § 50.75(e)(3) for part 52 COL holders. The NRC is seeking comment on whether advanced reactor COL holders under part 53 should have the same requirement as COL holders under part 52 to demonstrate that they have financial assurance in place no later than 30 days after the Commission issues the notice of intended operation under § 53.1452. Please provide your considerations and rationale for your answer.

Part 53, Subparts H and I –Risk Evaluation Information

Proposed § 53.1239(a)(18) in subpart H and the related references to this proposed requirement for the holders of OLs and COLs would require a description of

the risk evaluation required by § 53.450(a), and its results to be included in FSARs. However, guidance documents may further clarify the division of risk-related information needed to be in the FSAR, in other possible licensing basis documents, and controlled as plant records subject to inspections and audits. For example, a possible approach for part 53 could be to include a summary of the risk evaluation results in the FSAR and control that information under § 53.1545 and create a separate document related to the broader risk evaluation, analyses and related processes as a program document under § 53.1560. The program document would provide more detail than the summaries in the FSAR but still be a much-condensed source of information in comparison to the documentation of a PRA. This possible approach would reflect the role of risk in the licensing process under part 53 and in maintaining margins to the safety and evaluation criteria in subparts B and C but may allow a more appropriate evaluation process to address the particulars and complexities of the risk-related documents.

The NRC is seeking comment on the appropriate placement of risk-related information among various licensing basis documents and plant records. In addition to the placement of risk-related information, the NRC is seeking comment on the appropriate control of that information and on the routine submittal of updates to the NRC. Please provide your considerations and rationale for your answer.

Part 53, Subparts H and I – Changes to Manufacturing Licenses

Proposed § 53.1530 would not allow the holder of an ML or the holder of a COL using a manufactured reactor to make changes to the design of the manufactured reactor without requesting a license amendment from the NRC. The proposed requirements do not include a specific mention of the manufacturing processes for which the NRC could possibly provide finality under proposed § 53.1288.

The NRC is seeking comment on the appropriate change control provisions for MLs, including whether criteria could be developed to determine when a license amendment request would not be required and whether those criteria should address changes in manufacturing processes as well as changes in the design. Please provide your considerations and rationale for your recommendation. Operating Experience Programs

Proposed §§ 53.440, 53.610(a)(4), 53.620(a)(4), and 53.730(e) would require that licensees establish programs that evaluate and apply experience in the design, construction, manufacturing, and operating areas during the design, construction, manufacturing, and operation phases respectively. These programs parallel the unified requirement that was codified for licensees under parts 50 and 52 in § 50.34(f)(3)(i) with the addition of the coverage of manufacturing experience element in § 53.620(a)(4).

The NRC is seeking comment on whether there could be synergistic gains from unifying these as a single program under the quality assurance program requirements or elsewhere. Such a unified program might result in a greater degree of consideration of operating experience in the design, construction, or manufacturing phases, for example, although it could result in a broader scope of experience to be considered. Please provide your considerations and rationale for your answer.

Financial Qualifications

Utility new reactor applicants are exempt under § 50.33(f) from financial qualification reviews because they are generically presumed to be financially qualified for operations. In contrast, merchant power plant new reactor applicants are required under § 50.33(f)(2) to submit information that demonstrates they possess or have reasonable assurance of obtaining the funds necessary to cover estimated construction and operating costs for the period of the license. A “merchant power plant new reactor applicant” is a non-rate-regulated entity (e.g., a nonutility) that engages in the business

of production, manufacturing, generating, buying, aggregating, marketing, or brokering electricity for sale at wholesale or for retail sale to the public. Over the past decade, the agency has heard some concerns about the challenges that merchant power plant applicants face in demonstrating compliance with the current financial qualification requirements.

Does this standard continue to pose challenges for merchant power plant applicants? If so, please provide a detailed explanation of these challenges.

Should part 53 have the same financial qualification requirements as parts 50 and 52? Why or why not?

Are there categories of merchant new reactor applicants for which a part 70 "appears to be financially qualified" standard would be more appropriate?[15] If so, please explain what types of applicants should be able to use the part 70 financial qualification standard and what distinguishes these applicants from ones that should not be able to use this standard.

If a part 70 financial qualification standard were to apply to a category of merchant new reactor applicants, should it also apply to pre-construction license transfer applications for these reactors? Why or why not?

Is there another standard the agency should consider for financial qualification of merchant new reactor applicants? Commenters are encouraged to provide specific suggestions and the basis for those suggestions.

Part 73, Section 73.100 – Physical Security

The proposed § 73.100 would identify the proposed performance-based physical security requirements with which future commercial power reactor applicants or licensees' physical protection programs would need to demonstrate compliance, without

[15] Section 70.23(a)(5).

prescribing the specific methods that must be used to satisfy them. Applicants and licensees would have increased flexibility regarding the modern technologies and methods that they could use. Implementing guidance in DG-5076 (proposed RG 5.97), "Guidance for Technology Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants," would be available to assist applicants and licensees. For example, DG-5076 provides detailed guidance, including performance standard recommendations, on the probability of detection and alternative sources of power for exterior intrusion detection systems (subsection 4.1.1.1.A), interior intrusion detection (subsection 4.1.1.1.B), intrusion assessment (subsection 4.1.1.2.A), security response/neutralization subsection (4.1.1.4.A), security communication (subsection 4.1.1.3.A), and security delay (subsection 4.1.1.4.C).

Does the NRC's proposed approach in § 73.100 provide a sufficient level of detail to be readily understood and easily applied to the licensing and oversight of new and advanced power reactors, or should the NRC consider moving some objective and measurable security performance standard recommendations from the draft implementing guidance in DG-5076 into proposed § 73.100? If so, which objective and measurable security performance standard recommendations should be moved from DG-5076 to § 73.100? Please provide the basis for your response.

Part 73, Section 73.110 – Cyber Security

The proposed § 73.110 would require licensees to demonstrate protection against cyber attacks in a manner that is commensurate with the potential consequences from those attacks, without prescribing the specific methods that must be used to demonstrate protection. Under proposed § 73.110(a), licensees would need to ensure that digital computer and communications systems are adequately protected against a potential cyber attack that would, for example, result in adverse impacts to the

physical security digital assets used by the licensee to prevent unauthorized removal of material per § 53.860(a). Protecting against such a potential cyber attack would involve requiring cyber security for SNM at a commercial nuclear reactor licensed under part 53. Applicants and licensees would have increased flexibility regarding the modern technologies and methods that they could use for protecting against such a potential cyber attack. Detailed implementing guidance in DG-5075 (proposed RG 5.96), "Establishing Cyber Security Programs for Commercial Nuclear Plants licensed under 10 CFR part 53," would be available to assist applicants and licensees. For example, DG-5075 provides guidance on the implementation of security by design features (e.g., facility design) for negating the potential consequences from such a potential cyber attack.

If a cyber attack were to compromise the availability, integrity, or confidentiality of data or systems associated with security systems/measures for the protection of SNM at a commercial nuclear reactor licensed under part 53, do the potential consequences warrant requiring cyber security for such material? Please provide the basis for your response including a detailed explanation of challenges, if any, posed by requiring cyber security for SNM at a commercial nuclear reactor licensed under part 53.

VII. Section-by-Section Analysis

The following paragraphs describe the specific changes proposed by this rulemaking.

10 CFR part 1

Section 1.43 Office of Nuclear Reactor Regulation.

This proposed rule would revise § 1.43(a)(2) to extend the authority of the Office of Nuclear Reactor Regulation to regulate source, byproduct, and SNM at facilities licensed under part 53.

10 CFR part 2

Section 2.1 Scope.

This proposed rule would revise § 2.1(e) to apply to standard design approvals under part 53.

Section 2.4 Definitions.

This proposed rule would revise § 2.4 to update the definition of “Contested proceeding” to include NRC enforcement actions against applicants for a standard DC under part 53. It would also update the definition of “Facility” to encompass utilization facilities as defined in § 53.020 (there are no production facilities under part 53).

Section 2.100 Scope of subpart.

This proposed rule would revise § 2.100 to extend the scope of subpart A to licenses and standard design approvals issued under §§ 53.1200 through 53.1221.

Section 2.101 Filing of application.

This proposed rule would revise § 2.101 to be applicable to part 53 applicants in addition to part 50 and 52 applicants by adding references to part 53 in paragraphs (a)(3)(i), (a)(5), and (a)(9).

Section 2.104 Notice of hearing.

This proposed rule would extend the hearing notice requirement in § 2.104(a) to applications concerning facilities covered under part 53. Footnote 1 to § 2.104 would be revised in a corresponding manner.

Section 2.105 Notice of proposed action.

This proposed rule would revise § 2.105 to extend the requirement in § 2.104 to publish a notice of intended operation or a notice of proposed action, as applicable, to part 53 applicants in addition to part 50 and 52 applicants by adding corresponding references to part 53 in paragraphs (a), (a)(4), (a)(10), (a)(12), (a)(13), and (b)(3).

Section 2.106 Notice of issuance.

This proposed rule would revise § 2.106 to extend the issuance notice requirement to applications concerning facilities covered under part 53 through updated references in paragraphs (a)(2) and (3), and (b)(2).

Section 2.109 Effect of timely renewal application.

This proposed rule would revise § 2.109 to add references to part 53 in paragraphs (b), (c), and (d) regarding the timing of license renewal applications.

Section 2.110 Filing and administrative action on submittals for standard design approval or early review of site suitability issues.

This proposed rule would revise § 2.110 to include references to part 53 in paragraphs (a)(1) and (b).

Section 2.202 Orders.

This proposed rule would revise § 2.202(e) to add references to part 53 regarding the requirements to be followed for orders involving the modification of a license, COL, ESP, standard DC rule, standard design approval, or ML.

Section 2.309 Hearing requests, petitions to intervene, requirements for standing, and contentions.

This proposed rule would revise § 2.309 to include references to part 53 in paragraphs (a), (f)(1)(i), (f)(1)(vi) and (vii), (g), (h)(2), (i)(2), and (j) regarding a request for hearing under § 53.1452.

Section 2.310 Selection of hearing procedures.

This proposed rule would amend § 2.310 by revising paragraph (a), the introductory text for paragraph (h) and paragraphs (i) and (j) to incorporate references to part 53 regarding hearing procedures.

Section 2.329 Prehearing conference.

This proposed rule would revise § 2.329(a) to extend the timing requirements for prehearing conferences involving CPs and licenses under part 53.

Section 2.339 Expedited decisionmaking procedure.

This proposed rule would revise § 2.339(d) to include references to part 53 regarding expedited decisionmaking procedures.

Section 2.340 Initial decision in certain contested proceedings; immediate effectiveness of initial decisions; issuance of authorizations, permits and licenses.

This proposed rule would amend § 2.340 regarding initial decisions of a presiding officer in certain contested proceedings, the effective date of those decisions, and the issuance of authorizations, permits, and licenses, by incorporating references to part 53 in paragraphs (b), (c), (d), (d)(1), (d)(2), (f), (i), (j), and (j)(1).

Section 2.341 Review of decisions and actions of a presiding officer.

This proposed rule would revise § 2.341(a)(1) to include an updated reference to part 53 regarding the allowance of a period of interim operation.

Section 2.400 Scope of subpart.

This proposed rule would revise § 2.400 to extend the scope of subpart D of part 2 to part 53 applicants for licenses to construct or operate nuclear power reactors of identical design at multiple sites.

Section 2.401 Notice of hearing on construction permit or combined license applications for nuclear power plants of identical design at multiple sites.

This proposed rule would revise the section heading and § 2.401 to extend the hearing notice requirement to applications concerning facilities covered under part 53.

Section 2.402 Separate hearings on separate issues; consolidation of proceedings.

This proposed rule would revise § 2.402 to apply provisions regarding separate hearings and the consolidation of proceedings to part 53 applicants.

Section 2.403 Notice of proposed action on applications for operating licenses for nuclear power plants of identical design at multiple sites.

This proposed rule would revise the section heading and § 2.403 to require the Commission to publish a notice of proposed action in the *Federal Register* after applications under part 53 are docketed.

Section 2.404 Hearings on applications for operating licenses for nuclear power plants of identical design at multiple sites.

This proposed rule would amend the section heading and § 2.404 to apply to applications for an OL under part 53.

Section 2.405 Initial decisions in consolidated hearings.

This proposed rule would revise § 2.405 to be applicable to CPs, full-power OLs, and COLs under part 53.

Section 2.406 Finality of decisions on separate issues.

This proposed rule would revise § 2.406 to be applicable to proceedings conducted pursuant to part 53.

Section 2.500 Scope of subpart.

This proposed rule would revise § 2.500 to extend the provisions of subpart E of part 2 to applications for a license to manufacture nuclear power reactors under part 53.

Section 2.501 Notice of hearing on application under 10 CFR parts 52 or 53 for a license to manufacture nuclear power reactors.

This proposed rule would amend the section heading and § 2.501(a) by extending its provisions to applications for a license to manufacture nuclear power reactors under part 53.

Section 2.643 Acceptance and docketing of application for limited work authorization.

This proposed rule would revise § 2.643(b) regarding the acceptance and docketing of an application for a CP for a utilization facility of the type specified in part 53.

Section 2.645 Notice of hearing.

This proposed rule would amend § 2.645(a) to incorporate a reference to part 53.

Section 2.649 Partial decisions on limited work authorization.

This proposed rule would revise § 2.649 to extend its provisions to LWAs issued under part 53.

Section 2.800 Scope and applicability.

This proposed rule would amend § 2.800 by revising paragraphs (c) and (d) to incorporate references to part 53 regarding the scope and applicability of the rulemaking procedures contained in this subpart.

Section 2.801 Initiation of rulemaking.

This proposed rule would revise § 2.801 to include a reference to part 53.

Section 2.813 Written communications.

This proposed rule would revise § 2.813(a) to apply general requirements for correspondence with the Commission to communications concerning part 53, in addition to parts 50, 52, and 100.

Section 2.1103 Scope of subpart K.

This proposed rule would revise the first sentence of § 2.1103 to extend the provisions of subpart K of part 2 to licenses under part 53 to expand the spent fuel capacity at the site of a civilian nuclear power plant.

Section 2.1202 Authority and role of NRC staff.

This proposed rule would amend § 2.1202 by revising paragraphs (a)(1), (a)(2), (a)(3), and (a)(6) to include references to part 53.

Section 2.1301 Public notice of receipt of a license transfer application.

This proposed rule would revise § 2.1301(b) to include a corresponding reference to license transfers under part 53 in addition to parts 50 and 52.

Section 2.1403 Authority and role of the NRC staff.

This proposed role would update § 2.1403 to specify that “significant hazards considerations” has the same meaning as defined in part 53.

Section 2.1500 Purpose and scope.

This proposed rule would update § 2.1500 to extend the scope of subpart O of part 2 to DC rulemaking hearings under part 53.

Section 2.1502 Commission decision to hold legislative hearing.

This proposed rule would revise § 2.1502, paragraphs (a) and (b)(1) to incorporate references to part 53 regarding the Commission’s decision to hold a DC rulemaking.

10 CFR part 10

Section 10.1 Purpose.

This proposed rule would revise § 10.1(a)(3) to include a reference to part 53.

Section 10.2 Scope.

This proposed rule would revise § 10.2(b) to extend the scope of subpart A to applicants and holders of licenses, certificates, and standard design approvals under part 53 in addition to part 52.

10 CFR part 11

Section 11.7 Definitions.

This proposed rule would revise § 11.7 such that terms defined in part 53 have the same meaning when used in part 11.

10 CFR part 19

Section 19.2 Scope.

This proposed rule would revise § 19.2(a)(1) through (4) to include references to part 53.

Section 19.3 Definitions.

This proposed rule would revise the definitions of “License” and “Regulated entities” in § 19.3 to incorporate references to part 53.

Section 19.11 Posting of notices to workers.

This proposed rule would revise § 19.11 to be applicable to applicants and holders of licenses, permits, standard design approvals, and standard DCs under part 53 in addition to part 52.

Section 19.14 Presence of representatives of licenses and regulated entities, and workers during inspections.

This proposed rule would revise § 19.14(a) to apply to applicants and holders of a license, standard design approval, ESP, or standard DC under part 53 in addition to part 52.

Section 19.20 Employee protection.

This proposed rule would revise § 19.20 to include a reference to protected activities under part 53.

10 CFR part 20

Section 20.1002 Scope.

This proposed rule would revise the first sentence of 10 CFR part 20, “Standards for Protection Against Radiation,” § 20.1002 to extend the scope of part 20 to apply to persons licensed by the Commission to receive, use, transfer, or dispose of byproduct, source, or SNM or to operate a production or utilization facility under part 53.

Section 20.1003 Definitions.

This proposed rule would revise § 20.1003 to update the definition of “License” to include those issued under part 53.

Section 20.1101 Radiation protection programs.

This proposed rule would revise § 20.1101(d) to exclude licensees subject to § 53.260(b) from its requirements.

Section 20.1401 General provisions and scope.

This proposed rule would revise § 20.1401, paragraphs (a) and (c) to extend the scope of subpart E of part 20 to apply to the decommissioning of facilities licensed under part 53 and the release of part of a facility or site for unrestricted use in accordance with § 53.1080.

Section 20.1403 Criteria for license termination under restricted conditions.

This proposed rule would revise § 20.1403(d) to include decommissioning plans under part 53.

Section 20.1404 Alternate criteria for license termination.

This proposed rule would revise § 20.1404(a)(4) to include a reference to part 53 regarding alternate criteria for license termination.

Section 20.1406 Minimization of contamination.

This proposed rule would revise § 20.1406(a) to include references to applicants for licenses other than ESPs or MLs under part 53. It would also revise § 20.1406(b) to include references to standard DCs and standard design approvals under part 53 in addition to part 52.

Section 20.1501 General.

This proposed rule would revise § 20.1501 regarding the requirement for retention of records from surveys describing the location and amount of subsurface residual radioactivity at a site to include a reference to the retention requirements under part 53.

Section 20.1905 Exemptions to labeling requirements.

This proposed rule would revise § 20.1905(g) to apply to facilities licensed under part 53 in addition to parts 50 and 52 regarding exemptions to labeling requirements.

Section 20.2004 Treatment or disposal by incineration.

This proposed rule would revise § 20.2004(b)(1) to include references to part 53 regarding the treatment or disposal of waste oil by incineration.

Section 20.2201 Reports of theft or loss of licensed material.

This proposed rule would revise § 20.2201 to include references to part 53 in paragraphs (a)(2)(i), (b)(2)(i) and (c) regarding requirements for reports of theft or loss of licensed material.

Section 20.2202 Notification of incidents.

This proposed rule would revise § 20.2202(d)(1) to add references to part 53 regarding reports to the NRC Operations Center.

Section 20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

This proposed rule would revise § 20.2203(c) to refer to procedures under part 53 for reporting occurrences of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

Section 20.2206 Reports of individual monitoring.

This proposed rule would revise § 20.2206(a)(1) to include a reference to part 53.

10 CFR part 21

Section 21.2 Scope.

This proposed rule would revise § 21.2, paragraphs (a)(2) through (4), (b) and (c) to include references to part 53 regarding the scope and applicability of part 21 requirements.

Section 21.3 Definitions.

This proposed rule, in § 21.3 would revise the definitions of “Basic component,” “Commercial grade item,” “Critical characteristics,” “Dedicating entity,” “Dedication,” “Defect,” and “Substantial safety hazard” with references to part 53.

Section 21.21 Notification of failure to comply or existence of a defect and its evaluation.

This proposed rule would amend § 21.21, by incorporating references to part 53, to update the requirements for notifying the Commission of a failure to comply or defect in paragraphs (a)(3) and (d)(1).

Section 21.51 Maintenance and inspection of records.

This proposed rule would revise § 21.51 to apply to applicants for standard DC and applicants or holders of a standard design approval under part 53, in addition to part 52, regarding the retention of records.

Section 21.61 Failure to notify.

This proposed rule would revise § 21.61(b) to include references to part 53 licensees and applicants regarding failure to provide the notice required in § 21.21.

10 CFR part 25

Section 25.5 Definitions.

This proposed rule would update the definition of “License” § 25.5 to include those issued under part 53.

Section 25.17 Approval for processing applicants for access authorization.

This proposed rule would revise § 25.17(a) to add a reference to part 53 regarding AAs for individuals who need access to classified information in connection with activities under part 53.

Section 25.35 Classified visits.

This proposed rule would update § 25.35(a) to apply the requirements for classified visits to licensees, certificate holders, and applicants under part 53 in addition to part 52.

10 CFR part 26

Section 26.3 Scope.

This proposed rule would revise § 26.3 by adding new paragraph (f) which would establish the phase of construction or operation by which applicants and licensees under part 53 would be required to comply with subpart M of part 26, or all of the requirements of part 26 except subparts K and M. The proposed rule would also update paragraphs

(a) through (c) to reflect that entities described in those paragraphs do not need to comply with subpart M.

Section 26.4 FFD program applicability to categories of individuals.

The proposed rule would update paragraphs (a), (b), (c), (e), (f), (g), and (h) of § 26.4 to include references to part 53 and provisions for implementing an FFD program under subpart M.

Section 26.5 Definitions.

The proposed rule would amend § 26.5 by adding definitions for “biological marker,” “change,” “illicit substance,” reduction in FFD program effectiveness,” and “Special Nuclear Material.” It would also update definitions of “constructing or construction activities,” “contractor/vendor (C/V),” “other entity,” “questionable validity,” “reviewing official,” “safety-related structures, systems, and components (SSCs),” “security-related SSCs,” and “unit outage” within this section.

Section 26.8 Information collection requirements: OMB approval.

The proposed rule would update § 26.8 with the new information collection requirements contained in proposed §§ 26.202, 26.603, 26.604, 26.605, 26.606, 26.607, 26.608, 26.609, 26.611, 26.613, 26.617, and 26.619.

Section 26.21 Fitness-for-duty program.

The proposed rule would update § 26.21 to include a reference to § 26.3(f).

Section 26.51 Applicability.

The proposed rule would update § 26.51 to extend the requirements of subpart C of part 26 to licensees and other entities identified in § 26.3(f) that do not implement the requirements of subpart M of part 26, as well as licensees and other entities that implement the requirements of § 26.605.

Section 26.53 General provisions.

The proposed rule would update paragraphs (e), (g), (h), and (i) of § 26.53 to include references to § 26.3(f).

Section 26.63 Suitable inquiry.

The proposed rule would update § 26.63(d) with a reference to § 26.3(f).

Section 26.73 Applicability.

The proposed rule would update § 26.73 to extend the requirements of subpart D of part 26 to licensees and other entities identified in § 26.3(f) that do not implement the requirements of subpart M of part 26, as well as licensees and other entities that implement the requirements of § 26.605.

Section 26.81 Purpose and applicability.

The proposed rule would update § 26.81 to extend the requirements of subpart E of part 26 to licensees and other entities identified in § 26.3(f) that do not implement the requirements of subpart M of part 26, as well as licensees and other entities that implement the requirements of § 26.605.

Section 26.201 Applicability.

The proposed rule would update § 26.201 to include references to the proposed provisions in §§ 26.3(f) and 26.202, as well as revise the applicability of requirements in subpart I of part 26.

Section 26.202 General provisions for facilities licensed under part 53.

This proposed rule would add new § 26.202, which would require applicable licensees under part 53 to incorporate a policy for fatigue management into their FFD program in accordance with the provisions of this section.

Section 26.205 Work hours.

The proposed rule would update paragraphs (d)(7)(iii) and (d)(8) of § 26.205 to incorporate references to §§ 26.606 and 26.202(a) and (b).

Section 26.207 Waivers and exceptions.

The proposed rule would update § 26.207(a)(1)(ii) to include references to §§ 26.608 and 26.202(c) and to include provisions for implementing certain face-to-face supervisor assessments using electronic communications.

Section 26.211 Fatigue assessments.

The proposed rule would update § 26.211, paragraphs (a)(1), (a)(3), and (b) to incorporate references to §§ 26.202(c), 26.607(b), 26.608, and 26.619 and to include provisions for implementing certain face-to-face assessments using electronic communications.

Subpart M – Fitness for Duty Programs for Facilities Licensed Under Part 53

This proposed rule would add new Subpart M of part 26.

Section 26.709 Applicability.

This proposed rule would add paragraph (b) to § 26.709, which would extend the requirements of subpart N of part 26 to licensees and other entities identified in § 26.3(f) that do not implement the requirements of subpart M of part 26, as well as licensees and other entities that implement the requirements of § 26.605(b).

Section 26.711 General provisions.

This proposed rule would revise § 26.711 to incorporate references to § 26.3(d) and (f).

Section 26.825 Criminal penalties.

The proposed rule would update § 26.825(b) to include a reference to the proposed § 26.601.

10 CFR part 30

Section 30.4 Definitions.

This proposed rule would revise the definition for “Utilization facility” in § 30.4 to include utilization facilities defined in the regulations under part 53 in addition to part 50.

Section 30.50 Reporting requirements.

This proposed rule would revise § 30.50 to include references to part 53 in addition to part 50.

10 CFR part 40

Section 40.60 Reporting requirements.

This proposed rule would revise § 40.60(c)(3) to include references to part 53 in addition to part 50 regarding reporting requirements.

10 CFR part 50

Section 50.11 Exceptions and exemptions from licensing requirements.

This proposed rule would revise § 50.11 to incorporate the appropriate references to part 53.

Section 50.47 Emergency plans.

This proposed rule would amend § 50.47 by revising paragraph (a)(1)(ii) to apply to COLs under part 53 and adding paragraphs (a)(1)(v) and (vi) regarding proposed emergency plans under part 53 in connection with an application for an ESP under part 53.

Appendix B to 10 CFR part 50 – Quality Assurance Criteria for Nuclear Power Plants and Ruel Reprocessing Plants

This proposed rule would revise appendix B to part 50 by revising the Introduction and the first paragraphs of section III, “Design Control,” and section IV,

“Procurement Document Control,” to incorporate the appropriate terminology and references for part 53.

10 CFR part 51

Section 51.20 Criteria for and identification of licensing and regulatory actions requiring environmental impact statements.

This proposed rule would revise § 51.20(b)(1) and (2) to require an environmental impact statement prior to the issuance of a CP, LWA, or ESP under part 53, or the issuance to renewal of a full power or design capacity license to operate a nuclear power reactor, testing facility, or fuel reprocessing plant under part 53.

Section 51.22 Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.

This proposed rule would revise § 51.22 to include corresponding references to part 53 in paragraphs (c)(3), (c)(9), (c)(12), (c)(17), (c)(22) and (23).

Section 51.26 Requirement to publish notice of intent and conduct scoping process.

This proposed rule would revise § 51.26(d) to add a reference to part 53.

Section 51.30 Environmental assessment.

This proposed rule would revise the introductory text to paragraph (a) and revise paragraphs (d) and (e) of § 51.30 to incorporate the appropriate references to part 53 regarding environmental assessments.

Section 51.31 Determinations based on environmental assessment.

This proposed rule would revise § 51.31(a) to include a reference to part 53.

Section 51.32 Finding of no significant impact.

This proposed rule would revise § 51.32(b)(1) and (3), finding there is no significant environmental impact associated with the issuance of standard DCs and MLs under part 53.

Section 51.49 Environmental report-limited work authorization.

This proposed rule would revise the introductory text of § 51.49(c) to require applicants for an ESP under part 53 requesting a LWA to include the environmental report required by § 51.50(b).

Section 51.50 Environmental report – construction permit, early site permit, or combined license stage.

This proposed rule would revise § 51.50, paragraphs (a), (b)(4), and the introductory text for paragraph (c) to incorporate the appropriate references to part 53.

Section 51.53 Postconstruction environmental reports.

This proposed rule would revise § 51.53(d) to include the appropriate references to part 53 regarding a license termination plan or decommissioning plan and related requirements for postconstruction environmental reports.

Section 51.54 Environmental report – manufacturing license.

This proposed rule would update § 51.54(a) to require applicants for MLs under part 53 to submit an environmental report with the application.

Section 51.55 Environmental report – standard design certification.

This proposed rule would update § 51.55(a) to require applicants for a standard DC under part 53 to submit an environmental report with the application.

Section 51.58 Environmental report – number of copies; distribution.

This proposed rule would revise § 51.58(b) to incorporate the appropriate references to part 53.

Section 51.77 Distribution of draft environmental impact statement.

This proposed rule would revise the introductory text for § 51.77(a) to add a reference to part 53.

Section 51.92 Supplement to the final environmental impact statement.

This proposed rule would revise § 51.92(b) to apply to COL applications referencing an ESP under part 53.

Section 51.95 Postconstruction environmental impact statements.

This proposed rule would revise the introductory text for § 51.95(c) to include a reference to part 53 regarding the Commission's obligations to prepare an environmental impact statement following the renewal of an operating or COL for a nuclear plant under part 53.

Section 51.101 Limitations on actions.

This proposed rule would revise § 51.101(a)(2) to include the corresponding references to part 53 where appropriate.

Section 51.103 Record of decision – general.

This proposed rule would update § 51.103(a)(6) to apply to the issuance of a LWA in connection with a CP or COL under part 53.

Section 51.105 Public hearings in proceedings for issuance of construction permits or early site permits; limited work authorizations.

This proposed rule would update § 51.105(c)(1) to include the appropriate reference to LWAs under part 53 for CPs or ESPs.

Section 51.107 Public hearings in proceedings for issuance of combined licenses; limited work authorizations.

This proposed rule would amend § 51.107 by revising the introductory text for paragraphs (a) and (b) and updating paragraph (d)(1) to include the appropriate corresponding references to part 53.

Section 51.108 Public hearings on Commission findings that inspections, tests, analyses, and acceptance criteria of combined licenses are met.

This proposed rule would revise § 51.108 to incorporate the appropriate references to part 53.

10 CFR part 53— RISK-INFORMED, TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK FOR COMMERCIAL NUCLEAR PLANTS

This proposed rule would add a new part 53, “Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants,” to Title 10, “Energy,” of the Code of Federal Regulations after part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.” The new part would provide an alternative licensing framework for commercial nuclear plants licensed under Section 103 of the AEA.

10 CFR part 55

Section 55.1 Purpose.

This proposed rule would revise § 55.1 to include a reference to part 53.

Section 55.2 Scope.

This proposed rule would revise § 55.2 to include references to part 53.

Section 55.5 Communications.

This proposed rule would revise § 55.1 to include references to part 53.

10 CFR part 70

Section 70.20a General license to possess special nuclear material for transport.

This proposed rule would revise § 70.20a(b) to include a reference to part 53.

Section 70.22 Contents of applications.

This proposed rule would revise § 70.22, paragraphs (b), (h)(1), (j)(1), and (k) to include the appropriate references to part 53.

Section 70.24 Criticality accident requirements.

This proposed rule would revise § 70.24, paragraphs (d)(1) and (2) to include the appropriate references to part 53.

Section 70.32 Conditions of licenses.

This proposed rule would revise § 70.32(c)(1) and (d) to incorporate the appropriate references to part 53.

Section 70.50 Reporting requirements.

This proposed rule would revise § 70.50(d) to clarify the applicability of the reporting requirements of this section to part 53 licensees.

10 CFR part 72

Section 72.3 Definitions.

This proposed rule would revise the definition of “Independent spent fuel storage installation or ISFSI” in § 72.3 to include a reference to facilities licensed under part 53.

Section 72.30 Financial assurance and recordkeeping for decommissioning.

This proposed rule would revise § 72.30(e)(5) to include the appropriate references to part 53.

Section 72.32 Emergency plan.

This proposed rule would revise § 72.32 to include a reference to the exclusion area as defined in part 53.

Section 72.40 Issuance of license.

This proposed rule would revise § 72.40(c) regarding the issuance of a license under part 72 to include a reference to previous licensing actions, including the issuance of a CP under part 53.

Section 72.75 Reporting requirements for specific events and conditions.

This proposed rule would revise § 72.75(i)(1)(ii) regarding reporting requirements for specific events and conditions with references to reactors licensed under part 53.

Section 72.184 Safeguards contingency plan.

This proposed rule would revise § 72.184 regarding the requirements of a licensee's safeguarding contingency plan with a reference to nuclear facilities licensed under part 53.

Section 72.210 General license issued.

This proposed rule would revise § 72.210 to issue a general license for the storage of spent fuel in an independent spent storage installation at power to persons authorized to possess or operate nuclear power reactors under part 53.

Section 72.212 Conditions of general license issued under § 72.210.

This proposed rule would revise § 72.212 regarding the conditions of a general license issued under § 72.210 to include a reference to license amendments for a facility made pursuant to part 53.

Section 72.218 Termination of licenses.

This proposed rule would revise § 72.218(a) to include a reference to the notification required under part 53 regarding the plan for managing spent fuel prior to decommissioning. It would also extend the provisions of § 72.218(b) to a reactor operating or COL under part 53.

10 CFR part 73

Section 73.1 Purpose and scope.

This proposed rule would revise § 73.1 to extend the scope of part 73 to production and utilization facilities licensed under part 53, in addition to parts 50 and 52.

Section 73.2 Definitions.

This proposed rule would revise § 73.2(a) such that terms defined in part 53 have the same meaning in part 73.

Section 73.8 Information collection requirements: OMB approval.

This proposed rule would revise § 73.8 with the new information collection requirements contained in proposed §§ 73.77, 73.100, 73.110, and 73.120.

Section 73.50 Requirements for physical protection of licensed activities.

This proposed rule would revise § 73.50 to exempt nuclear reactor facilities licensed under part 53, in addition to parts 50 and 52, from the requirements of this section.

Section 73.55 Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage.

This proposed rule would revise § 73.55, paragraphs (a)(4), (i)(4)(iii), (l)(1), (l)(7)(ii), (p)(1)(i), (r)(2), and (r)(4)(iii) to incorporate the appropriate references to part 53 regarding requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage.

Section 73.56 Personnel access authorization requirements for nuclear power plants.

This proposed rule would revise § 73.56(a)(3) to apply this section's personnel AA requirements to applicants for an OL or holders of a COL under part 53 who do not demonstrate compliance with certain requirements under part 53.

Section 73.57 Requirements for criminal history records checks of individuals granted unescorted access to a nuclear power facility, a non-power reactor, or access to Safeguards Information.

This proposed rule would revise § 73.57(a)(3) to incorporate the appropriate references to OLs granted under part 53 and Commission findings under § 53.1452(g) regarding the requirement for license applicants to submit fingerprints for all personnel with unescorted access.

Section 73.58 Safety/security interface requirements for nuclear power reactors.

This proposed rule would revise § 73.58(a) to extend the requirements of this section to part 53 licensees.

Section 73.67 Licensee fixed site and in-transit requirements for the physical protection of special nuclear material of moderate and low strategic significance.

This proposed rule would revise § 73.67(d) and (f) to include a reference to licensees authorized who are licensed to operate a nuclear power plant reactor pursuant to part 53.

Section 73.77 Cyber security event notifications.

This proposed rule would revise § 73.77, paragraphs (a), (b), (c)(6) and (7) regarding the notification process for cyber security events to include notifications for the declaration of an emergency class made in accordance with part 53.

Section 73.100 Technology-inclusive requirements for physical protection of licensed activities at commercial nuclear plants against radiological sabotage.

This proposed rule would add § 73.100, which would establish a performance-based regulatory framework for physical protection as an alternative to the prescriptive requirements of § 73.55, which also governs physical protection programs for part 50 and 52 licensees.

Section 73.110 Technology-inclusive requirements for protection of digital computer and communication systems and networks.

This proposed rule would add § 73.110, which would establish a consequence-based approach to cyber security and would require that part 53 licensees under Frameworks A and B demonstrate reasonable assurance that digital computer and communication systems and networks are adequately protected against cyberattacks in a manner that is commensurate with the potential consequences of those attacks.

Section 73.120 Access authorization program for commercial nuclear plants.

This proposed rule would add § 73.120, which would establish performance objectives as an alternative to compliance with the AA provisions of §§ 73.55, 73.56, and 73.57. This proposed rule would afford part 53 licensees additional flexibility in establishing an AA program that demonstrates compliance with the performance objectives and requirements of this section.

Section 73.1200 Notification of physical security events.

This proposed rule would revise § 73.1200, to add appropriate references to part 53 in paragraphs (o)(5)(i) and (o)(6)(i).

Section 73.1205 Written follow-up reports of physical security events.

This proposed rule would revise § 73.1205, to add appropriate references to part 53.

Appendix B to part 73 – General Criteria for Security Personnel

This proposed rule would revise appendix B to part 73 to state that terms defined in part 53 have the same meaning when used in this appendix.

10 CFR part 74

Section 74.31 Nuclear material control and accounting for special nuclear material of low strategic significance.

This proposed rule would revise § 74.31(a) to include a reference to production or utilization facilities licensed under part 53, in addition to parts 50 and 70.

Section 74.41 Nuclear material control and accounting for special nuclear material of moderate strategic significance.

This proposed rule would revise § 74.41(a) to include a reference to nuclear reactors licensed under part 53.

Section 74.51 Nuclear material control and accounting for strategic special nuclear material.

This proposed rule would revise § 74.51(a) to include a reference to nuclear reactors licensed under part 53.

10 CFR part 75

Section 75.4 Definitions.

This proposed rule would revise § 75.4 such that terms defined in § 53.020 have the same meaning when used in this part. The definition of “Facility” would also be revised to include any plant or location where more than 1 effective kilogram of nuclear material is licensed pursuant to part 53.

10 CFR part 95

Section 95.5 Definitions.

This proposed rule would revise the definition of “License” in § 95.5 to include those issued under part 53.

Section 95.39 External transmission of documents and material.

This proposed rule would revise § 95.39(a) to apply restrictions to the external transmission of documents and material containing classified information in connection with NRC licenses, certificates, standard design approvals, or standard DCs issued under part 53.

10 CFR part 140

Section 140.2 Scope.

This proposed rule would revise § 140.2(a)(1) and (2) to include part 53 applicants and licensees within the scope of part 140 regulations.

Section 140.10 Scope.

This proposed rule would revise § 140.10 to apply the provisions of subpart B to applicants or holders of a license to operate a nuclear reactor under part 53, as well as applicants and holders of a COL under part 53.

Section 140.11 Amounts of financial protection for certain reactors.

This proposed rule would revise § 140.11 to require the licensee's primary financial protection to cover all reactors in any case where a person is authorized under part 53 to operate two or more nuclear reactors at the same location.

Section 140.12 Amount of financial protection required for other reactors.

This proposed rule would revise § 140.12 to require the licensee's primary financial protection to cover all reactors in any case where a person is authorized under part 53 to operate two or more nuclear reactors at the same location.

Section 140.13 Amount of financial protection required of certain holders of construction permits and combined licenses under 10 CFR part 52.

This proposed rule would revise § 140.13 with the appropriate references to part 53 regarding the requirement for holders of a CP or COL under part 53 to obtain financial protection.

Section 140.20 Indemnity agreements and liens.

This proposed rule would revise § 140.20(a)(1)(i) and (ii) with appropriate references to part 53.

10 CFR part 150

Section 150.15 Persons not exempt.

The proposed rule would revise § 150.15, paragraphs (a)(7)(iii) and (a)(8) to add a reference to facilities licensed under parts 53 and 52.

10 CFR part 170

Section 170.3 Definitions.

The proposed rule would revise § 170.3 to incorporate references to part 53 into the definitions of “Manufacturing license,” “Part 55 Reviews,” “Power reactor,” and “Special projects.”

Section 170.12 Payment of fees.

The proposed rule would revise § 170.12(d)(1)(v) regarding special project fees in connection with Final Safety Analysis Reports to include part 53.

Section 170.21 Schedule of fees for production and utilization facilities, review of standard referenced design approvals, special projects, inspections, and import and export licenses.

The proposed rule would revise § 170.21, footnote 1 to include fees charged for approvals issued under the exemption provision in § 53.080.

Section 170.41 Failure by applicant or licensee to pay prescribed fees.

The proposed rule would revise § 170.41 to include a general reference to part 53 in connection with remedial actions that the Commission might take when an applicant or licensee fails to pay a prescribed fee required by this part.

10 CFR part 171

Section 171.3 Scope.

The proposed rule would revise § 171.3 to apply the provisions of this part to any person holding an OL for a power reactor licensed under part 53 or a COL issued under part 53.

Section 171.5 Definitions.

This proposed rule would revise the definitions of “Operating license” and “Power reactor” in § 171.5 to incorporate the appropriate references to part 53.

Section 171.15 Annual fees: Non-power production or utilization licenses, reactor licenses, and independent spent fuel storage licenses.

This proposed rule would revise § 171.15, paragraphs (a), (b)(2)(iii), (c)(1), and (d)(1) regarding annual fees that are applicable to part 53 licensees.

Section 171.17 Proration.

This proposed rule would revise § 171.17, paragraphs (a), (a)(1)(ii) and (a)(2) with references to part 53 licenses.

VIII. Regulatory Flexibility Certification

The Regulatory Flexibility Act of 1980 (RFA), as amended at 5 U.S.C. 601 *et seq*, requires that agencies consider the impact of their rulemakings on small entities and, consistent with applicable statutes, consider alternatives to minimize these impacts on the businesses, organizations, and government jurisdictions to which they apply.

In accordance with the Small Business Administration’s (SBA's) regulation at 13 CFR 121.903(c), the NRC has developed its own size standards for performing an RFA analysis and has verified with the SBA Office of Advocacy that its size standards are appropriate for NRC analyses. The NRC size standards at § 2.810, “NRC size standards,” are used to determine whether an applicant or licensee qualifies as a small

entity in the NRC's regulatory programs. Section 2.810 defines the following types of small entities:

Small business is a for-profit concern and is a— (1) Concern that provides a service or a concern not engaged in manufacturing with average gross receipts of $8.0 million or less over its last 5 completed fiscal years; or (2) Manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months.

Small organization is a not-for-profit organization which is independently owned and operated and has annual gross receipts of $8.0 million or less.

Small governmental jurisdiction is a government of a city, county, town, township, village, school district, or special district with a population of less than 50,000.

Small educational institution is one that is— (1) Supported by a qualifying small governmental jurisdiction; or (2) Not State or publicly supported and has 500 or fewer employees.

Number of Small Entities Affected

The NRC is currently not aware of any known small entities as defined in § 2.810 that are planning to apply for a commercial nuclear plant ESP, CP, OL, ML, or COL under part 53 that would be impacted by this proposed rule. Based on this finding, the NRC has preliminarily determined that the proposed rule would not have a significant economic impact on a substantial number of small entities.

Economic Impact on Small Entities

Depending on how the ownership and/or operating responsibilities for such an enterprise were structured, applicants for a commercial nuclear plant rated 8 Megawatts electric (MWe) or less could conceivably qualify small entities as defined by § 2.810. Owners that operate power reactors rated greater than 8 MWe could generate sufficient

electricity revenue that exceeds the gross annual receipts limit of $8 million, assuming a 90 percent capacity factor and the June 2021 DOE's Energy Information Administration U.S. average price of electricity to the ultimate customer for all sectors of 11.3 cents per kilowatt-hour.

Although the NRC is not aware of any small entities that would be affected by the proposed rule, there is a possibility that future applications for a commercial nuclear plant permit or license could be submitted by small entities who plan to own and operate a commercial nuclear plant rated 8 MWe or less. Commercial nuclear plants that are rated 8 MWe or less would most likely be used to support electrical demand for military bases or small remote towns and would provide process heat, so they would not directly compete with a larger commercial nuclear plant that would typically produce electricity for the grid. As a result of these differing purposes, the NRC would expect that small and large entities would not be in direct competition with each other.

Therefore, the NRC preliminarily concludes that this proposed rule would not have a significant economic impact on a substantial number of small entities.

Request for Comments

The NRC is seeking comments on both its initial RFA analysis and on its preliminary conclusion that this proposed rule would not have a significant economic impact on a substantial number of small entities because of the likelihood that most expected applicants would not qualify as a small entity. Additionally, the NRC is seeking comments on its preliminary conclusion that if a small entity were to submit a commercial nuclear plant application, the small entity would not incur a significant economic impact as it would most likely not be in competition with a large entity.

Any small entity that could be subject to this regulation that determines, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this opinion in a comment that indicates—

1. The applicant's size and how the proposed regulation would impose a significant economic burden on the applicant as compared to the economic burden on a larger applicant;

2. How the proposed regulations could be modified to take into account the applicant's differing needs or capabilities;

3. The benefits that would accrue or the detriments that would be avoided if the proposed regulations were modified as suggested by the applicant;

4. How the proposed regulation, as modified, would more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individual or group; and

5. How the proposed regulation, as modified, would still adequately demonstrate compliance with the NRC's obligations under the AEA.

IX. Regulatory Analysis

The NRC has prepared a draft regulatory analysis for this proposed rule. The analysis examines the costs and benefits of the alternatives considered by the NRC. The conclusion from the analysis is that this proposed rule and associated guidance would result in net averted costs to the industry and the NRC of $ 26.1 million using a 7-percent discount rate and $ 31.9 million using a 3-percent discount rate due to reductions in exemption requests. The analysis also assumes one applicant under part 53. As the number of applicants increases, so do the estimated averted costs. The NRC requests public comment on the draft regulatory analysis, which is available as indicated in the "Availability of Documents" section of this document. Comments on the draft

regulatory analysis may be submitted to the NRC as indicated under the ADDRESSES caption of this document.

X. Backfitting and Issue Finality

This section describes the backfitting and issue finality implications of this proposed rule and the draft guidance documents described in section XVIII, “Availability of Guidance,” in this document, as applied to pertinent NRC approvals and certain applicants that reference NRC approvals in their applications. The NRC’s current backfitting provisions associated with nuclear power plants appear in § 50.109, “Backfitting,” and apply to CPs and OLs under part 50 as well as design approvals, MLs and COLs under part 52. Issue finality provisions (analogous to the backfitting provisions in § 50.109) for approvals under part 52 are located in various provisions of part 52. NRC Management Directive 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,” describes the Commission’s policies on backfitting and issue finality.

This proposed rule would provide a regulatory scheme for entities to apply for approvals under part 53. The part 50 backfitting provisions and part 52 issue finality provisions apply to actions taken by the NRC under part 50 or part 52, respectively, or actions taken by the NRC under other parts of 10 CFR chapter I that, for holders of certain approvals under part 50 or part 52, inextricably affect their activities regulated under part 50 or part 52. Issuance and implementation of proposed part 53 would not constitute actions taken under part 50 or part 52. Also, proposed part 53 would not allow an applicant to reference approvals issued under part 50 or part 52. Therefore, the issuance and implementation of proposed part 53 would not affect part 50 or part 52 entities’ activities regulated under part 50 or part 52. Therefore, the addition of part 53

through this proposed rule would not be within the scope of the part 50 backfitting and part 52 issue finality provisions.

The NRC also proposes conforming changes to parts 1, 2, 10, 11, 19, 20, 21, 25, 26, 30, 40, 50, 51, 55, 70, 72, 73, 74, 75, 95, 140, 150, 170, and 171 to reflect the addition of part 53. These changes would not meet the definition of "backfitting" in § 50.109 or § 70.76, "Backfitting," because the proposed changes would not modify or add to the systems, structures, components, or design of a facility or to the procedures or organization required to operate a facility under part 50 or 70. These changes would not meet the definition of "backfitting" in § 72.62, "Backfitting," because the proposed changes would not add, eliminate, or modify the SSCs of an ISFSI or the procedures or organization required to operate an ISFSI. These proposed changes would not inextricably affect activities regulated under parts 50, 52, 70, or 72. Therefore, the proposed changes to parts 1, 2, 10, 11, 19, 20, 21, 25, 26, 30, 40, 50, 51, 55, 70, 72, 73, 74, 75, 95, 140, 150, 170, and 171 would not constitute backfitting under parts 50, 70, or 72 or affect the issue finality of an approval under part 52.

The NRC is issuing 10 draft guidance documents that, if issued as final guidance documents, would provide guidance on the methods acceptable to the NRC for complying with aspects of this proposed rule. These documents would not apply to holders of approvals issued under part 50 or part 52. Further, as discussed in the guidance documents, applicants and licensees would not be required to comply with the positions set forth in the guidance. Therefore, issuance of the guidance documents as final guidance would not constitute backfitting under part 50 or affect the issue finality of any approval issued under part 52.

XI. Cumulative Effects of Regulation

The NRC seeks to minimize any potential negative consequences resulting from the cumulative effects of regulation (CER). The CER describes the challenges that licensees, or other impacted entities such as State partners, may face while implementing new regulatory positions, programs, or requirements (e.g., rules, generic letters, backfits, inspections). The CER is an organizational effectiveness challenge that may result from a licensee or impacted entity implementing a number of complex regulatory actions, programs, or requirements within limited available resources. The NRC's CER process involved engaging with external stakeholders throughout this proposed rule and related regulatory activities. Public involvement has included numerous public meetings to examine the part 53 risk-informed, technology-inclusive requirements for commercial nuclear plants and the publication of numerous versions of preliminary proposed rule language. The NRC is considering holding additional public meetings during the remainder of the rulemaking process.

In parallel with this proposed rule, the NRC is issuing 10 draft implementing guidance documents for comment to support informed external stakeholder feedback. Section XVIII, "Availability of Guidance," of this document describes how the public can access the draft implementing guidance.

In addition to the questions in the "Specific Requests for Comments" section of this document, the NRC is requesting CER feedback on the following questions:

1. In light of any current or projected CER challenges, does the proposed rule's effective date provide sufficient time to implement the new proposed requirements, including changes to programs, procedures, and the facility?

2. If CER challenges currently exist or are expected, what should be done to address them? For example, if more time is required for implementation of the new requirements, what period of time is sufficient?

3. Do other (NRC or other agency) regulatory actions (e.g., orders, generic communications, license amendment requests, inspection findings of a generic nature) influence the implementation of the proposed rule's requirements?

4. Are there unintended consequences? Does the proposed rule create conditions that would be contrary to the proposed rule's purpose and objectives? If so, what are the unintended consequences, and how should they be addressed?

5. Please comment on the NRC's cost and benefit estimates in the regulatory analysis that supports this proposed rule. The draft regulatory analysis is available as indicated under the "Availability of Documents" section of this document.

XII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998 (63 FR 31885). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

XIII. Environmental Assessment and Proposed Finding of No Significant Environmental Impact

The Commission has preliminarily determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and an environmental impact statement is not

required. The implementation of the proposed rule requirements does not have a significant impact on the environment. The proposed rulemaking would either have requirements that are administrative in application, matters of procedure, or provide an equivalent level of safety as existing requirements; therefore, there would be similar environmental impacts from the implementation of the part 53 regulations as there are for existing requirements.

The preliminary determination of this environmental assessment is that there will be no significant effect on the quality of the human environment from this action. Public stakeholders should note, however, that comments on any aspect of this environmental assessment may be submitted to the NRC as indicated under the ADDRESSES caption. The environmental assessment is available as indicated under the “Availability of Documents” section.

The NRC has sent a copy of the environmental assessment, and this proposed rule to every State Liaison Officer and has requested comments.

XIV. Paperwork Reduction Act

This proposed rule contains new collections of information contained in parts 26, 53, and 73 and NRC Forms 361S, 366, 366A, 366B, 893, and 894 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). The collections of information have been submitted to the OMB for review and approval. The proposed changes to parts 2, 10, 11, 19, 20, 21, 25, 30, 40, 50, 51, 55, 70, 72, 74, 75, 95, 140, 150, 170, and 171 do not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995. Existing collections of information were approved by the OMB, approval numbers 3150-0062 (part 11), 3150-0044 (part 19), 3150-0014 (part 20), 3150-0035 (part 21), 3150-0046 (part 25), 3150-0017 (part 30), 3150–0020 (part 40), 3150–0011 (part 50), 3150-0021 (part 51), 3150-0024 (part 55), 3150-0090 (part 55), 3150-0009

(part 70), 3150–0132 (part 72), 3150-0123 (part 74), 3150–0055 (part 75), 3150-0047 (part 95), 3150-0039 (part 140), and 3150-0032 (part 150).

Type of submission, new or revision: Revision and new.

The title of the information collection: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors.

The form number if applicable: NRC Forms 361S, 366, 366A, 366B, 893, and 894.

How often the collection is required or requested: Once, on occasion, every 30 days, biannually, annually, biennially, every four years, every five years, every ten years.

Who will be required or asked to respond: Part 53 commercial nuclear plant licensees and license applicants for commercial nuclear plants to be licensed under part 53.

An estimate of the number of annual responses: 30. (3 responses for Part 26, 27 responses for Part 53, and 0 responses for Part 73 and NRC Forms 361S, 366, 366A, 366B, 893, and 894)

The estimated number of annual respondents: 6 (3 respondents for Part 26, 6 respondents for Part 53, and 0 respondents for Part 73 and NRC Forms 361S, 366, 366A, 366B, 893, and 894)

An estimate of the total number of hours needed annually to comply with the information collection requirement or request: 377,059 hours. (984 hours for Part 26, 376,075 hours for Part 53, and 0 hours for Part 73 and NRC Forms 361S, 366, 366A, 366B, 893, and 894)

Abstract: The NRC is proposing to establish an optional technology-inclusive regulatory framework for use by applicants for new commercial nuclear plant designs. The regulatory requirements developed in this rulemaking would use methods of evaluation, including risk-informed and performance-based methods, that are flexible and practicable for application to a variety of new reactor technologies. The NRC's goals in

amending these regulations are to continue to provide reasonable assurance of adequate protection of public health and safety and the common defense and security at reactor sites at which new nuclear reactor designs are deployed to at least the same degree of protection as required for current-generation LWRs; protect health and minimize danger to life or property to at least the same degree of protection as required for current-generation LWRs; provide greater operational flexibilities where supported by enhanced margins of safety that may be provided in new nuclear designs; and promote regulatory stability, predictability, and clarity.

The proposed rule covers diverse topics across one alternative licensing frameworks that result in recordkeeping and reporting requirements related to contents of applications, plant design and analysis, siting, construction and manufacturing, licensing basis information, facility operations, programs, staffing, FFD, physical security, cyber security, AA, decommissioning, and quality assurance.

In addition to the new information collections in the proposed regulations, part 53 would result in new collections via NRC Forms 361S, 366, 366A, 366B, 893, and 894. NRC Forms 366, 366A, and 366B would be modified to include part 53 reportable events covering an equivalent scope as the requirements in 10 CFR 50.73, but without LWR-specific terminology to ensure technology-inclusiveness. The proposed rule also would require part 53 licensees to use NRC Forms 893 and 894 to report on positive drug and alcohol test results (NRC Form 893) and annual fitness-for-duty program performance (NRC Form 894). Finally, a new version of NRC Form 361 (NRC Form 361S) would be created for use by Part 53 licensees, covering an equivalent scope as the requirements in 10 CFR 50.72, but without LWR-specific terminology to ensure technology-inclusiveness.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility? Please explain your response.

2. Is the estimate of the burden of the proposed information collection accurate? Please explain your response.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected? Please explain your response.

4. How can the burden of the proposed information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology? Please explain your response.

The OMB clearance documents and proposed rule is available as indicated under the “Availability of Documents” section in this document or may be viewed free of charge by contacting the NRC’s PDR reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.resource@nrc.gov. You may obtain information and comment submissions related to the OMB clearance package by searching on http://www.regulations.gov under Docket ID NRC-2019-0062.

You may submit comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by the following methods:

- **Federal rulemaking website:** Go to http://www.regulations.gov and search for Docket ID NRC-2019-0062.
- **Mail comments to:** FOIA, Library, and Information Collections Branch, Office of the Chief Information Officer, Mail Stop: T6-A10M, U.S. Nuclear Regulatory

Commission, Washington, DC 20555-0001 or by e-mail to Infocollects.Resource@nrc.gov or to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-XXXX, 3150-0002, -0104, -0146, -0238), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: oira_submission@omb.eop.gov.

Submit comments by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XV. Criminal Penalties

For the purposes of Section 223 of the AEA, the NRC is issuing this proposed rule that would add a new part 53 and amend parts 26 and 73 under one or more of Sections 161b, 161i, or 161o of the AEA, except as noted in proposed § 53.9010(b) and § 26.825(b). Willful violations of the part 53 and part 26 regulations not listed in proposed § 53.9010(b) and § 26.825(b) would be subject to criminal enforcement. Criminal penalties as they apply to regulations in part 53 would be discussed in § 53.9010.

XVI. Voluntary Consensus Standards

The NTTAA requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC would revise regulations by adding a risk-informed, technology-inclusive

regulatory framework for commercial advanced nuclear reactors. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XVII. Availability of Guidance

As discussed in the section II, Background, the NRC's development of proposed part 53 built upon recent and ongoing activities such as those described in SECY-19-0117. Because a number of those activities are ongoing to support new reactor applications under the existing regulatory framework of 10 CFR parts 50 and 52, the NRC staff identified in its response to SRM-SECY-20-0032 that the timing of guidance document development to support the part 53 rulemaking was a key risk and uncertainty to publishing the final part 53 rule. To mitigate this risk, the NRC engaged external stakeholders to ensure a common prioritization of the development of these guidance documents and to work diligently on those that would be needed to support this rulemaking, forthcoming applications, or broader efforts such as the Advanced Reactor Demonstration Program being sponsored by the DOE. The NRC also recognizes that guidance development to support part 53 and advanced reactors will continue as the industry and NRC learn lessons from licensing reviews and operating experience. Therefore, the NRC categorized guidance supporting the part 53 rulemaking into four categories: (1) guidance issued to support applications under the existing regulatory framework; (2) guidance under development to support applications under the existing regulatory framework; (3) implementing guidance for part 53-specific proposed rule language; and (4) future guidance activities that would need to be completed after the part 53 proposed rule is published for public comment.

(1) Hundreds of guidance documents exist for the current fleet of operating reactors. While some of the guidance is specific to LWR technologies, other guidance is

technology-inclusive in nature and should be considered, as appropriate, in the development of all licensing applications and NRC reviews. In addition, the NRC has undertaken efforts to incorporate or reference the most relevant guidance in its efforts to develop additional guidance for future advanced reactors. The NRC has issued the following guidance to support licensing reviews of advanced reactors under the existing regulatory framework that will continue to inform applicant development and NRC reviews under parts 50 and 52. Conforming changes to these guidance documents would be needed to ensure they are applicable under part 53. The NRC will issue revisions to these guidance documents for public comment after the publication of this proposed rule and then finalize and issue the guidance documents with or after the final part 53 rule.

- RG 1.233, “Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light Water Reactors”
- RG 1.232, “Guidance for Developing Principal Design Criteria for Non-Light Water Reactors”
- RG 1.247 for trial use, “Acceptability of Probabilistic Risk Assessment Results for Non-Light-Water Reactor Risk-Informed Activities”
- NUREG-2246, “Fuel Qualification for Advanced Reactors”
- RG 1.87, Revision 2, “Acceptability of ASME Code, Section III, Division 5, “High Temperature Reactors”
- RG 1.246, “Acceptability of ASME Code, Section XI, Division 2, ‘Requirements for Reliability And Integrity Management (RIM) Programs for Nuclear Power Plants,’ for Non-Light Water Reactors”

(2) The NRC is developing additional guidance to support licensing reviews of advanced reactors under the existing regulatory framework. These guidance documents will be issued before the finalization of part 53 to support near-term applicants and NRC reviews. Conforming changes to these documents would be needed to ensure they are applicable under part 53, and these revisions would occur between publication of the proposed rule and the final rule. The NRC is currently engaged with the DOE and industry to develop content of application guidance for advanced reactors, initially developed to support applications under the existing regulatory framework. These guidance documents, the industry-led Technology-Inclusive Content of Application Project (TICAP) guidance found in NEI 21-07 and the NRC-led Advanced Reactor Content of Application Project (ARCAP) interim staff guidance (ISG) documents, will support developers in preparing advanced reactor applications and facilitate the NRC's review of applications for CPs, OLs, COLs, MLs, standard design approval, and DCs under part 53. These guidance documents provide an overview of the information that should be included in an advanced reactor application, a review roadmap for the NRC with the principal purpose of ensuring consistency, quality, and uniformity of NRC reviews, and a well-defined base from which the NRC can evaluate proposed changes in the scope and requirements of reviews. While specific sections of the information are primarily aligned with the LMP methodology, as endorsed in RG 1.233, as one acceptable process for applicants to use when developing portions of an application, the concepts and general information may be used to inform the review of an application submitted using other traditional licensing approach methodologies (as applicable). Other sections of the information are generally applicable and independent of the methodology used to develop an advanced reactor application. The ARCAP ISGs provide references to numerous regulatory guidance documents that should be

considered by both applicants and the NRC in developing and reviewing, respectively, advanced reactor applications. The NRC will issue the following documents for public comment separately from this proposed rule and then finalize and issue the guidance documents with or after the final part 53 rule.

- DG-1404, “Guidance for a Technology Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors”
- DANU-ISG-2022-01, “Advanced Reactor Content of Application Project, ‘Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications – Roadmap’”
- DANU-ISG-2022-02, “Advanced Reactor Content of Application Project Chapter 2, ‘Site Information’”
- DANU-ISG-2022-03, “Advanced Reactor Content of Application Project Chapter 9, ‘Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste’”
- DANU-ISG-2022-04, “Advanced Reactor Content of Application Project Chapter 10, ‘Control of Occupational Dose’”
- DANU-ISG-2022-05, “Advanced Reactor Content of Application Project Chapter 11, ‘Organization and Human-System Considerations’”
- DANU-ISG-2022-06, “Advanced Reactor Content of Application Project Chapter 12, ‘Post-Construction Inspection, Testing, and Analysis Program’”
- DANU-ISG-2022-07, “Advanced Reactor Content of Application Project, ‘Risk-Informed Inservice Inspection/Inservice Testing’”
- DANU-ISG-2022-08, “Advanced Reactor Content of Application Project, ‘Risk-Informed Technical Specifications’”

- DANU-ISG-2022-09, “Advanced Reactor Content of Application Project, ‘Risk-Informed, Performance-Based Fire Protection Program (for Operations)’”
- DG-1350 (RG 1.242), “Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities”
- RG 4.7, “General Site Suitability Criteria for Nuclear Power Stations”

(3) The NRC is issuing for comment ten draft guidance documents for the implementation of the proposed requirements in this rulemaking. The guidance is available in ADAMS under the Accession Numbers as indicated under the “Availability of Documents” section in this document. Comments on this draft regulatory guidance may be submitted by the methods outlined in the ADDRESSES section of this document. Interested persons may obtain information and comment submissions related to the draft guidance by searching on http://www.regulations.gov under Docket ID NRC-2019-0062.

- DG-1413, “Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants”

This DG describes an acceptable approach for identifying licensing events that can be used to inform the design basis, licensing basis, and content of applications for commercial nuclear plants, including large LWRs and non-LWRs. It applies to nuclear power reactor designers, applicants, and licensees of commercial nuclear plants applying for permits, licenses, certifications, and approvals under parts 50, 52, and 53. In this DG, the term “licensing events” is used in a generic sense to refer to collections of designated event categories such as, but not limited to AOOs, DBAs, DBEs, and postulated accidents. Specifically, this DG provides an acceptable approach for: (1) conducting a comprehensive and systematic search for initiating events; (2) using a

systematic process to delineate a comprehensive set of event sequences; (3) grouping initiating events and event sequences into designated licensing event categories; and (4) providing assurance that the set of licensing events is complete.

- DG-1414, “Alternative Evaluation for Risk Insights Methodology”

This DG describes an acceptable approach for performing an AERI. Applicants for permits, licenses, certifications, and approvals under part 53 may elect to develop an AERI in lieu of a PRA when the AERI entry conditions are met. Specifically, this DG provides an acceptable approach to: (1) identifying and characterizing a bounding event or events; (2) confirming that the commercial nuclear plant design demonstrate compliance with the AERI entry conditions by determining a dose estimate for the bounding event or events; (3) developing a demonstrably conservative risk estimate for the bounding event to show that the Commission’s safety goals and associated QHOs as stated in “Safety Goals for the Operation of Nuclear Power Plants,” (51 FR 28044; August 4, 1986 as corrected and republished at 51 FR 30028; August 21, 1986) are met; (4) searching for severe accident vulnerabilities for the entire set of licensing events; (5) identifying risk insights for the entire set of licensing events; (6) assessing defense in depth adequacy for the entire set of licensing events; (7) maintaining and upgrading the AERI; (8) considering application-specific aspects such as developing an AERI to support a CP application when an applicant may have a conceptual design that does not include sufficient information to demonstrate that AERI entry conditions are met at the time of application; and (9) addressing procedural and other non-technical aspects such as independent review and the use of expert opinion.

- DG-5073, “Fitness For Duty Programs for Commercial Nuclear Plants And Manufacturing Facilities Licensed Under 10 CFR Part 53”

This DG describes guidance for applicants under part 53 and licensees and other entities described in § 26.3(f) who would elect to or be required to implement FFD programs for facilities licensed under part 53. The FFD program requirements would be detailed in subpart M of part 26 and involve, in part, policies, procedures, drug and alcohol testing, laboratory requirements, behavioral observation, MRO responsibilities, fitness determinations, reporting, and recordkeeping. The FFD program for facilities licensed under part 53 subject to part 26 would also include requirements for a PMRP and FFD program change control that licensees or other entities must implement to maintain an effective FFD program.

- DG-5074, “Access Authorization Program for Commercial Nuclear Plants”

This DG describes a method that the staff considers acceptable to comply with requirements in proposed § 73.120, “Access authorization program for commercial nuclear plants,” related to an AA program. This document provides guidance and would be one NRC-approved method (not the only method) for meeting regulatory requirements for part 53. The proposed language in § 73.120 would provide flexibility through availability of the use of an alternate approach, commensurate with risk and consequence to public health and safety, for part 53 applicants who demonstrate in an analysis that the offsite consequences satisfy the criterion defined in proposed § 53.860(a)(2)(i).

- DG-5075, “Establishing Cyber Security Programs for Commercial Nuclear Plants Licensed Under 10 CFR Part 53”

This DG describes an approach the NRC staff deems acceptable for complying with the Commission’s proposed regulations for establishing, implementing, and maintaining a cyber security program at commercial nuclear plants that would be licensed under part 53. This guidance provides an approach for meeting the

requirements of proposed § 73.110, “Technology-inclusive requirements for protection of digital computer and communication systems and networks.”

- DG-5076, “Guidance for Technology Inclusive Requirements For Physical Protection Of Licensed Activities At Commercial Nuclear Plants”

This DG describes methods and approaches that the NRC staff considers acceptable for meeting the proposed physical security requirements of part 53 and § 73.100. The guidance is intended to provide methods and considerations for complying with § 53.440(f) safety and security design process considerations, determining eligibility for meeting the performance criterion in § 53.860 to relieve the applicant from the applicable requirements to defend against radiological sabotage outlined in § 73.55 or § 73.100, and (if the required analysis for eligibility is not satisfied) applying the physical security requirements of § 73.100 as an alternative pathway from § 73.55 for protection against radiological sabotage.

- DG-5078, “Fatigue Management For Nuclear Power Plant Personnel At Commercial Nuclear Plants Licensed Under 10 CFR Part 53”

This DG describes proposed methods that the NRC staff considers acceptable for addressing certain aspects of FFD programs that would be established at commercial nuclear facilities licensed under part 53. This guidance, in conjunction with the existing RG 5.73, “Fatigue Management for Nuclear Plant Personnel,” would provide comprehensive guidance regarding acceptable methods for the development and implementation of licensee fatigue-management programs.

The NRC is issuing for public comment the following draft ISG documents for the implementation of NRC staff review of applications under the proposed requirements in this rulemaking:

- DRO-ISG-2023-01, “Operator Licensing Programs”

This draft ISG provides guidance for the review of tailored operator licensing programs that are submitted for review consistent with the technical requirements of proposed § 53.730(g). This guidance primarily addresses the review of operator licensing examination processes to facilitate the ability of reviewers to assess whether a proposed approach to the testing of licensed operators and trainees reflects sound assessment testing practices that are suitable for the screening of competent licensed operators. Additionally, this ISG provides further review guidance in other areas such as licensed operator continuing training and proficiency programs.

- DRO-ISG-2023-02, "Interim Staff Guidance Augmenting NUREG-1791, 'Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m),' for Licensing Commercial Nuclear Plants under 10 CFR Part 53"

This draft ISG provides guidance for the review of customized facility operator staffing plans that are submitted for review consistent with the technical requirements of proposed § 53.730(f). This ISG is structured as a companion document to the existing NUREG-1791 and adapts the existing HFE-based methodologies of that document for use in the evaluation of staffing plans that would be submitted within the context of part 53 facilities. Additionally, this ISG provides further guidance to address other staffing-related considerations, such as provisions for engineering expertise.

- DRO-ISG-2023-03, "Development of Scalable Human Factors Engineering Review Plans"

This draft ISG applies to the HFE review of applications for OLs, COLs, DCs, and standard design approvals for commercial nuclear plants submitted under proposed part 53. The purpose of this ISG is to facilitate NRC understanding of an acceptable method for developing a scalable (i.e., application-specific) plan for the review of these

applications for compliance with applicable HFE requirements. The ISG describes a process and provides implementation guidance for the NRC to tailor HFE review plans to each application to achieve an effective and efficient review.

(4) The NRC has identified future guidance activities that would need to be completed after the part 53 proposed rule is published for public comment to support advanced reactor applications and NRC reviews.

Accordingly, the NRC has prioritized development of content of application guidance that would serve the same purpose as the TICAP and ARCAP efforts underway to support applications under part 53. The NRC has not yet initiated the development of these guidance documents but will engage stakeholders during the development of these documents to ensure common prioritization. In addition, the NRC works with standards development organizations, advanced reactor developers, DOE, and other stakeholders to identify and facilitate new consensus codes and standards needed for advanced reactor development. The NRC will continue its membership and participation on standards development committees and working groups to support standards for advanced reactor technologies, where appropriate.

XVIII. Public Meeting

The NRC will conduct a public meeting on this proposed rule for the purpose of describing the proposed rule and implementation guidance to the public and answering questions from the public on the proposed rule and implementation guidance.

The NRC will publish a notice of the public meeting's location, time, and agenda on the NRC's public meeting Web site at least 10 calendar days before the meeting. Stakeholders should monitor the NRC's public meeting Web site for information about the public meeting at: http://www.nrc.gov/public-involve/public-meetings/index.cfm.

XIX. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS Accession No. / Web link / *Federal Register* Citation
Proposed Rule Documents	
SECY-23-XXXX, "Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31)," <INSERT DATE>	ML21162A095
SECY-23-XXXX, Enclosure 2, "Draft Environmental Assessment for the Proposed Rule—Risk Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," <INSERT DATE>	ML21162A104
SECY-23-XXXX, Enclosure 3, "Draft Regulatory Analysis for the Proposed Rule: Risk Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," <INSERT DATE>	ML21165A112
SECY-23-XXXX, Enclosure 4, "Alternative Approaches Considered for Selected Topics During the Development of 10 CFR Part 53"	ML22244A001
SECY-23-XXXX, Enclosure 5, "Estimated Resources For The Risk-Informed, Technology-Inclusive Regulatory Framework For Advanced Reactors Rulemaking"	ML22304A099 (non-public)
Information Collection Documents	
Draft Supporting Statement for Information Collection Analysis – 10 CFR Part 53	ML21162A109
Draft Supporting Statement for Information Collection Analysis – 10 CFR Part 26	ML23030A400
Draft Supporting Statement for Information Collection Analysis – 10 CFR Part 73	ML23030A576
Draft NRC Form 361S, "Part 53 Plant Event Notification Worksheet"	ML23032A443
Draft NRC Form 366, "Licensee Event Report (LER)"	ML23032A445
Draft NRC Form 366A, "Licensee Event Report (LER) Continuation Sheet"	ML23032A447
Draft NRC Form 366B, "Licensee Event Report (LER) (Failure Continuation)"	ML23032A454
Draft NRC Form 893, "10 CFR Part 26, Subpart M, Single FFD Policy Violation Form"	ML23032A435

Draft NRC Form 894, “10 CFR Part 26, Subpart M, Annual Reporting Form for FFD Performance Information”	ML23032A439
Draft Regulatory Guidance Documents	
DG-1413, “Technology-Inclusive Identification Of Licensing Events For Commercial Nuclear Plants,” <INSERT DATE>	ML22257A173
DG-1414, "Alternative Evaluation for Risk Insights Methodology," <INSERT DATE>	ML22257A248
DG-5073, “Fitness-For-Duty Programs For Commercial Nuclear Plants And Manufacturing Facilities Licensed Under 10 CFR Part 53,” <INSERT DATE>	ML22200A037
DG-5074, “Access Authorization Program for Commercial Nuclear Plants,” <INSERT DATE>	ML22199A246
DG-5075, “Establishing Cyber Security Programs For Commercial Nuclear Plants Licensed Under 10 CFR Part 53,” <INSERT DATE>	ML22199A257
DG-5076, “Guidance for Technology Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants,” <INSERT DATE>	ML22203A131
DG-5078, “Fatigue Management For Nuclear Power Plant Personnel At Commercial Nuclear Plants Licensed Under 10 CFR Part 53,” <INSERT DATE>	ML22264A109
Draft ISG Documents	
Draft ISG DRO-ISG-2023-01, “Operator Licensing Programs,” <INSERT DATE>	ML22266A066
Draft ISG DRO-ISG-2023-02, “Interim Staff Guidance Augmenting NUREG-1791, ‘Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m),’ for Licensing Commercial Nuclear Plants under 10 CFR Part 53,” <INSERT DATE>	ML22266A068
Draft ISG DRO-ISG-2023-03, “Development of Scalable Human Factors Engineering Review Plans,” <INSERT DATE>	ML22266A072
Other References	
American National Standards Institute/ANS-3.4-2013, “Medical Certification And Monitoring Of Personnel Requiring Operator Licenses For Nuclear Power Plants”	https://webstore.ansi.org/Standards/ANSI/ansians2013

ASME/ANS RA-S-1.4-2021, "Probabilistic Risk Assessment Standard for Advanced Non-Light Water Reactor Nuclear Power Plants"	https://www.asme.org/codes-standards/find-codes-standards/ra-s-1-4-probabilistic-risk-assessment-standard-advanced-non-light-water-reactor-nuclear-power-plants/2021/drm-enabled-pdf
ASCE/SEI 43-19, "Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities"	https://doi.org/10.1061/9780784415405
Federal Register notice—Final policy statement, "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement," dated August 16, 1995	60 FR 42622
Federal Register notice—Final rule, "Fitness-for-Duty Programs," dated June 7,1989	54 FR 24473
Federal Register notice—Final rule, "Fitness for Duty Programs," dated March 31, 2008	84 FR 16970
Federal Register notice—Final rule, "Licenses, Certifications, and Approvals for Nuclear Power Plants," dated August 28, 2007	72 FR 49351
Federal Register notice—Final rule, "Loss of all alternating current power," dated June 21, 1988	52 FR 23203
Federal Register notice—Final rule, "Technical Specifications," dated July 19,1995	60 FR 36953, 36955
Federal Register notice—Guidance, "Mandatory Guidelines for Federal Workplace Drug Testing Programs," dated January 23, 2017	82 FR 7920
Federal Register notice—Guidance, "Mandatory Guidelines for Federal Workplace Drug Testing Programs – Oral/Fluid," dated October 25, 2019	84 FR 57554
Federal Register notice—Policy Statement, "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants," dated August 8, 1985	50 FR 32138
Federal Register notice—Policy Statement, "Safety Goals for the Operation of Nuclear Power Plants; Policy Statement; Correction and Republication," dated August 21, 1986	51 FR 30028
Federal Register notice—Policy Statement, "Tribal Policy Statement," dated January 9, 2017	82 FR 2402

Federal Register notice—Policy Statement, "Policy Statement on the Regulation of Advanced Reactors," dated October 14, 2008	73 FR 60612
Federal Register notice—Policy Statement, "Final Safety Culture Policy Statement," dated June 14, 2011	76 FR 34773
Federal Register notice—Proposed rule, "Emergency Preparedness for Small Modular Reactors and Other New Technologies," dated May 12, 2020	85 FR 28436
Federal Register notice—Proposed rule, "Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning," dated March 3, 2022	87 FR 12254
Federal Register notice—Public meeting, "Reporting Requirements for Nonemergency Events at Nuclear Power Plants," dated November 29, 2021	86 FR 67669
ICRP, Publication 2 "Permissible dose for internal radiation," dated 1960	https://www.icrp.org/publication.asp?id=icrp%20publication%202
ICRP, Publication 26 "Recommendations of the ICRP," dated 1977	https://www.icrp.org/publication.asp?id=ICRP%20Publication%2026
ICRP, Publication 30 "Limits for Intakes of Radionuclides by Workers," dated 1979	https://www.icrp.org/publication.asp?id=ICRP%20Publication%2030%20(Index)
Letter to Chairman Hanson, NRC, "Final Letter on Draft 10 CFR Part 53 Rulemaking Language," dated November 22, 2022	ML22319A104
Letter to Chairman Hanson, NRC, "Fourth Interim Letter on 10 CFR Part 53 Rulemaking Language," dated August 2, 2022	ML22196A292
Letter to Chairman Hanson, NRC, "Preliminary Proposed Rule Language For 10 CFR Part 53, Regulation of Advanced Nuclear Reactors, Interim Report," dated May 30, 2021	ML21140A354
Letter to Chairman Hanson, NRC, "Preliminary Rule Language For 10 CFR Part 53, Subpart F, 'Requirements for Operations,' Interim Report.," dated February 17, 2022	ML22040A361
Letter to Chairman Rempe, ACRS, "Response to the Advisory Committee on Reactor Safeguards, 'Fourth Interim Letter on 10 CFR Part 53 Rulemaking Language,'" dated September 30, 2022	ML22249A073

Letter to Chairman Rempe, ACRS, "Response to the Advisory Committee on Reactor Safeguards Letter on Preliminary Rule Language for 10 CFR Part 53, Subpart F, 'Requirements for Operations,' Interim Report," dated March 30, 2022	ML22063A012
Letter to Chairman Sunseri, ACRS, "Part 53, Licensing and Regulation of Advanced Nuclear Reactors," dated November 24, 2020	ML20311A006
Letter to Chairman Svinicki, NRC, "10 CFR Part 53, Licensing and Regulation of Advanced Nuclear Reactors," dated October 21, 2020	ML20295A647
Michigan v. EPA, 135 S. Ct. 2699 (2015)	
National Laboratory of Medicine, National Institutes of Health, Workshop Summary, "The Evolution of Telehealth: Where Have We Been and Where Are We Going?," dated November 2012	https://www.ncbi.nlm.nih.gov/books/NBK207141/
NEI 18-04, Rev. 1, "Risk-Informed Performance-Based Technology-Inclusive Guidance for Non-Light Water Reactors," dated August 2019	ML19241A472
NIA, "Clarifying 'Major Portions' of a Reactor Design in Support of a Standard Design Approval," dated April 2017	https://www.nuclearinnovationalliance.org/clarifying-major-portions-reactor-design-support-standard-design-approval
NRC, "A Regulatory Review Roadmap for Non-Light Water Reactors," dated December 2017	ML17312B567
NRC, "Manufacturing License ML-1 for Production of Up to Eight Floating Nuclear Plants," dated September 30, 1982	ML20070J215
NRC, "Risk-Informed and Performance-Based Human-System Considerations for Advanced Reactors," dated March 2021	ML21069A003
NRC Form 890, "Single Positive Test Form"	ML22013B187
NRC Form 891, "Annual Reporting for Drug and Alcohol Tests"	ML22013B240
NRC From 892, "Annual Fatigue Reporting Form"	ML220138250
NUREG-0654/FEMA-REP-1, Revision 2, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," dated December 2019	ML19347D139
NUREG-0880, "Safety Goals for Nuclear Power Plant Operation," dated May 1983	ML071770230

NUREG-1530, Revision 1, “Reassessment of NRC’s Dollar Per Person-Rem Conversion Factor Policy, Final Report,” dated February 2022	ML22053A025
NUREG/BR-0058, Revision 5, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” dated April 2017	ML17100A480
NUREG/CR-5884, “Revised Analyses of Decommissioning for the Reference Pressurized Water Reactor Power Station,” dated November 1995	ML14008A187
NUREG/CR-6187, Volume 1, “Revised Analyses of Decommissioning for the Reference Boiling Water Reactor Power Station,” dated July 1996	ML14008A186
OMB Circular No. A-119, “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,” dated February 19, 1998	https://obamawhitehouse.archives.gov/omb/circulars_a119_a119fr
PNNL, Technical Letter Report, “The Use of Electronic Communications to Perform Determinations of Fitness,” dated August 2017	ML18081A607
Pre-decisional DG, “Technology-Inclusive, Risk-Informed, and Performance-Based Methodology for Seismic Design of Commercial Nuclear Plants,” dated October 3, 2022	ML22276A149
Research Information Letter 2021-04, “Feasibility Study on a Potential Consequence-Based Seismic Design Approach for Nuclear Facilities,” dated April 2021	ML21113A066
RG 1.110, Revision 1, “Cost-Benefit Analysis for Radwaste Systems for Light-Water-Cooled Nuclear Power Reactors,” dated October 2013	ML13241A052
RG 1.134, Revision 4, “Medical Assessment Of Licensed Operators Or Applicants For Operator Licenses At Nuclear Power Plants,” dated September 2014	ML14189A385
RG 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” Revision 3, dated January 2018	ML17317A256

RG 1.208, “A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion,” dated March 2007	ML070310619
RG 1.232, “Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors,” Revision 0, dated April 2018	ML17325A611
RG 1.233, Revision 0, “Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light Water Reactors,” dated June 2020	ML20091L698
RG 1.247, “Acceptability of Probabilistic Risk Assessment Results for Non-Light-Water Reactor Risk-Informed Activities,” issued March 2022 for trial use	ML21235A008
RG 5.73, “Fatigue Management for Nuclear Power Plant Personnel,” dated March 20, 2009	ML083450028
RG 5.77, “Insider Mitigation Program,” Revision 1, dated September 08, 2022.	ML16342B024
RG 5.81, “Target Set Identification and Development for Nuclear Power Reactors,” Revision 1, dated December 2019	ML13151A355
SECY-18-0096, “Functional Containment Performance Criteria For Non-Light-Water-Reactors,” dated September 28, 2018	ML18115A157
SECY-19-0117, “Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,” dated December 2019	ML18311A264
SECY-20-0032, “Rulemaking Plan on ‘Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062,’” dated April 13, 2020	ML19340A056
SECY-20-0070, “(Redacted) Technical Evaluation of the Security Bounding Time Concept for Operating Nuclear Power Plants,” dated November 8, 2021	ML20126G265
SECY-22-0052, “Proposed Rule: Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150-AI66),” dated June 6, 2022	ML21159A057

SECY-22-0072, “Proposed Rule: Alternative Physical Security Requirements for Advanced Reactors (RIN 3150-AK19),” dated August 2, 2022	ML21334A003
SECY-83-293, “Amendments to 10 CFR 50 Related to Anticipated Transients Without Scram (ATWS) Events," dated July 19, 1983	ML21278A823 (non-public) ML21278A994 (non-public)
SECY-93-092, “Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and their Relationship to Current Regulatory Requirements,” dated April 8, 1993	ML040210725
SRM-SECY-10-0121, “Modifying the Risk-Informed Regulatory Guidance for New Reactors,” dated March 2, 2011	ML110610166
SRM-SECY-17-0100, “Security Baseline Inspection Program Assessment Results and Recommendations for Program Efficiencies,” dated October 8, 2018	ML18283A072
SRM-SECY-20-0032, “Rulemaking Plan on ‘Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062),’” dated October 2, 2020	ML20276A293
SRM-SECY-20-0045, “Population Related Siting Considerations for Advanced Reactors,” dated July 30, 2022	ML22194A885
SRM-SECY-98-144, “Staff Requirements—SECY-98-144—White Paper on Risk-Informed and Performance-Based Regulations,” dated February 24, 1999	ML003753593

Throughout the development of this rule, the NRC may post documents related to this rule, including public comments, on the Federal rulemaking website at https://www.regulations.gov under Docket ID NRC-2019-0062. The Federal rulemaking website allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder (NRC-2019-0062); (2) click the “Sign up for E-mail Alerts” link; and (3) enter your e-mail address and select how frequently you would like to receive e-mails (daily, weekly, or monthly).

List of Subjects

10 CFR Part 1

Flags, Organization and functions (Government Agencies), Seals and insignia.

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Confidential business information, Freedom of information, Environmental protection, Hazardous waste, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 10

Administrative practice and procedure, Classified information, Government employees, Security measures.

10 CFR Part 11

Hazardous materials transportation, Investigations, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Security measures, Special nuclear material.

10 CFR Part 19

Criminal penalties, Environmental protection, Nuclear Energy, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements, Sex discrimination.

10 CFR Part 20

Byproduct material, Criminal penalties, Hazardous waste, Licensed material, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 21

Nuclear power plants and reactors, Penalties, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 25

Classified information, Criminal penalties, Investigations, Penalties, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 26

Administrative practice and procedure, Alcohol abuse, Alcohol testing, Appeals, Chemical testing, Drug abuse, Drug testing, Employee assistance programs, Fitness for duty, Management actions, Nuclear power plants and reactors, Privacy, Protection of information, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear energy, Nuclear materials, Penalties, Radiation protection, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR Part 40

Criminal penalties, Exports, Government contracts, Hazardous materials transportation, Hazardous waste, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Source material, Uranium, Whistleblowing.

10 CFR Part 50

Administrative practice and procedure, Antitrust, Backfitting, Classified information, Criminal penalties, Education, Emergency planning, Fire prevention, Fire protection, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Penalties, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statements, Hazardous waste, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 53

Administrative practice and procedure, Antitrust, Backfitting, Construction permit, Combined license, Classified information, Criminal penalties, Early site permit, Emergency planning, Fees, Fire prevention, Fire protection, Inspection, Intergovernmental relations, Limited work authorization, Manufacturing license, Nuclear power plants and reactors, Operating license, Penalties, Prototype, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Standard design, Standard design certification, Training programs.

10 CFR Part 55

Criminal penalties, Manpower training programs, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements.

10 CFR Part 70

Classified information, Criminal penalties, Emergency medical services, Hazardous materials transportation, Material control and accounting, Nuclear energy, Nuclear materials, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material, Whistleblowing.

10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

10 CFR Part 73

Criminal penalties, Exports, Hazardous materials transportation, Imports, Incorporation by reference, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 74

Accounting, Criminal penalties, Hazardous materials transportation, Material control and accounting, Nuclear energy, Nuclear materials, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Special nuclear material.

10 CFR Part 75

Criminal penalties, Intergovernmental relations, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Security measures, Treaties.

10 CFR Part 95

Classified information, Criminal penalties, Penalties, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 140

Criminal penalties, Extraordinary nuclear occurrence, Insurance, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements.

10 CFR Part 150

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Security measures, Source material, Special nuclear material.

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Non-payment penalties, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Annual charges, Approvals, Byproduct material, Holders of certificates, Intergovernmental relations, Nonpayment penalties, Nuclear materials, Nuclear power plants and reactors, Registrations, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 1, 2, 10, 11, 19, 20, 21, 25, 26, 30, 40, 50, 51, 70, 72, 73, 74, 75, 95, 140, 150, 170, and 171 and adding 10 CFR part 53:

PART 1 – STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

1. The authority citation for part 1 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 23, 25, 29, 161, 191 (42 U.S.C. 2033, 2035, 2039, 2201, 2241); Energy Reorganization Act of 1974, secs. 201, 203, 204, 205, 209 (42 U.S.C. 5841, 5843, 5844, 5845, 5849); Administrative Procedure Act (5 U.S.C. 552, 553); Reorganization Plan No. 1 of 1980, 5 U.S.C. Appendix (Reorganization Plans).

§ 1.43 [Amended]

2. In § 1.43, add “53,” after “52,”.

PART 2 – AGENCY RULES OF PRACTICE AND PROCEDURE

3. The authority citation for part 2 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 29, 53, 62, 63, 81, 102, 103, 104, 105, 161, 181, 182, 183, 184, 186, 189, 191, 234 (42 U.S.C. 2039, 2073, 2092, 2093, 2111, 2132, 2133, 2134, 2135, 2201, 2231, 2232,2233, 2234, 2236, 2239, 2241, 2282); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); Nuclear Waste Policy Act of 1982, secs. 114(f), 134, 135, 141 (42 U.S.C. 10134(f), 10154, 10155, 10161); Administrative Procedure Act (5 U.S.C. 552, 553, 554, 557, 558); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note. Section 2.205(j) also issued under 28 U.S.C. 2461 note.

§ 2.1 [Amended]

4. In § 2.1(e), remove “part 52” and add in its place “parts 52 or 53”.

5. In § 2.4, revise the definitions for “*Contested proceeding*” and “*Facility*” to read as follows:

§ 2.4 Definitions.

* * * * *

Contested proceeding means –

(1) A proceeding in which there is a controversy between the NRC staff and the applicant for a license or permit concerning the issuance of the license or permit or any of the terms or conditions thereof;

(2) A proceeding in which the NRC is imposing a civil penalty or other enforcement action, and the subject of the civil penalty or enforcement action is an applicant for or holder of a license or permit, or is or was an applicant for or holder of a license or permit, or is or was an applicant for a standard design certification under parts 52 or 53 of this chapter; and

(3) A proceeding in which a petition for leave to intervene in opposition to an application for a license or permit has been granted or is pending before the Commission.

* * * * *

Facility means production facility or a utilization facility as defined in §§ 50.2 and 53.020 of this chapter.

* * * * *

§ 2.100 [Amended]

6. In § 2.100, add “or under subpart H of part 53” after “part 52”.

7. In § 2.101, revise paragraphs (a)(3)(i), (a)(5), (a)(9) introductory text and paragraph (a)(9)(i) to read as follows:

§ 2.101 Filing of application.

(a)* * *

(3)* * *

(i) Submit to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, such additional copies as the regulations in part 50, part 53, and subpart A of part 51 of this chapter require;

* * * * *

(5) An applicant for a construction permit under part 50 or part 53 of this chapter or a combined license under part 52 or part 53 of this chapter for a production or utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in § 50.21(b)(2) or (b)(3) or § 50.22 or part 53 of this chapter, or is a testing facility, may submit the information required of applicants by parts 50, 52, or 53 of this chapter in two parts. One part shall be accompanied by the information required by § 50.30(f) of this chapter, § 52.80(b) of this chapter, or § 53.1100(f), as applicable. The other part shall include any information required by § 50.34(a) and, if applicable, § 50.34a of this chapter; or §§ 52.79 and 52.80(a); or §§ 53.1306 and 53.1312; or §§ 53.1416, and 53.1419, as applicable. One part may precede or follow other parts by no longer than 6 months. If it is determined that either of the parts as described above is incomplete and not acceptable for processing, the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, will inform the applicant of this determination and the respects in which the document is deficient. Such a determination of completeness will generally be made within a period of 30 days. Whichever part is filed first shall also include the fee required

by § 50.30(e) or § 53.1100(e)and § 170.21 of this chapter and the information required by §§ 50.33 and 50.34(a)(1); or §§ 50.33 and 52.79(a)(1); or §§ 53.1109, 53.1306, and 53.1309; or §§ 53.1413 and 53.1416(a)(1), as applicable, and § 50.37 or § 53.1115, as applicable, of this chapter. The Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, will accept for docketing an application for a construction permit under part 50 or part 53 of this chapter or a combined license under part 52 or part 53 of this chapter for a production or utilization facility that is subject to § 51.20(b) of this chapter, and is of the type specified in § 50.21(b)(2) or (b)(3), or § 50.22, or part 53, as applicable, of this chapter or is a testing facility where one part of the application as described above is complete and conforms to the requirements of part 50 of this chapter. The additional parts will be docketed upon a determination by the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, that it is complete.

* * * * *

(9) An applicant for a construction permit for a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specified in § 50.21(b)(2) or (b)(3), or § 50.22, or part 53 of this chapter, an applicant for or holder of an early site permit under part 52 or part 53 of this chapter, or an applicant for a combined license under part 52 or part 53 of this chapter, who seeks to conduct the activities authorized under § 50.10(d) or § 53.1130 of this chapter may submit a complete application under paragraphs (a)(1) through (a)(4) of this section which includes the information required by § 50.10(d) or § 53.1130 of this chapter. Alternatively, the applicant (other than an applicant for or holder of an early site permit) may submit its application in two parts:

(i) Part one must include the information required by § 50.33(a) through (f), § 53.1109(a) through (e), and § 53.1306 of this chapter, as applicable, and the information required by § 50.10(d)(2) and (d)(3) or § 53.1130(b)(2) and (b)(3) of this chapter, as applicable.

* * * * *

8. In § 2.104, revise paragraph (a) to read as follows:

§ 2.104 Notice of hearing.

(a) In the case of an application on which a hearing is required by the Act or this chapter, or in which the Commission finds that a hearing is required in the public interest, the Secretary will issue a notice of hearing to be published in the *Federal Register*. The notice must be published at least 15 days, and in the case of an application concerning a limited work authorization, construction permit, early site permit, or combined license for a facility of the type described in § 50.21(b) or 50.22, or part 53 of this chapter, as applicable, or a testing facility, at least 30 days, before the date set for hearing in the notice.[1] In addition, in the case of an application for a limited work authorization, construction permit, early site permit, or combined license for a facility of the type described in § 50.22 or part 53 of this chapter, as applicable, or a testing facility, the notice must be issued as soon as practicable after the NRC has docketed the application. If the Commission decides, under § 2.101(a)(2), to determine the acceptability of the application based on its technical adequacy as well as completeness, the notice must be issued as soon as practicable after the application has been tendered.

[1] If the notice of hearing concerning an application for a limited work authorization, construction permit, early site permit, or combined license for a facility of the type described in § 50.21(b) or § 50.22, or part 53 of this chapter, as applicable, or a testing facility, does not specify the time and place of initial hearing, a subsequent notice will be published in the *Federal Register* which will provide at least 30-day notice of the time and place of that hearing. After this notice is given, the presiding officer may reschedule the commencement of the initial hearing for a later date or reconvene a recessed hearing without again providing at least 30-day notice.

* * * * *

9. In § 2.105:

a. Revise paragraph (a) introductory text and paragraphs (a)(4), (a)(10), (a)(12), (a)(13); and

b. Revise paragraph (b)(3) introductory text and (b)(3)(i), (ii), and (iv).

The revisions read as follows:

§ 2.105 Notice of proposed action.

(a) If a hearing is not required by the Act or this chapter, and if the Commission has not found that a hearing is in the public interest, it will, before acting thereon, publish in the *Federal Register*, as applicable, or on the NRC's Web site, http://www.nrc.gov, or both, at the Commission's discretion, either a notice of intended operation under § 52.103(a) or § 53.1452(a) of this chapter, as applicable, and a proposed finding that inspections, tests, analyses, and acceptance criteria for a combined license under subpart C of part 52 or under subpart H of part 53, have been or will be met, or a notice of proposed action with respect to an application for:

* * * * *

(4) An amendment to an operating license, combined license, or manufacturing license for a facility licensed under §§ 50.21(b) or 50.22 or under subpart H of part 53 of this chapter, as applicable, or for a testing facility, as follows:

(i) If the Commission determines under § 50.58 or § 53.1515 of this chapter that the amendment involves no significant hazards consideration, though it will provide notice of opportunity for a hearing pursuant to this section, it may make the amendment immediately effective and grant a hearing thereafter; or

(ii) If the Commission determines under §§ 50.58 and 50.91 or § 53.1515 of this chapter, as applicable, that an emergency situation exists or that exigent circumstances

exist and that the amendment involves no significant hazards consideration, it will provide notice of opportunity for a hearing pursuant to § 2.106 (if a hearing is requested, it will be held after issuance of the amendment);

* * * * *

(10) In the case of an application for an operating license for a facility of a type described in § 50.21(b) or § 50.22, or part 53 of this chapter or a testing facility, a notice of opportunity for hearing shall be issued as soon as practicable after the application has been docketed; or

* * * * *

(12) An amendment to an early site permit issued under subpart A of part 52, or under subpart H of part 53 of this chapter, as follows:

(i) If the early site permit does not provide authority to conduct the activities allowed under § 50.10(e)(1) or § 53.1130(b)(1) of this chapter, the amendment will involve no significant hazards consideration, and though the NRC will provide notice of opportunity for a hearing under this section, it may make the amendment immediately effective and grant a hearing thereafter; and

(ii) If the early site permit provides authority to conduct the activities allowed under § 50.10(e)(1) or § 53.1130(b)(1), and the Commission determines under §§ 50.58 and 50.91 or § 53.1515 of this chapter that an emergency situation exists or that exigent circumstances exist and that the amendment involves no significant hazards consideration, it will provide notice of opportunity for a hearing under § 2.106 of this chapter (if a hearing is requested, which will be held after issuance of the amendment).

(13) A manufacturing license under subpart F of part 52 or subpart H of part 53 of this chapter.

(b) * * *

(3) For a notice of intended operation under § 52.103(a) or § 53.1452(a) of this chapter, the following information:

(i) The identification of the NRC action as making the finding required under § 52.103(g) or § 53.1452(g) of this chapter;

(ii) The manner in which the licensee notifications under 10 CFR 52.99(c) or 10 CFR 53.1449(c) that are required to be made available by 10 CFR 52.99(e)(2) or 10 CFR 53.1449(e)(2) may be obtained and examined;

* * * * *

(iv) Any conditions, limitations, or restrictions to be placed on the license in connection with the finding under § 52.103(g) or § 53.1452(g) of this chapter, and the expiration date or circumstances (if any) under which the conditions, limitations or restrictions will no longer apply.

* * * * *

10. In § 2.106, revise paragraphs (a)(2), (a)(3), and (b)(2) introductory text to read as follows:

§ 2.106 Notice of issuance.

(a) * * *

(2) An amendment of a license for a facility of the type described in § 50.21(b) or § 50.22, or part 53 of this chapter, as applicable, or a testing facility, whether or not a notice of proposed action has been previously published; and

(3) The finding under § 52.103(g) or § 53.1452(g) of this chapter.

(b) * * *

(2) In the case of a finding under § 52.103(g) or § 53.1452(g) of this chapter:

* * * * *

11. In § 2.109, revise paragraphs (b), (c), and (d) to read as follows:

§ 2.109 Effect of timely renewal application.

* * * * *

(b) If the licensee of a nuclear power plant licensed under 10 CFR 50.21(b) or 10 CFR 50.22 or under 10 CFR part 53 files a sufficient application for renewal of either an operating license or a combined license at least 5 years before the expiration of the existing license, the existing license will not be deemed to have expired until the application has been finally determined.

(c) If the holder of an early site permit licensed under subpart A of part 52 or under subpart H of part 53 of this chapter, as applicable, files a sufficient application for renewal under § 52.29 or § 53.1173 of this chapter, as applicable, at least 12 months before the expiration of the existing early site permit, the existing permit will not be deemed to have expired until the application has been finally determined.

(d) If the licensee of a manufacturing license under subpart F of part 52 or under subpart H of part 53 of this chapter files a sufficient application for renewal under § 52.177 or § 53.1295 of this chapter at least 12 months before the expiration of the existing license, the existing license will not be deemed to have expired until the application has been finally determined.

* * * * *

12. In § 2.110, revise paragraphs (a)(1) and (b) to read as follows:

§ 2.110 Filing and administrative action on submittals for standard design approval or early review of site suitability issues.

(a)(1) A submittal for a standard design approval under subpart E of part 52 or under subpart H of part 53 of this chapter shall be subject to §§ 2.101(a) and 2.390 to the same extent as if it were an application for a permit or license.

* * * * *

(b) Upon initiation of review by the NRC staff of a submittal for an early review of site suitability issues under Appendix Q of part 50 of this chapter, or for a standard design approval under subpart E of part 52 or under subpart H of part 53 of this chapter, the Director, Office of Nuclear Reactor Regulation, shall publish in the *Federal Register* a notice of receipt of the submittal, inviting comments from interested persons within 60 days of publication or other time as may be specified, for consideration by the NRC staff and ACRS in their review.

* * * * *

13. In § 2.202, revise paragraph (e) to read as follows:

§ 2.202 Orders.

*** * * * ***

(e)(1) If the order involves the modification of a part 53 license, except for a combined license, early site permit, manufacturing license, or general license under § 53.810 of this chapter, or a part 50 license and is a backfit, the requirements of § 50.109 or § 53.1590 of this chapter, as applicable, shall be followed, unless the licensee has consented to the action required.

(2) If the order involves the modification of combined license under subpart C of part 52, or subpart H of part 53 of this chapter, the requirements of § 52.98 or § 53.1443 of this chapter, as applicable, shall be followed unless the licensee has consented to the action required.

(3) If the order involves a change to an early site permit under subpart A of part 52 or under subpart H of part 53 of this chapter, the requirements of § 52.39 or § 53.1188 of this chapter, as applicable, must be followed, unless the applicant or licensee has consented to the action required.

(4) If the order involves a change to a standard design certification rule referenced by that plant's application, the requirements, if any, in the referenced design certification rule with respect to changes must be followed, or, in the absence of these requirements, the requirements of § 52.63 or § 53.1263 of this chapter, as applicable, must be followed, unless the applicant or licensee has consented to follow the action required.

(5) If the order involves a change to a standard design approval referenced by that plant's application, the requirements of § 52.145 or § 53.1221 of this chapter, as applicable, must be followed unless the applicant or licensee has consented to follow the action required.

(6) If the order involves a modification of a manufacturing license under subpart F of part 52 or under subpart H of part 53 of this chapter, the requirements of § 52.171 or § 53.1288 of this chapter, as applicable, must be followed, unless the applicant or licensee has consented to the action required.

14. In § 2.309, revise paragraphs (a), (f)(1)(i), (f)(1)(vi) and (vii), (g), (h)(2), (i)(2), (j) to read as follows:

§ 2.309 Hearing requests, petitions to intervene, requirements for standing, and contentions.

(a) *General requirements*. Any person whose interest may be affected by a proceeding and who desires to participate as a party must file a written request for hearing and a specification of the contentions which the person seeks to have litigated in the hearing. In a proceeding under § 52.103 or § 53.1452 of this chapter, as applicable, the Commission, acting as the presiding officer, will grant the request if it determines that the requestor has standing under the provisions of paragraph (d) of this section and has

proposed at least one admissible contention that meets the requirements of paragraph (f) of this section.

* * * * *

(f) * * *

(1) * * *

(i) Provide a specific statement of the issue of law or fact to be raised or controverted, provided further, that the issue of law or fact to be raised in a request for hearing under § 52.103(b) or § 53.1452(b) of this chapter must be directed at demonstrating that one or more of the acceptance criteria in the combined license have not been, or will not be met, and that the specific operational consequences of nonconformance would be contrary to providing reasonable assurance of adequate protection of the public health and safety;

* * * * *

(vi) In a proceeding other than one under § 52.103 or § 53.1452 of this chapter provide sufficient information to show that a genuine dispute exists with the applicant/licensee on a material issue of law or fact. This information must include references to specific portions of the application (including the applicant's environmental report and safety report) that the petitioner disputes and the supporting reasons for each dispute, or, if the petitioner believes that the application fails to contain information on a relevant matter as required by law, the identification of each failure and the supporting reasons for the petitioner's belief; and

(vii) In a proceeding under § 52.103(b) or § 53.1452(b) of this chapter provide sufficient information, including supporting information showing, prima facie, that one or more of the acceptance criteria in the combined license have not been, or will not be met, and that the specific operational consequences of nonconformance would be

contrary to providing reasonable assurance of adequate protection of the public health and safety. This information must include the specific portion of the report required by § 52.99(c) or § 53.1449(c) of this chapter, as applicable, that the requestor believes is inaccurate, incorrect, and/or incomplete (i.e., fails to contain the necessary information required by § 52.99(c) or § 53.1449(c) of this chapter, as applicable). If the requestor identifies a specific portion of the report under § 52.99(c) or § 53.1449(c) of this chapter, as applicable, as incomplete and the requestor contends that the incomplete portion prevents the requestor from making the necessary *prima facie* showing, then the requestor must explain why this deficiency prevents the requestor from making the *prima facie* showing.

* * * * *

(g) *Selection of hearing procedures*. A request for hearing and/or petition for leave to intervene may, except in a proceeding under § 52.103 or § 53.1452, also address the selection of hearing procedures, taking into account the provisions of § 2.310. If a request/petition relies upon § 2.310(d), the request/petition must demonstrate, by reference to the contention and the bases provided and the specific procedures in subpart G of this part, that resolution of the contention necessitates resolution of material issues of fact which may be best determined through the use of the identified procedures.

(h) * * *

(1) * * *

(2) If the proceeding pertains to a production or utilization facility (as defined in § 50.2 or § 53.020 of this chapter) located within the boundaries of the State, local governmental body, or Federally-recognized Indian Tribe seeking to participate as a party, no further demonstration of standing is required. If the production or utilization

facility is not located within the boundaries of the State, local governmental body, or Federally-recognized Indian Tribe seeking to participate as a party, the State, local governmental body, or Federally-recognized Indian Tribe also must demonstrate standing.

* * * * *

(i) * * *

(2) Except in a proceeding under § 52.103 or § 53.1452 of this chapter, the participant who filed the hearing request, intervention petition, or motion for leave to file new or amended contentions after the deadline may file a reply to any answer. The reply must be filed within 7 days after service of that answer.

* * * * *

(j) *Decision on request/petition*.

(1) In all proceedings other than a proceeding under § 52.103 or § 53.1452 of this chapter, the presiding officer shall issue a decision on each request for hearing or petition to intervene within 45 days of the conclusion of the initial pre-hearing conference or, if no pre-hearing conference is conducted, within 45 days after the filing of answers and replies under paragraph (i) of this section. With respect to a request to admit amended or new contentions, the presiding officer shall issue a decision on each such request within 45 days of the conclusion of any pre-hearing conference that may be conducted regarding the proposed amended or new contentions or, if no pre-hearing conference is conducted, within 45 days after the filing of answers and replies, if any. In the event the presiding officer cannot issue a decision within 45 days, the presiding officer shall issue a notice advising the Commission and the parties, and the notice shall include the expected date of when the decision will issue.

(2) The Commission, acting as the presiding officer, shall expeditiously grant or deny the request for hearing in a proceeding under § 52.103 or § 53.1452 of this chapter. The Commission's decision may not be the subject of any appeal under § 2.311.

15. In § 2.310:

a. Add “53,” in sequential order to paragraph (a) and paragraph (h) introductory text; and

b. Revise paragraphs (i) and (j).

The revisions read as follows:

§ 2.310 Selection of hearing procedures.

* * * * *

(i) In design certification rulemaking proceedings under part 52 or part 53 of this chapter, any informal hearing held under § 52.51 or § 53.1242 of this chapter, must be conducted under the procedures of subpart O of this part.

(j) Proceedings on a Commission finding under § 52.103(c) and (g) or § 53.1452(c) and (g) of this chapter, shall be conducted in accordance with the procedures designated by the Commission in each proceeding.

* * * * *

16. In § 2.329, revise paragraph (a) to read as follows:

§ 2.329 Prehearing conference.

(a) *Necessity for prehearing conference; timing*. The Commission or the presiding officer may, and in the case of a proceeding on an application for a construction permit or an operating license for a facility of a type described in § 50.21(b) or § 50.22, or part 53 of this chapter, or a testing facility, must direct the parties or their counsel to appear at a specified time and place for a conference or conferences before

trial. A prehearing conference in a proceeding involving a construction permit or operating license for a facility of a type described in § 50.21(b) or § 50.22 or part 53 of this chapter must be held within sixty (60) days after discovery has been completed or any other time specified by the Commission or the presiding officer.

* * * * *

17. In § 2.339, revise paragraph (d) to read as follows:

§ 2.339 Expedited decision-making procedure.

*** * * * ***

(d) The provisions of this section do not apply to an initial decision directing the issuance of a limited work authorization under § 50.10 or § 53.1130 of this chapter; an early site permit under subpart A of part 52 or under subpart H of part 53 of this chapter; a construction permit under part 50 or part 53 of this chapter; a combined license under subpart C of part 52 or under subpart H of part 53 of this chapter; or a manufacturing license under subpart F of part 52 or under subpart H of part 53.

18. In § 2.340:

a. In paragraph (b), add the phrase “or part 53” after the phrase “part 52” wherever it appears;

b. Revise paragraph (c);

c. In paragraph (d) introductory text, add the phrase “or part 53” after the phrase “part 52”; in paragraphs (d)(1) and (2), add the phrase “or subpart H of part 53” after the phrase “part 52”;

d. Revise paragraph (f) and (i); and

e. Revise paragraph (j) introductory text and paragraph (j)(1).

The revisions read as follows:

§ 2.340 Initial decision in certain contested proceedings; immediate effectiveness of initial decisions; issuance of authorizations, permits and licenses.

* * * * *

(c) *Initial decision on findings under 10 CFR 52.103 or 53.1452 with respect to acceptance criteria in nuclear power reactor combined licenses*. In any initial decision under § 52.103(g) or § 53.1452(g) of this chapter with respect to whether acceptance criteria have been or will be met, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties, and any matter designated by the Commission to be decided by the presiding officer. Matters not put into controversy by the parties but identified by the presiding officer as matters requiring further examination, shall be referred to the Commission for its determination; the Commission may, in its discretion, treat any of these referred matters as a request for action under § 2.206 and process the matter in accordance with § 52.103(f) or § 53.1452(f) of this chapter.

* * * * *

(f) *Immediate effectiveness of certain presiding officer decisions*. A presiding officer's initial decision directing the issuance or amendment of a limited work authorization under § 50.10 or § 53.1130 of this chapter; an early site permit under subpart A of part 52 or under subpart H of part 53; a construction permit or construction authorization under part 50 or part 53 of this chapter; an operating license under part 50 or part 53 of this chapter; a combined license under subpart C of part 52 or part 53 of this chapter; a manufacturing license under subpart F of part 52 or part 53 of this chapter; a renewed license under part 53 or part 54 of this chapter; or a license under part 72 of this chapter to store spent fuel in an independent spent fuel storage facility (ISFSI) or a monitored retrievable storage installation (MRS); an initial decision directing

issuance of a license under part 61 of this chapter; or an initial decision under § 52.103(g) or § 53.1452(g) of this chapter that acceptance criteria in a combined license have been met, is immediately effective upon issuance unless the presiding officer finds that good cause has been shown by a party why the initial decision should not become immediately effective.

* * * * *

(i) *Issuance of authorizations, permits, and licenses—production and utilization facilities*. The Commission or the Director, Office of Nuclear Reactor Regulation, as appropriate, shall issue a limited work authorization under § 50.10 or § 53.1130 of this chapter; an early site permit under subpart A of part 52 or subpart H of part 53 of this chapter; a construction permit under part 50 or part 53 of this chapter; an operating license under part 50 or part 53 of this chapter; a combined license under subpart C of part 52 or part 53 of this chapter; or a manufacturing license under subpart F of part 52 or part 53 of this chapter within 10 days from the date of issuance of the initial decision:

* * * * *

(j) *Issuance of finding on acceptance criteria under 10 CFR 52.103 or 10 CFR 53.1452*. The Commission or the Director, Office of Nuclear Reactor Regulation, as appropriate, shall make the finding under § 52.103(g) or § 53.1452(g) of this chapter that acceptance criteria in a combined license are met within 10 days from the date of the presiding officer's initial decision:

(1) If the Commission or the Director is otherwise able to make the finding under § 52.103(g) or § 53.1452(g) of this chapter, that the prescribed acceptance criteria are met for those acceptance criteria not within the scope of the initial decision of the presiding officer;

* * * * *

§ 2.341 [Amended]

19. In § 2.341(a)(1), add “or § 53.1452(c)” after “§ 52.103(c),”.

§ 2.400 [Amended]

20. In § 2.400, add the phrase “, or § 53.1470” after the phrase, “appendix N of parts 50 or 52”.

21. In § 2.401, revise the section heading and paragraph (a) to read as follows:

§ 2.401 Notice of hearing on construction permit or combined license applications for nuclear power plants of identical design at multiple sites.

(a) In the case of applications under appendix N of part 50, or § 53.1470 of this chapter for construction permits for nuclear power reactors of the type described in § 50.22 or part 53 of this chapter, or applications under appendix N of part 52, or § 53.1470 of this chapter for combined licenses, the Secretary will issue notices of hearing pursuant to § 2.104.

* * * * *

§ 2.402 [Amended]

22. In § 2.402**:**

a. Add the phrase, “or § 53.1470” after the phrase “appendix N of part 50”;

b. Add “or part 53” after “10 CFR 50.22”; and

c. Add “or § 53.1470” after “appendix N of part 52”.

23. In § 2.403, revise the section heading and the unnumbered paragraph to read as follows:

§ 2.403 Notice of proposed action on applications for operating licenses for nuclear power plants of identical design at multiple sites.

In the case of applications pursuant to appendix N of part 50 or § 53.1470 of this chapter for operating licenses for nuclear power reactors, if the Commission has not

found that a hearing is in the public interest, the Commission or the Director, Office of Nuclear Reactor Regulation, as appropriate, will, prior to acting thereon, cause to be published in the Federal Register, pursuant to § 2.105, a notice of proposed action with respect to each application as soon as practicable after the applications have been docketed.

24. In § 2.404, revise the section heading and the unnumbered paragraph to read as follows:

§ 2.404 Hearings on applications for operating licenses for nuclear power plants of identical design at multiple sites.

If a request for a hearing and/or petition for leave to intervene is filed within the time prescribed in the notice of proposed action on an application for an operating license pursuant to appendix N of part 50 or § 53.1470 of this chapter with respect to a specific reactor(s) at a specific site, and the Commission, the Chief Administrative Judge, or a presiding officer has issued a notice of hearing or other appropriate order, then the Commission, the Chief Administrative Judge, or the presiding officer may order separate hearings on particular phases of the proceeding and/or consolidate for hearing two or more proceedings in the manner described in § 2.402.

§ 2.405 [Amended]

25. In § 2.405, add “or part 53” after “part 52”.

§ 2.406 [Amended]

26. In § 2.406, add “§ 53.1470” after “appendix N of parts 50 or 52”.

§ 2.500 [Amended]

27. In § 2.500, add “or subpart H of part 53” after “of part 52”.

28. In § 2.501, revise the section heading and paragraph (a) introductory text to read as follows:

§ 2.501 Notice of hearing on application under 10 CFR parts 52 or 53 for a license to manufacture nuclear power reactors.

(a) In the case of an application under subpart F of part 52, or subpart H of part 53 of this chapter for a license to manufacture nuclear power reactors of the type described in § 50.22 or part 53 of this chapter to be operated at sites not identified in the license application, the Secretary will issue a notice of hearing to be published in the *Federal Register* at least 30 days before the date set for hearing in the notice.[1] The notice shall be issued as soon as practicable after the application has been docketed. The notice will state:

* * * * *

§ 2.643 [Amended]

29. In § 2.643(b):

a. Add "; or part 53" after "or § 50.22"; and

b. Add "or § 53.1130(a)(3)" after "§ 50.10(d)(3)".

30. In § 2.645(a), revise paragraph (a) to read as follows:

§ 2.645 Notice of hearing

(a) The notice of hearing on part one of the application must set forth the matters of fact and law to be considered, as required by § 2.104, which will be modified to state that the hearing will relate only to the matters related to § 50.33(a) through (f) of this chapter, or § 53.1109 and § 53.1306 or § 53.1413 of this chapter, as applicable, and the limited work authorization.

§ 2.649 [Amended]

31. In § 2.649, add "or 10 CFR 53.1130(b)" after "10 CFR50.10(d)".

§ 2.800 [Amended]

32. In § 2.800, add “or subpart H of part 53” after “subpart B of part 52” wherever it may appear.

§ 2.801 [Amended]

33. In § 2.801, add “or subpart H of part 53” after “subpart B of part 52”.

§ 2.813 [Amended]

34. In § 2.813(a), add “, 53” after “parts 50, 52”.

§ 2.1103 [Amended]

35. In § 2.1103, add “or part 53” after “part 50”.

36. In § 2.1202, revise paragraphs (a)(1) through (3) and (a)(6) to read as follows:

§ 2.1202 Authority and role of NRC staff.

(a) * * *

(1) An application to construct and/or operate a production or utilization facility (including an application for a limited work authorization under § 50.12 or § 53.1130 of this chapter, or an application for a combined license under subpart C of 10 CFR part 52, or under subpart H of 10 CFR part 53;

(2) An application for an early site permit under subpart A of 10 CFR part 52 or under subpart H of 10 CFR part 53;

(3) An application for a manufacturing license under subpart F of 10 CFR part 52 or under subpart H of 10 CFR part 53;

* * * * *

(6) Production or utilization facility licensing actions that involve significant hazards considerations as defined in § 50.92 or § 53.1520 of this chapter.

* * * * *

§ 2.1301 [Amended]

37. In § 2.1301(b), remove “part 50 and part 52” and add in its place “parts 50, 52, and 53”.

§ 2.1403 [Amended]

38. In § 2.1403(a)(3), add “or 10 CFR 53.1520” after “10 CFR 50.92”.

§ 2.1500 [Amended]

39. In § 2.1500, add “or under subpart H of part 53” after “subpart B of part 52”.

§ 2.1502 [Amended]

40. In § 2.1502:

a. In paragraph (a), add “or § 53.1242(b)(2)” after “§ 52.51(b)".

b. In paragraph (b)(1), wherever it may appear, add “or § 53.1242(b)” after “§ 52.51(a)”.

PART 10 – CRITERIA AND PROCEDURES FOR DETERMINING ELIGIBILITY FOR ACCESS TO RESTRICTED DATA OR NATIONAL SECURITY INFORMATION OR AN EMPLOYMENT CLEARANCE

41. The authority citation for part 10 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 145, 161 (42 U.S.C. 2165, 2201); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); E.O. 10450, 18 FR 2489, 3 CFR, 1949-1953 Comp., p. 936, as amended; E.O. 10865, 25 FR 1583, 3 CFR, 1959-1963 Comp., p. 398, as amended; E.O. 12968, 60 FR 40245, 3 CFR, 1995 Comp., p. 391.

§ 10.1 [Amended]

42. In § 10.1(a)(3), add “or part 53” after “under part 52”.

§ 10.2 [Amended]

43. In § 10.2(b), wherever it may appear, add “or part 53” after “under part 52”.

PART 11 – Criteria and Procedures for Determining Eligibility for Access to or Control Over Special Nuclear Material

44. The authority citation for 10 CFR part 11 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 161, 223 (42 U.S.C. 2201, 2273); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 44 U.S.C. 3504 note. Section 11.15(e) also issued under 31 U.S.C. 9701; 42 U.S.C. 2214.

§ 11.7 [Amended]

45. In § 11.7 introductory text, add the number “53” in numerical order.

PART 19 – NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTION AND INVESTIGATIONS

46. The authority citation for part 19 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 63, 81, 103, 104, 161, 223, 234, 1701 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 211, 401 (42 U.S.C. 5841, 5851, 5891); 44 U.S.C. 3504 note.

§ 19.2 [Amended]

47. In § 19.2:

a. In paragraph (a)(1), remove “under parts 50 or 52” and add in its place “under parts 50, 52, or 53”;

b. In paragraph (a)(2) add “53,” after “52,”; and

c. In paragraphs (a)(3) and (4) add “or under subpart H of part 53" after “of part 52”, wherever it may appear.

48. In § 19.3, revise the definitions for “*License*” and “*Regulated entities*” to read as follows:

§ 19.3 Definitions.

* * * * *

License means a license issued under the regulations in parts 30 through 36, 39, 40, 60, 61, 63, 70, or 72 of this chapter, including licenses to manufacture, construct and/or operate a production or utilization facility under parts 50, 52, 53, or 54 of this chapter.

* * * * *

Regulated entities means any individual, person, organization, or corporation that is subject to the regulatory jurisdiction of the NRC, including (but not limited to) an applicant for or holder of a standard design approval under subpart E of part 52 or under subpart H of part 53 of this chapter or a standard design certification under subpart B of part 52 or under subpart H of part 53 of this chapter.

* * * * *

§ 19.11 [Amended]

49. In § 19.11, add “or under subpart H of part 53" after “of part 52”, wherever it may appear.

§ 19.14 [Amended]

50. In § 19.14(a), add “or under subpart H of part 53" after “of part 52”, wherever it may appear.

§ 19.20 [Amended]

51. In § 19.20, add “53,” after “52,”.

PART 20 – STANDARDS FOR PROTECTION AGAINST RADIATION

52. The authority citation for part 20 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 53, 63, 65, 81, 103, 104, 161, 170H, 182, 186, 223, 234, 274, 1701 (42 U.S.C. 2014, 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2210h, 2232, 2236, 2273, 2282, 2021, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Low-Level Radioactive Waste Policy Amendments Act of 1985, sec. 2 (42 U.S.C. 2021b); 44 U.S.C. 3504 note.

§ 20.1002 [Amended]

53. In § 20.1002, add “53,” after “52,”.

§ 20.1003 [Amended]

54. In § 20.1003, revise the definition for “*License*” by adding “52, 53, ” after “50,”.

§ 20.1101 [Amended]

55. In § 20.1101(d), add “or § 53.260(b) of this chapter” after “subject to § 50.34a”.

§ 20.1401 [Amended]

56. In § 20.1401, in paragraph (a) add “53,” after “52,”; and in paragraphs (a) and (c) add “or § 53.1080” after “in accordance with § 50.83”.

§ 20.1403 [Amended]

57. In § 20.1403(d) introductory text, remove “§§ 30.36(d), 40.42(d), 50.82 (a) and (b), § 70.38(d), or § 72.54” and add in its place “§ 30.36(d), § 40.42(d), § 50.82(a) and (b), subpart G of part 53, § 70.38(d), or § 72.54”.

§ 20.1404 [Amended]

58. In § 20.1404(a)(4) introductory text, remove “§§ 30.36(d), 40.42(d), 50.82 (a) and (b), 70.38(d), or 72.54” and add in its place “§ 30.36(d), § 40.42(d), § 50.82(a) and (b), subpart G of part 53, § 70.38(d), or § 72.54”.

§ 20.1406 [Amended]

59. In § 20.1406, add “or part 53” after “under part 52” wherever it may appear.

§ 20.1501 [Amended]

60. In § 20.1501(b), remove “§§ 30.35(g), 40.36(f), 50.75(g), 70.25(g), or 72.30(d),” and add in its place “§ 30.35(g), § 40.36(f), § 50.75(g), subpart G part 53, § 70.25(g), or § 72.30(d) of this chapter,”.

§ 20.1905 [Amended]

61. In § 20.1905(g) introductory text, remove “Parts 50 or 52” and add in its place “parts 50, 52, or 53”.

62. In § 20.2004, revise paragraph (b)(1) to read as follows:

§ 20.2004 Treatment or disposal by incineration.

* * * * *

(b)(1) Waste oils (petroleum derived or synthetic oils used principally as lubricants, coolants, hydraulic or insulating fluids, or metalworking oils) that have been radioactively contaminated in the course of the operation or maintenance of a nuclear power reactor licensed under parts 50, 52, or 53 of this chapter may be incinerated on the site where generated provided that the total radioactive effluents from the facility, including the effluents from such incineration, conform to the requirements of appendix I to part 50 or § 53.425(d) of this chapter and the effluent release limits contained in applicable license conditions other than effluent limits specifically related to incineration of waste oil. The licensee shall report any changes or additions to the information supplied under § 50.34, § 50.34a, or under subpart H of part 53 of this chapter associated with this incineration pursuant to § 50.71 or § 53.1620 of this chapter, as appropriate. The licensee shall also follow the procedures of § 50.59 or § 53.1565 of this chapter with respect to such changes to the facility or procedures.

* * * * *

63. In § 20.2201, revise paragraphs (a)(2)(i), (b)(2)(i), and (c) to read as follows:

§ 20.2201 Reports of theft or loss of licensed material.

(a) * * *

(2) * * *

(i) Licensees having an installed Emergency Notification System shall make the reports to the NRC Operations Center under § 50.72 or § 53.1630 of this chapter, and

* * * * *

(b) * * *

(2) * * *

(i) For holders of an operating license for a nuclear power plant, the events included in paragraph (b) of this section must be reported under the procedures

described in § 50.73(b), (c), (d), (e), and (g) or § 53.1640(b), (c), (d), (e), and (g) of this chapter and must include the information required in paragraph (b)(1) of this section, and

* * * * *

(c) A duplicate report is not required under paragraph (b) of this section if the licensee is also required to submit a report pursuant to § 30.55(c), § 37.57, § 37.81, § 40.64(c), § 50.72, § 50.73, § 53.1630, § 53.1640, § 70.52, § 73.27(b), § 73.67(e)(3)(vii), § 73.67(g)(3)(iii), § 73.71, or § 150.19(c) of this chapter.

* * * * *

§ 20.2202 [Amended]

64. In § 20.2202(d)(1), remove “10 CFR 50.72 and add in its place “§ 50.72 or § 53.1630 of this chapter;”.

65. In § 20.2203, revise paragraph (c) to read as follows:

§ 20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

*** * * * ***

(c) For holders of an operating license or a combined license for a nuclear power plant, the occurrences included in paragraph (a) of this section must be reported under the procedures described in § 50.73(b), (c), (d), (e), and (g) or § 53.1640(b), (c), (d), (e), and (g) of this chapter, and must include the information required by paragraph (b) of this section. Occurrences reported under § 50.73 or § 53.1640 of this chapter need not be reported by a duplicate report under paragraph (a) of this section.

* * * * *

§ 20.2206 [Amended]

66. In § 20.2206(a)(1), remove “or § 50.22” and add in its place “, § 50.22, or part 53”.

PART 21 – REPORTING OF DEFECTS AND NONCOMPLIANCE

67. The authority citation for part 21 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 63, 81, 103, 104, 161, 223, 234, 1701 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

68. In § 21.2:

a. In paragraph (a)(2), remove “or 52” and add in its place “, 52, or 53” and add “53,” after “40, 50, 52,”;

b. In paragraphs (a)(3) and (4) add “or part 53” after “under part 52”, wherever it may appear; and

c. Revise paragraphs (b) and (c) to read as follows:

§ 21.2 Scope.

* * * * *

(b) For persons licensed to construct a facility under either a construction permit issued under § 50.23 or § 53.1333 of this chapter or a combined license under part 52 or part 53 of this chapter (for the period of construction until the date that the Commission makes the finding under § 52.103(g) or § 53.1452(g)of this chapter), or to manufacture a facility under part 52 or part 53 of this chapter, evaluation of potential defects and failures to comply and reporting of defects and failures to comply under § 50.55(e) or § 53.605 of this chapter satisfies each person’s evaluation, notification, and reporting obligation to report defects and failures to comply under this part and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.

(c) For persons licensed to operate a nuclear power plant under part 50, part 52, or part 53 of this chapter, evaluation of potential defects and appropriate reporting of defects under § 50.72, § 50.73, § 53.1630, § 53.1640, or §§ 73.1200 and 73.1205 of

this chapter, satisfies each person's evaluation, notification, and reporting obligation to report defects under this part, and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.

* * * * *

69. In § 21.3, revise the definitions for "*Basic component*", "*Commercial grade item*", "*Critical characteristics*", "*Dedicating entity*", "*Dedication*", "*Defect*", and "*Substantial safety hazard*" to read as follows:

§ 21.3 Definitions.

* * * * *

Basic component. (1)(i) When applied to nuclear power plants licensed under part 53 of this chapter, basic component means a safety-related structure, system, or component, or part thereof, and when applied to nuclear power plants licensed under part 50 or part 52, of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

* * * * *

(2) When applied to standard design certifications and approvals under part 53 of this chapter, basic component means the design or procurement information approved or to be approved within the scope of the design certification or approval for a safety-related structure, system, or component, or part thereof. When applied to standard design certifications under subpart B of part 52 of this chapter and standard design approvals under part 52 of this chapter, basic component means the design or procurement information approved or to be approved within the scope of the design certification or approval for a structure, system, or component, or part thereof, that affects its safety function necessary to assure:

* * * * *

(4) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under part 52 or part 53 of this chapter, whether these services are performed by the component supplier or others.

Commercial grade item. (1) When applied to nuclear power plants licensed under 10 CFR part 50 or 10 CFR part 53, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

* * * * *

Critical characteristics. When applied to nuclear power plants licensed under parts 50, 52, or 53 of this chapter, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedicating entity. When applied to nuclear power plants licensed under parts 50, 52, or 53 of this chapter, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, under § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.

Dedication. (1) When applied to nuclear power plants licensed pursuant to parts 50, 52, or 53 of this chapter, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a quality assurance program under appendix B to part 50 of this chapter. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted under the applicable provisions of appendix B to part 50 of this chapter. The process is considered complete when the item is designated for use as a basic component.

* * * * *

Defect means:

(1) * * *

(3) A deviation in a portion of a facility subject to the early site permit, standard design certification, standard design approval, construction permit, combined license or manufacturing licensing requirements of parts 50, 52, or 53 of this chapter, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance;

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued under parts 50, 52, or 53 of this chapter; or

* * * * *

Substantial safety hazard means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC, other than for export, under parts 30, 40, 50, 52, 53, 60, 61, 63, 70, 71, or 72 of this chapter.

* * * * *

§ 21.21 [Amended]

70. In § 21.21:

a. In paragraph (a)(3) add “or part 53” after “under part 52” wherever it may appear; and

b. In paragraph (d)(1) add “53,” after “40, 50, 52” wherever they may appear.

§ 21.51 [Amended]

71. In § 21.51, add “or under subparts H or R of part 53” after “of part 52”, wherever it may appear.

§ 21.61 [Amended]

72. In § 21.61(b), add “or part 53” after “under part 52”, wherever it may appear.

PART 25 – ACCESS AUTHORIZATION

73. The authority citation for part 25 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 145, 161, 223, 234 (42 U.S.C. 2165, 2201, 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 44 U.S.C. 3504 note; E.O. 10865, 25 FR 1583, as amended, 3 CFR, 1959-1963 Comp., p. 398; E.O. 12829, 58 FR 3479, 3 CFR, 1993 Comp., p. 570; E.O. 13526, 75 FR 707, 3 CFR, 2009 Comp., p. 298; E.O. 12968, 60 FR 40245, 3 CFR, 1995 Comp., p. 391. Section 25.17(f) and Appendix A also issued under 31 U.S.C. 9701; 42 U.S.C. 2214.

§ 25.5 [Amended]

74. In § 25.5, in the definition for "*License*", add "53," after "50, 52".

§ 25.17 [Amended]

75. In § 25.17(a), add "53," after "50, 52".

§ 25.35 [Amended]

76. In § 25.35(a), add "or part 53" after "under part 52", wherever it may appear.

PART 26—FITNESS FOR DUTY PROGRAMS.

77. The authority citation for part 26 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 103, 104, 107, 161, 223, 234, 1701 (42 U.S.C. 2073, 2133, 2134, 2137, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

78. In § 26.3, revise paragraphs (a) through (d) and add paragraph (f) to read as follows:

§ 26.3 Scope.

(a) Licensees who are authorized to operate a nuclear power reactor under 10 CFR 50.57, and holders of a combined license under 10 CFR Part 52 after the Commission has made the finding under 10 CFR 52.103(g) shall comply with the requirements of this part, except for subparts K and M of this part. Licensees who receive their authorization to operate a nuclear power reactor under 10 CFR 50.57 after the date of publication of this final rule in the Federal Register and holders of a combined license under 10 CFR Part 52 after the Commission has made the finding under 10 CFR 52.103(g) shall implement the FFD program before the receipt of special nuclear material in the form of fuel assemblies.

(b) Licensees who are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) under Part 70 of this chapter, and any corporation, firm, partnership, limited liability company, association, or other organization

who obtains a certificate of compliance or an approved compliance plan under Part 76 of this chapter, only if the entity elects to engage in activities involving formula quantities of SSNM shall comply with the requirements of this part, except for subparts I, K and M of this part.

(c) Before the receipt of special nuclear material in the form of fuel assemblies, the following licensees and other entities shall comply with the requirements of this part, except for subparts I and M of this part; and, no later than the receipt of special nuclear material in the form of fuel assemblies, the following licensees and other entities shall comply with the requirements of this part:

* * * * *

(d) Contractor/vendors (C/Vs) who implement FFD programs or program elements, to the extent that the licensees and other entities specified in paragraphs (a) through (c) and (f) of this section rely on those C/V FFD programs or program elements to meet the requirements of this part, shall comply with the requirements of this part.

* * * * *

(f) No later than the start of construction activities, licensees of commercial nuclear plants and holders of limited work authorizations under part 53 of this chapter, must implement the requirements in subpart M of this part or all the requirements of this part except subparts I and M. Holders of a manufacturing license under part 53 of this chapter must implement the requirements in subpart M or all the requirements of this part except subparts K and M, before commencing manufacturing activities .

79. In § 26.4, revise paragraphs (a), (b), (c), (e), (f), (g) introductory text, and (h) to read as follows:

§ 26.4 FFD program applicability to categories of individuals.

(a) All persons who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a) and, as applicable, (c) and perform the following duties shall be subject to an FFD program that meets all of the requirements of this part, except subpart K of this part, and those persons who are granted unescorted access to either nuclear power reactor protected areas or remote facilities where safety-significant systems or components may be operated within the design basis of a licensed commercial nuclear plant, by the licensees and other entities in § 26.3(f) and perform the following duties must be subject to an FFD program that satisfies the requirements in subpart M of this part, unless the licensee or other entity subjects these individuals to an FFD program that satisfies all of the requirements of this part except for those requirements in subparts K and M:

(1) Operating or onsite directing of the operation of systems and components that a risk-informed evaluation process has shown to be significant to public health and safety (for commercial nuclear plants licensed under part 53 of this chapter, onsite directing of operation includes directing of operations at remote facilities described in paragraph (a) of this section);

* * * * *

(4) Performing maintenance or onsite directing of the maintenance of SSCs that a risk-informed evaluation process has shown to be significant to public health and safety (for commercial nuclear plants licensed under part 53 of this chapter, onsite direction of maintenance includes the directing of maintenance at remote facilities described in paragraph (a) of this section); and

* * * * *

(b) All persons who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a) and, as applicable, (c) and who do not

perform the duties described in paragraph (a) of this section must be subject to an FFD program that meets all of the requirements of this part, except §§ 26.205 through 26.209 and subpart K of this part. All persons who are granted unescorted access to a facility licensed under part 53 of this chapter, and who do not perform the duties described in paragraph (a) of this section, must be subject to the requirements in subpart M of this part, unless the licensee or other entity implements an FFD program that satisfies all of the requirements of this part, except §§ 26.205 through 26.209 and subparts K and M.

(c) All persons who are required by a licensee in § 26.3(a) and, as applicable, (c) to physically report to the licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF) by licensee emergency plans and procedures shall be subject to an FFD program that meets all of the requirements of this part, except §§ 26.205 through 26.209 and subpart K of this part. All persons who are required by a licensee in § 26.3(f) to participate remotely in emergency response activities or physically report to the TSC or EOF (or an equivalent facility), must be subject to an FFD program that satisfies all of the requirements described in subpart M of this part, unless the licensee or other entity implements an FFD program that satisfies all of the requirements of this part, except §§ 26.205 through 26.209 and subparts K and M.

* * * * *

(e) When construction activities, as defined in § 26.5, begin, any individual whose duties for the licensees and other entities in § 26.3(c) require him or her to have the following types of access or perform the following activities at the location where the nuclear power plant will be constructed and operated shall be subject to an FFD program that meets all of the requirements of this part, except subparts I, K, and M of this part, and for any individual whose duties for the licensees and other entities in § 26.3(f) require him or her to have the following types of access, perform construction

activities as defined in § 26.5, or perform the following activities must be subject to an FFD program as described in subpart M or an FFD program that satisfies all of the requirements of this part, except subparts I, K, and M:

* * * * *

(4) Witnesses or determines inspections, tests, and analyses certification required under Parts 52 or 53 of this chapter;

* * * * *

(f) Any individual who is constructing, manufacturing or directing the construction or manufacture of safety- or security-related SSCs shall be subject to an FFD program that meets the requirements of subpart K, or, if applicable, subpart M of this part, unless the licensee or other entity subjects these individuals to an FFD program that meets all of the requirements of this part, except for subparts I, K, and M of this part.

(g) All FFD program personnel who are involved in the day-to-day operations of the program, as defined by the procedures of the licensees and other entities in § 26.3(a) through (c), and, as applicable, (d) and whose duties require them to have the following types of access or perform the following activities shall be subject to an FFD program that meets all of the requirements of this part, except subparts I, K, and M of this part, and, at the licensee's or other entity's discretion, subpart C of this part. All personnel whose duties require them to have the following types of access or perform the following activities at facilities licensed under part 53 of this chapter must be subject to the requirements in subpart M or an FFD program that satisfies all of the requirements of this part, except subparts I, K, and M, and, at the licensee's or other entity's discretion, subpart C of this part.

* * * * *

(h) Individuals who have applied for authorization to have the types of access or perform the activities described in paragraphs (a) through (d) of this section shall be subject to §§ 26.31(c)(1), 26.35(b), 26.37, 26.39, and the applicable requirements of subparts C, E through H, and M of this part.

* * * * *

80. In § 26.5:

a. Add the definitions for "*Biological marker*", "*Change*", "*Illicit substance*", "*Reduction in FFD program effectiveness*", and "*Special nuclear material*", in alphabetical order; and

b. Revise the definitions for "*Constructing or construction activities*", "*Contractor/vendor (C/V)*", "*Other entity*", "*Questionable validity*", "*Reviewing official*", "*Safety-related structures, systems, and components (SSCs)*", "*Security-related SSCs*", and "*Unit outage*".

The additions and revisions to read as follows:

§ 26.5 Definitions.

* * * * *

Biological marker means, for a part 53 licensee implementing subpart M of this part, an endogenous substance that is used to validate that the biological specimen collected for testing was produced by the donor.

* * * * *

Change as used in § 26.603(e) means an action that results in a modification of, addition to, or removal from the licensee's or other entity's FFD program.

* * * * *

Constructing or construction activities means, for the purposes of this part, the tasks involved in building a nuclear power plant that are performed at the location where

the nuclear power plant will be constructed and operated. These tasks include fabricating, erecting, integrating, and testing safety- and security-related SSCs, and the installation of their foundations, including the placement of concrete. For a licensee or other entity described in § 26.3(f), construction is defined in § 53.020 of this chapter.

Contractor/vendor (C/V) means any company, or any individual not employed by a licensee or other entity specified in § 26.3(a) through (c) and (f), who is providing work or services to a licensee or other entity covered in § 26.3(a) through (c) and (f), either by contract, purchase order, oral agreement, or other arrangement.

* * * * *

Illicit substance means a substance that causes impairment and possible addiction but is not an illegal drug as defined in § 26.5.

* * * * *

Other entity means any corporation, firm, partnership, limited liability company, association, C/V, or other organization who is subject to this part under § 26.3(a) through (c) and (f) but is not licensed by the NRC.

* * * * *

Questionable validity means the results of validity screening or initial validity tests at a licensee testing facility indicating that a urine specimen may be adulterated, substituted, dilute, or invalid. For a part 53 licensee or other entity, *questionable validity* means the results of validity screening or initial validity tests indicating that a biological specimen obtained from an individual pursuant to subpart M of this part may be adulterated, substituted, dilute, or invalid.

Reduction in FFD program effectiveness means, for a part 53 licensee or other entity implementing subpart M of this part, a change or series of changes to an element of the FFD program that reduces or eliminates the licensee’s ability to satisfy or maintain

site-specific FFD program performance when compared to historical site-specific performance, the licensee's fleet-level program performance, or industry performance.

Reviewing official means an employee of a licensee or other entity specified in § 26.3(a) through (c), and (f) who is designated by the licensee or other entity to be responsible for reviewing and evaluating any potentially disqualifying FFD information about an individual, including, but not limited to, the results of a determination of fitness, as defined in § 26.189, in order to determine whether the individual may be granted or maintain authorization.

Safety-related structures, systems, and components (SSCs), for persons described in § 26.3(a) through (d) and (f), has the same meaning as that in § 50.2 or § 53.020 of this chapter, as applicable.

Security-related SSCs means, for the purposes of this part, those structures, systems, and components that the licensee will rely on to implement the licensee's physical security and safeguards contingency plans that either are required under Part 73 of this chapter if the licensee is a construction permit applicant or holder or an early site permit holder, as described in § 26.3(c)(3) through (c)(5), respectively, or are included in the licensee's application if the licensee is a combined license applicant or holder, as described in § 26.3(c)(1) and (c)(2), respectively, or a licensee or other entity described in § 26.3(d) and (f).

* * * * *

Special nuclear material (SNM) has the same meaning as that in § 70.4 of this chapter.

* * * * *

Unit outage means, for the purposes of this part that the reactor unit is neither connected to the electrical grid, for a reactor that generates electricity nor connected to

the loads to which its output is supplied under normal operating conditions, for a reactor with non-electric outputs.

* * * * *

§ 26.8 [Amended]

81. In § 26.8(b), add “26.202, 26.603, 26.604, 26.605, 26.606, 26.607, 26.608, 26.609, 26.611, 26.613, 26.617, 26.619”, in numerical order.

82. Revise § 26.21 to read as follows:

§ 26.21 Fitness-for-duty program.

The licensees and other entities specified in § 26.3(a) through (c) and (f) (for those licensees and other entities that do not implement the requirements in subparts M and K of this part) shall establish, implement, and maintain FFD programs that, at a minimum, comprise the program elements contained in this subpart. The individuals specified in § 26.4(a) through (e) and (g), and, at the licensee's or other entity's discretion, § 26.4(f), and, if necessary, § 26.4(j) shall be subject to these FFD programs. Licensees and other entities may rely on the FFD program or program elements of a C/V, as defined in § 26.5, if the C/V's FFD program or program elements satisfy the applicable requirements of this part.

83. Revise § 26.51 to read as follows:

§ 26.51 Applicability.

The requirements in this subpart apply to the licensees and other entities identified in § 26.3(a), (b), and, as applicable, (c) for the categories of individuals in § 26.4(a) through (d), and, at the licensee's or other entity's discretion, in § 26.4(g) and, if necessary, § 26.4(j). The requirements in this subpart also apply to the licensees and other entities specified in § 26.3(c), as applicable, for the categories of individuals in § 26.4(e). At the discretion of a licensee or other entity in § 26.3(c), the requirements of

this subpart also may be applied to the categories of individuals identified in § 26.4(f). In addition, the requirements in this subpart apply to the entities in § 26.3(d) to the extent that a licensee or other entity relies on the C/V to satisfy the requirements of this subpart. Certain requirements in this subpart also apply to the individuals specified in § 26.4(h). The requirements in this subpart apply to the FFD programs of licensees and other entities identified in § 26.3(f) that elect not to implement the requirements in subpart M for the categories of individuals in § 26.4 and those licensees and other entities that elect to implement the requirements in § 26.605.

§ 26.53 [Amended]

84. In § 26.53:

a. In paragraph (e), add ", and (f)" after "§ 26.3(a) through (c)", wherever it may appear;

b. In paragraphs (g), (h), and (i) add ", (d), and (f)" after "as applicable (c)", wherever it may appear.

§ 26.63 [Amended]

85. In § 26.63(d), add "and (f)" after "§ 26.3(a) through (d)".

86. Revise § 26.73 to read as follows:

§ 26.73 Applicability.

The requirements in this subpart apply to the licensees and other entities identified in § 26.3(a), (b), and, as applicable, (c) for the categories of individuals specified in § 26.4(a) through (d) and (g). The requirements in this subpart also apply to the licensees and other entities specified in § 26.3(c), as applicable, for the categories of individuals in § 26.4(e). At the discretion of a licensee or other entity in § 26.3(c), the requirements of this subpart also may be applied to the categories of individuals identified in § 26.4(f). In addition, the requirements in this subpart apply to the entities in

§ 26.3(d) to the extent that a licensee or other entity relies on the C/V to satisfy the requirements of this subpart. The regulations in this subpart also apply to the individuals specified in § 26.4(h) and (j), as appropriate. The requirements in this subpart apply to the FFD programs of licensees and other entities identified in § 26.3(f) that elect not to implement the requirements in subpart M for the categories of individuals in § 26.4 and those licensees and other entities that elect to implement the requirements in § 26.605(b).

87. Revise § 26.81 to read as follows:

§ 26.81 Purpose and applicability.

This subpart contains requirements for collecting specimens for drug testing and conducting alcohol tests by or on behalf of the licensees and other entities in § 26.3(a) through (d) for the categories of individuals specified in § 26.4(a) through (d) and (g). At the discretion of a licensee or other entity in § 26.3(c), specimen collections and alcohol tests must be conducted either under this subpart for the individuals specified in § 26.4(e) and (f) or the licensee or other entity may rely on specimen collections and alcohol tests conducted under the requirements of 49 CFR Part 40 for the individuals specified in § 26.4(e) and (f). The requirements of this subpart do not apply to specimen collections and alcohol tests that are conducted under the requirements of 49 CFR Part 40, as permitted in this paragraph and under §§ 26.4(j) and 26.31(b)(2) and Subpart K. The requirements in this subpart apply to the FFD programs of licensees and other entities identified in § 26.3(f) that elect not to implement the requirements in subpart M for the categories of individuals in § 26.4 and those licensees and other entities that elect to implement the requirements in § 26.605.

88. In § 26.201, redesignate the introductory text as new paragraph (a), revise it and add new paragraph (b) to read as follows:

§ 26.201 Applicability.

(a) The requirements in this subpart, with the exception of § 26.202, apply to the licensees and other entities identified in § 26.3(a); if applicable, (c) and (d); and (f), for licensees and other entities not implementing the requirements in subparts K and M. For the licensees and other entities to whom the requirements in this subpart, with the exception of § 26.202, apply, the requirements in §§ 26.203 and 26.211 apply to the individuals identified in § 26.4(a) through (c). In addition, the requirements in § 26.205 through § 26.209 apply to the individuals identified in § 26.4(a).

(b) The requirements in this subpart, with the exception of § 26.203, apply to the licensees or other entities identified in § 26.3(f) implementing this subpart under §§ 26.604 and 26.605. For these licensees and other entities, the requirements in §§ 26.202 and 26.211 apply to the individuals identified in § 26.4(a) through (c) and any NRC-licensed operator; and the requirements in §§ 26.205 through 26.209 apply to the individuals identified in § 26.4(a).

89. Add § 26.202 to read as follows:

§ 26.202 General provisions for facilities implementing subpart M of this part

(a) *Policy*. Licensees must establish a policy for the management of fatigue for all individuals who are subject to the licensee's FFD program and incorporate it into the written policy required in § 26.606(a).

(b) *Procedures*. In addition to the procedures required in § 26.606(b), licensees must develop, implement, and maintain procedures that—

(1) Describe the process to be followed when any individual identified in § 26.4(a) through (c) makes a self-declaration that he or she is not fit to safely and competently perform his or her duties for any part of a working tour as a result of fatigue. The procedure must—

(i) Describe the individual's and licensee's rights and responsibilities related to self-declaration;

(ii) Describe requirements for establishing controls and conditions under which an individual may be permitted or required to perform work after that individual declares that he or she is not fit due to fatigue; and

(iii) Describe the process to be followed if the individual disagrees with the results of a fatigue assessment that is required under § 26.211(a)(2);

(2) Describe the process for implementing the controls required under § 26.205 for the individuals who are performing the duties listed in § 26.4(a);

(3) Describe the process to be followed in conducting fatigue assessments under § 26.211; and

(4) Describe the disciplinary actions that the licensee may impose on an individual following a fatigue assessment, and the conditions and considerations for taking those disciplinary actions.

(c) *Training and assessments*. Licensees must include the following KAs in the content of the training and trainee assessments required in § 26.608:

(1) Knowledge of the contributors to worker fatigue, circadian variations in alertness and performance, indications and risk factors for common sleep disorders, shiftwork strategies for obtaining adequate rest, and the effective use of fatigue countermeasures; and

(2) Ability to identify symptoms of worker fatigue and contributors to decreased alertness in the workplace.

(d) *Recordkeeping*. Licensees must retain the following records for at least 3 years or until the completion of all related legal proceedings, whichever is later:

(1) Records of work hours for individuals who are subject to the work hour controls in § 26.205;

(2) For licensees implementing the requirements of § 26.205(d)(3), records of shift schedules and shift cycles, or, for licensees implementing the requirements of § 26.205(d)(7), records of shift schedules and records showing the beginning and end times and dates of all averaging periods, of individuals who are subject to the work hour controls in § 26.205;

(3) The documentation of waivers that is required in § 26.207(a)(4), including the bases for granting the waivers;

(4) The documentation of work hour reviews that is required in § 26.205(e)(3) and (e)(4); and

(5) The documentation of fatigue assessments that is required in § 26.211(g).

(e) *Reporting*. Licensees must include the following information in a standard format in the annual FFD program performance report required under § 26.617(b)(2):

(1) A summary for each nuclear power plant site of all instances during the previous calendar year when the licensee waived one or more of the work hour controls specified in § 26.205(d)(1) through (d)(5)(i) and (d)(7) for individuals described in § 26.4(a). The summary must include only those waivers under which work was performed. If it was necessary to waive more than one work hour control during any single extended work period, the summary of instances must include each of the work hour controls that were waived during the period. For each category of individuals specified in § 26.4(a), the licensee must report—

(i) The number of instances when each applicable work hour control specified in § 26.205(d)(1)(i) through (iii), (d)(2)(i) and (ii), (d)(3)(i) through (v), and (d)(7) was waived for individuals not working on outage activities;

(ii) The number of instances when each applicable work hour control specified in § 26.205(d)(1)(i) through (iii), (d)(2)(i) and (ii), (d)(3)(i) through (v), (d)(4) and (d)(5)(i), and (d)(7) was waived for individuals working on outage activities; and

(iii) A summary that shows the distribution of waiver use among the individuals applicable within each category of individuals identified in § 26.4(a) (e.g., a table that shows the number of individuals who received only one waiver during the reporting period, the number of individuals who received a total of two waivers during the reporting period).

(2) A summary of corrective actions, if any, resulting from the analyses of these data, including fatigue assessments.

(f) *Audits*. Licensees must audit the management of worker fatigue under § 26.615.

90. In § 26.205, revise paragraphs (d)(7)(iii) and (d)(8) to read as follows:

§ 26.205 Work Hours.

* * * * *

(d) * * *

(7) * * *

(iii) Each licensee shall state, in its FFD policy and procedures required by either § 26.27 and § 26.203(a) and (b) or § 26.202(a) and (b) and § 26.606, the work hour counting system in § 26.205(d)(7)(ii) the licensee is using.

(8) Each licensee shall state, in its FFD policy and procedures required by either § 26.27 and § 26.203(a) and (b) or § 26.202(a) and (b) and § 26.606, the requirements with which the licensee is complying: the minimum days off requirements in § 26.205(d)(3) or maximum average work hours requirements in § 26.205(d)(7).

* * * * *

91. In § 26.207, revise paragraph (a)(1)(ii) to read as follows:

§ 26.207 Waivers and exceptions.

(a) * * *

(1) * * *

(ii) A supervisor assesses the individual face to face and determines that there is reasonable assurance that the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver will be granted. The supervisor performing the assessment shall be trained as required by either § 26.29 and § 26.203(c) or § 26.202(c) and § 26.608 and must be qualified to direct the work to be performed by the individual. If there is no supervisor on site who is qualified to direct the work, the assessment may be performed by a supervisor who is qualified to provide oversight of the work to be performed by the individual. At a minimum, the assessment must address the potential for acute and cumulative fatigue considering the individual's work history for at least the past 14 days, the potential for circadian degradations in alertness and performance considering the time of day for which the waiver will be granted, the potential for fatigue-related degradations in alertness and performance to affect risk-significant functions, and whether any controls and conditions must be established under which the individual will be permitted to perform work. For licensees and other entities in § 26.3(f), the assessment may be performed remotely using electronic communications. In such instances, the assessment must be supported by someone who is present in-person with the individual whose alertness may be impaired, and that supporting person must be trained under the requirements of either § 26.29 and § 26.203(c) or § 26.202(c) and § 26.608.

* * * * *

92. In § 26.211, revise paragraphs (a)(1) and (3), and (b) introductory text to read as follows:

§ 26.211 Fatigue assessments.

(a) * * *

(1) *For-cause*. In addition to any other test or determination of fitness that may be required under §§ 26.31(c), 26.77, 26.607(b), and 26.619, a fatigue assessment must be conducted in response to an observed condition of impaired individual alertness creating a reasonable suspicion that an individual is not fit to safely and competently perform his or her duties, except if the condition is observed during an individual's break period. If the observed condition is impaired alertness with no other behaviors or physical conditions creating a reasonable suspicion of possible substance abuse, then the licensee need only conduct a fatigue assessment. If the licensee has reason to believe that the observed condition is not due to fatigue, the licensee need not conduct a fatigue assessment;

* * * * *

(3) *Post-event*. A fatigue assessment must be conducted in response to events requiring post-event drug and alcohol testing as specified in § 26.31(c) or post-event tests in § 26.607(b)(4). Licensees may not delay necessary medical treatment in order to conduct a fatigue assessment; and

* * * * *

(b) Only supervisors and FFD program personnel who are trained under either §§ 26.29 and 26.203(c) or §§ 26.202(c) and 26.608 may conduct a fatigue assessment. The fatigue assessment must be conducted face to face with the individual whose alertness may be impaired. For licensees and other entities in § 26.3(f), a fatigue assessment may be performed remotely using electronic communications. In such

instances, the fatigue assessment must be supported by someone who is present in-person with the individual whose alertness may be impaired, and that supporting person must be trained in accordance with the requirements of either §§ 26.29 and 26.203(c) or §§ 26.202(c) and 26.608.

* * * * *

93. Add subpart M – Fitness for Duty Programs for Facilities Licensed Under 10 CFR part 53 and new §§ 26.601 through 26.619 to read as follows:

Subpart M – Fitness for Duty Programs for Facilities Licensed Under 10 CFR Part 53

Sec.

§ 26.601 Applicability.

A licensee or other entity in § 26.3(f), at its discretion, may establish, implement, and maintain an FFD program that satisfies the requirements of this subpart for those categories of individuals in § 26.4, as applicable, and any NRC-licensed operator. If a licensee or other entity in § 26.3(f) does not elect to implement an FFD program that satisfies the requirements of this subpart, then those categories of individuals in § 26.4, as applicable, and any NRC-licensed operator must be subject to an FFD program that satisfies all part 26 requirements, except for those requirements in subparts K and M.

§ 26.603 General provisions.

(a) *FFD program description*. An applicant's description of the FFD program in its Final Safety Analysis Report, required by subparts H or R of part 53 of this chapter, as applicable, must include—

(1) If the applicant performed the analysis under § 26.603(c), a summary of the analysis, including the assumptions, methodology, conclusion, and references;

(2) A statement whether the FFD program will be implemented pursuant to § 26.604 or § 26.605, or will satisfy all part 26 requirements, except for the requirements in subparts K and M;

(3) A discussion of the applicability of the FFD program to those individuals described in § 26.4 and how the program will be implemented offsite at an NRC-licensed facility authorized to assemble or test a manufactured reactor, if applicable;

(4) A description of the drug and alcohol testing and fitness determination process to be implemented through the licensee's or other entity's procedures, including the collection and testing facilities to be used, biological specimens to be collected, and sanctions to be imposed upon a confirmed FFD policy violation; and

(5) A summary of the FFD performance monitoring and review program, including the measures and thresholds required by § 26.603(d)(1).

(b) *FFD program implementation and availability*. For the licensees and other entities in § 26.3(f), other than the holder of a manufacturing license, the FFD program must be implemented no later than the start of construction activities, as defined in § 26.5, and maintained until the NRC's docketing of the license holder's certifications described in § 53.1070 or § 53.4670 of this chapter. For holders of a manufacturing license, the FFD program must be implemented no later than the start of activities that assemble the manufactured reactor and maintained until expiration of the manufacturing license.

(c) *FFD performance monitoring and review*. A licensee or other entity must establish performance measures and associated thresholds as described in § 26.603(c)(1) and monitor the effectiveness of its FFD program by comparing performance data against these performance measures and thresholds, in a manner sufficient to satisfy the § 26.23 performance objectives.

(1) The performance monitoring and review program (PMRP) must be documented and maintained and include the following program elements:

(i) *Performance measures*. Performance measures must be identified and designed to monitor FFD program performance.

(A) If the licensee or other entity is subject to the requirements in § 26.604, then the monitoring program must include performance measures for the following: the behavioral observation program; occurrence of FFD policy violations categorized by licensee employee, contractor/vendor, and labor category; and occurrence of individuals with potentially disqualifying information or who possessed FFD prohibited items.

(B) If the licensee or other entity is subject to the requirements in § 26.604 and has implemented a drug testing program at its discretion or is subject to the requirements of § 26.605, then the monitoring program must include performance measures identified in § 26.603(d)(1)(i)(A). This monitoring program must also include performance measures for the pre-access and random positive testing rates, random testing rate for licensee employees and contractor/vendors, and the number of subversion attempts categorized by licensee employee, contractor/vendor, and labor category.

(ii) *Thresholds*. Licensee- or other entity-specific thresholds for its site-specific performance measures must be established and used to facilitate corrective actions to maintain FFD program performance. Initial thresholds must be based on FFD

performance data from comparable facilities subject to part 26, the licensee's or other entity's fleet-level program performance if applicable, and industry FFD performance data.

(iii) *Monitoring program*. Licensees and other entities must monitor the performance of their FFD programs against licensee- or other entity-established performance measures and thresholds as FFD performance data is received to determine whether a threshold has been exceeded. Licensees and other entities must perform year-to-year comparisons of site-specific performance; site-specific performance to the licensee's or other entity's fleet-level program performance, if applicable; and site-specific to industry performance.

(iv) *Quantitative and qualitative reviews*. The PMRP must include a documented review of the elements in § 26.603(a)(1)(i) through (iii) and the following qualitative elements.

(A) *Worker protections*. The review must include a documented assessment of the licensee's or other entity's implementation of the protections described in §§ 26.606(b)(1)(iii), 26.611, and 26.613.

(B) *Laboratory test results and Medical Review Officer performance*. The review must include a documented assessment of whether the actions taken by the Medical Review Officer (MRO) met the requirements in § 26.185 based on the laboratory test results reported under § 26.169. This review must include a comparative analysis between the point of collection testing and assessment (POCTA) screening result(s) and the corresponding specimen test results obtained from the U.S. Department of Health and Human Services (HHS)-certified laboratory if the POCTA indicated a positive, adulterated, substituted, or invalid screening result or discrepant biological marker, to

assess the effectiveness of the POCTA and to inform MRO decisions under § 26.185 or § 26.607(m)(6).

(C) *Change control*. The review must include a documented assessment of the changes made under § 26.603(d) to verify that the summation of program changes has not resulted in a reduction in FFD program effectiveness.

(2) *Corrective actions*. Corrective actions must be implemented to address when FFD performance meets a licensee-established performance threshold or to resolve a finding resulting from a qualitative review or audit in a manner that restores performance and corrects root causes, contributing causes, or both.

(3) *Program review periodicity*. The documented review in § 26.603(a)(1)(iv) must be conducted biennially to assess and modify licensee or other entity implementation of its FFD program. This documented review must demonstrate that the performance measures and thresholds are appropriate and adjusted as necessary based on site-level and licensee's or other entity's fleet-level, if applicable, program performance, and industry performance.

(i) Identified program weaknesses and corrective actions must be summarized in the annual reporting requirement described in § 26.617(b)(2) or § 26.717, as applicable.

(ii) The program review must be completed and approved by the licensee or other entity to support the reporting of PMRP weaknesses and corrective actions as required in § 26.603(c)(3)(i) every odd-numbered year, and the implementation of corrective actions before May 15 of that odd-numbered year.

(d) *FFD program change control.*

(1) The licensee or other entity may make changes to its FFD program under this subpart if—

(i) The licensee or other entity performs and retains an analysis demonstrating that the changes do not reduce the effectiveness of the FFD program; or

(ii) The change was necessitated or justified by a change to part 26, laboratory processes or procedures, or guidance issued by the HHS or NRC, as implemented by the licensee or other entity though its procedures.

(2) A licensee or other entity desiring to make a change that decreases FFD program effectiveness must implement a mitigating strategy so the FFD program, as revised, will continue to satisfy the performance objectives in § 26.23 and not result in a reduction in program effectiveness.

(3) Except for phencyclidine, and notwithstanding § 26.603(b)(1)(ii), the change control process may not be used to reduce the minimum panel of drugs to be tested in § 26.607(c)(1).

(4) The licensee must retain a record of each change made under this section for a period of at least 5 years from the date the change was implemented and summarize this change in its annual FFD performance report required by § 26.617(b)(2) or § 26.717, as applicable.

§ 26.604 FFD program requirements for low consequence facilities.

(a) *Low consequence facilities*. A low consequence facility is one for which the radiological consequences from a design-basis threat initiated event involving the loss of engineered systems for decay heat removal and possible breaches in physical structures surrounding the reactor, spent fuel, and other inventories of radioactive materials result in offsite doses below the values in § 53.210 of this chapter.

(b) *FFD program*. A licensee or other entity that performs a site-specific analysis that demonstrates that its facility and operation satisfies the criterion in paragraph (a) of

this section may elect to establish, implement, and maintain an FFD program under this section. That FFD program must contain the following elements:

(1) Applies to those individuals described in § 26.4, as applicable; and

(2) Implements the following requirements and subparts in this part:

(i) § 26.23, Performance objectives;

(ii) § 26.603, General provisions;

(iii) § 26.606, Written policies and procedures, (a) and, if applicable (b);

(iv) § 26.608, FFD program training;

(v) § 26.609, Behavioral observation;

(vi) § 26.610, Sanctions;

(vii) § 26.611, Protection of information;

(viii) § 26.613, Appeals process;

(ix) § 26.615, Audits;

(x) § 26.617, Recordkeeping and reporting;

(xi) § 26.619, Suitability and fitness determinations;

(xii) Subpart A—Administrative Provisions;

(xiii) Subpart I—Managing Fatigue; and

(xiv) Subpart O—Inspections, Violations, and Penalties.

(c) *Update of analysis*. A licensee that follows the provisions of this section must maintain the analysis, including updates to reflect changes made to the staffing, FFD programs, or offsite support resources described in the analysis to show that the facility and its operation continue to satisfy the criterion of paragraph (a) of this section until permanent cessation of operations under § 53.1070 of this chapter. If the criterion of paragraph (a) is no longer met, the licensee must establish, implement, and maintain an FFD program under § 26.605.

§ 26.605 FFD program requirements for facilities that do not implement § 26.604.

(a) *Program elements*. Licensees and other entities subject to this subpart that do not meet the criteria in § 26.604(a) or do not elect to establish, implement and maintain a fitness-for-duty (FFD) program under § 26.604 must establish, implement, and maintain an FFD program under this section that contains the following elements:

(1) Applies to those individuals described in § 26.4, as applicable; and,

(2) Implements the following requirements and subparts in this part—

(i) § 26.23, Performance objectives;

(ii) § 26.603, General provisions;

(iii) § 26.606, Written policy and procedures;

(iv) § 26.607, Drug and alcohol testing;

(v) § 26.608, FFD program training;

(vi) § 26.609, Behavioral observation;

(vii) § 26.610, Sanctions;

(viii) § 26.611, Protection of information;

(ix) § 26.613, Appeals process;

(x) § 26.615, Audits;

(xi) § 26.617, Recordkeeping and reporting;

(xii) § 26.619, Suitability and fitness determinations;

(xiii) Subpart A—Administrative Provisions;

(xiv) Subpart I—Managing Fatigue, in the case of holders of a manufacturing license that allows the assembly, testing, or both of a manufactured reactor; and

(xv) Subpart O—Inspections, Violations, and Penalties.

(b) Licensees and other entities subject to this section, before the loading of fuel onsite into a reactor vessel; before receiving a manufactured reactor; or before

individuals subject to part 26 operate, test, perform maintenance of, or direct the maintenance or surveillance of security-related equipment or equipment that a risk-informed evaluation process or alternative method for evaluating safety significance has shown to be significant to public health and safety, must establish, implement, and maintain an FFD program that—

(1) Applies to those individuals described in § 26.4, as applicable; and,

(2) Implements the following requirements and subparts—

(i) § 26.23, Performance objectives;

(ii) § 26.603, General provisions;

(iii) § 26.606, Written policy and procedures;

(iv) § 26.607, Drug and alcohol testing;

(v) § 26.608, FFD program training;

(vi) § 26.609, Behavioral observation;

(vii) § 26.611, Protection of information;

(viii) § 26.613, Appeals process;

(ix) § 26.615, Audits;

(x) Subpart A—Administrative Provisions;

(xi) Subpart C—Granting and Maintaining Authorization;

(xii) Subpart D—Management Actions and Sanctions to be Imposed;

(xiii) Subpart H—Determining Fitness-for-Duty Policy Violations and Determining Fitness, unless using the HHS Guidelines for MRO evaluation of drug test results, and determining fitness;

(xiv) Subpart I—Managing Fatigue;

(xv) Subpart N—Recordkeeping and Reporting Requirements; and

(xvi) Subpart O—Inspections, Violations, and Penalties.

§ 26.606 Written policy and procedures.

(a) Licensees and other entities that implement an FFD program under this subpart must ensure that—

(1) A written FFD policy statement is provided to each individual who is subject to the program before the individual is subject to behavioral observation, drug and alcohol testing, or both.

(2) The FFD policy statement describes the performance objectives in § 26.23.

(3) The FFD policy statement describes the minimum days off requirements in § 26.205(d)(3) or maximum average work hours requirements in § 26.205(d)(7), if applicable.

(4) The FFD policy statement must be written in sufficient detail to provide affected individuals with information on what is expected of them and what consequences may result from a lack of adherence to the policy, including those elements described in § 26.606(b), part 26-required sanctions, and required medical/clinical treatment and follow-up testing for FFD policy violations.

(5) The FFD policy statement describes the individual's responsibilities to report for work in a physiological and psychological condition that enables the safe and competent performance of assigned duties and responsibilities and inform a licensee- or other entity-designated representative when the individual determines that this cannot be accomplished.

(b) Licensees and other entities must establish, implement, and maintain written procedures that address the following topics:

(1) If implementing a drug and alcohol testing program under this subpart,

(i) The methods and techniques to collect and test for drugs and alcohol and for the shipping and temporary storage of biological specimens used for drug testing at HHS-certified laboratories,

(ii) The urine specimen volumes, techniques for split specimen collections, and the acceptability of a urine specimen as described in § 26.111 or as described in the HHS Guidelines,

(iii) Protecting the privacy of an individual who provides a specimen, protecting the integrity of the specimen, and ensuring that the test results are valid and attributable to the correct individual, and

(iv) If the licensee or other entity elects to use the HHS Guidelines, the name of the specific HHS Guideline and revision being implemented by the licensee or other entity and a description of the specific sections in the guideline that are being implemented in the procedure, including specimen collections, drug testing, and evaluation of test results.

(2) The immediate and follow-up actions that will be taken, and the procedures to be used, in those cases in which individuals who are subject to the FFD program:

(i) Have been involved in the use, sale, or possession of illegal substances, illegal drugs, or illicit substances;

(ii) Are impaired by any illegal substances, illegal drugs, or illicit substances or the consumption of alcohol as determined by behavioral observation or a test that measures blood alcohol concentration;

(iii) If drug and alcohol testing is conducted, attempted to subvert the testing process by adulterating or diluting specimens (*in vivo* or *in vitro*), substituting specimens, or by any other means;

(iv) If drug and alcohol testing is conducted, refused to provide a specimen for analysis or follow instructions provided by FFD program personnel;

(v) Had legal action taken relating to drug or alcohol use; or

(vi) Demonstrated character or actions indicating that the individual cannot be trusted or relied upon to perform those duties and responsibilities or maintain access to NRC-licensed facilities, SNM, or sensitive information.

(3) The process, including the duties and responsibilities of FFD program personnel, to be followed if an individual's behavior or condition raises a concern regarding the possible use, sale, or possession of illegal drugs on- or offsite; the possible use or possession of alcohol on the NRC-licensed facility; impairment from any cause that in any way could adversely affect the individual's ability to safely and competently perform the individual's duties; or the receipt of credible information indicating that the individual cannot be trusted or relied on to perform those duties and responsibilities making the individual subject to this part.

(4) Operation and oversight of an onsite or offsite collection facility.

(5) The fatigue management requirements in §§ 26.202(b), 26.205(d)(3) and 26.205(d)(7), if applicable.

(6) Measures to prevent subversion of drug and alcohol tests conducted onsite and offsite.

§ 26.607 Drug and alcohol testing.

Licensees and other entities implementing § 26.604, at their discretion, and licensees and other entities implementing § 26.605 must perform drug and alcohol testing that complies with the following requirements—

(a) *Split specimens.* Split specimen collections of oral fluid or urine must be used for the test conditions described in § 26.607(b). A split specimen collection need not be

used if the licensee or other entity elects to use a POCTA device for a screening test conducted during random testing under § 26.607(b)(2) and (h) or a protected area portal monitor indication that drugs or alcohol were detected under § 26.607(j). Testing of the split specimen (specimen B) requires the donor's permission unless ordered by the MRO to resolve an invalid test result obtained for specimen A.

(b) *Test conditions.* Individuals identified in § 26.4 must be subject to drug and alcohol testing under the following conditions:

(1) *Pre-access*. A pre-access test must be conducted for drugs and alcohol before performing or directing the conduct of roles and responsibilities making the individual subject to this subpart or being granted unescorted access to the protected areas of the NRC-licensed facility. A pre-access test must have been conducted no more than 14 days before the individual is granted unescorted access.

(2) *Random testing*. Random testing for drugs and alcohol must—

(i) Be administered in a manner that provides reasonable assurance that individuals are unable to predict the time periods during which specimens will be collected;

(ii) Require individuals who are selected for random testing to report to the onsite collection site as soon as reasonably practicable after notification, within the time period specified in the FFD program procedure;

(iii) Ensure that all individuals in the population that is subject to random testing on a given day have an equal probability of being selected and tested;

(iv) Ensure that an individual completing a test is immediately eligible for another random test; and

(v) Ensure that the sampling process used to select individuals for random testing provides that the number of random tests performed annually is equal to at least

50 percent for licensee employees and 50 percent for contractor/vendors at the NRC-licensed site.

(3) *For-cause*. A for-cause drug test, alcohol test, or both, must be conducted onsite in response to an individual's observed behavior or physical condition indicating possible substance abuse or after receiving credible information that an individual is engaging in substance abuse, as defined in § 26.5;

(4) *Post-event*. A post-event test for drugs and alcohol must be conducted—

(i) As soon as practical after an event involving a human error that was committed by an individual specified in § 26.4, where the human error may have caused or contributed to the event. This test must be conducted onsite unless the individual requires offsite medical care. The licensee or other entity must test the individual(s) who committed or directed the error and need not test individuals who were affected by the event and whose actions likely did not cause or contribute to the event for use in subpart M implementation. The licensee or other entity must describe in its procedures what constitutes a human error and event.

(ii) Within 4 hours of an accident unless immediate medical intervention precludes the conduct of the test on the individual(s) who caused or contributed to the accident(s), if the accident results in—

(A) An illness or personal injury to any individual which results in death, days away from work, restricted work, transfer to another job, medical treatment beyond first aid, loss of consciousness, or other significant illness or injury, as diagnosed by a licensee- or other entity-designated physician or other licensed health care professional, even if the illness or injury does not result in death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness; or

(B) Damage to any safety- or security-related SSC; and

(5) *Follow-up*. An individual subject to part 26 who has violated the FFD policy for substance use or abuse, or the sale, use, or possession of illegal drugs must be subject to a follow-up series of tests for drugs, alcohol, or both to verify an individual's continued abstinence from substance abuse.

(c) *Urine and oral fluid specimens.*

(1) All urine or oral fluid specimens must be subject to validity testing, including an adulterant and biological marker, and tested for the substances listed in § 26.31(d)(1), except as allowed by § 26.603(e)(3).

(2) For the use of urine as the biological specimen to be tested, the following requirements must be implemented—

(i) § 26.115, Collecting a urine specimen under direct observation;

(ii) § 26.119, Determining “shy” bladder; and

(iii) § 26.163, Cutoff levels for validity testing, (a)(2) regarding special analysis testing.

(3) For alcohol testing onsite, the following requirements must be implemented—

(i) § 26.91, Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use;

(ii) § 26.93, Preparing for alcohol testing;

(iii) § 26.95, Conducting an initial test for alcohol using a breath specimen;

(iv) § 26.97, Conducting an initial test for alcohol using a specimen of oral fluids;

(v) § 26.99, Determining the need for a confirmatory test for alcohol;

(vi) § 26.101, Conducting a confirmatory test for alcohol; and,

(vii) § 26.103, Determining a confirmed positive test result for alcohol.

(4) For all test conditions in § 26.607(b), except for the use of a POCTA screening device in § 26.607(h), and for MRO-directed tests under § 26.185, drug

testing must be performed at an HHS-certified laboratory for the specific biological specimen to be tested. Only HHS-certified laboratory test results using urine or oral fluid may be used for the issuance of a part 26-required sanction. The licensee or other entity must establish and maintain a contract with a primary and a back-up HHS-certified laboratory (with a different Certifying Scientist) for the specimen(s) to be tested. These contracts must stipulate that the laboratories are subject to inspection or audit by the licensee or other entity and that records and documents must be provided and/or able to be photocopied and removed from the premise to support the inspection or audit.

(d) *Privacy and integrity*. The specimen collection and drug and alcohol testing procedures of FFD programs must protect the donor's privacy and the integrity of the specimen and implement quality controls to ensure that test results are valid and attributable to the correct individual.

(e) *Offsite collection facilities.* At the licensee's or other entity's discretion, specimen collections and alcohol testing may be conducted at a local hospital or other facility licensed to conduct specimen collections and perform alcohol testing and audited by the State or a State-designated entity. The licensee or other entity must audit these facilities, if used, before their initial use and then on a biennial basis to confirm that the facility procedures are comparable to those described in subpart E of this part or the HHS Guidelines for urine and oral fluid.

(f) *Initial testing*. A licensee or other entity subject to this subpart performing an initial test must use an immunoassay, or an alternative technology established in its FFD program through § 26.603(e), that satisfies the requirements of the U.S. Food and Drug Administration (FDA) for commercial distribution. Specimens that yield positive, adulterated, substituted, or invalid initial validity or drug test results or discrepant biological markers must be subject to confirmatory testing by the HHS-certified

laboratory, certified for that biological specimen, except for invalid specimens that cannot be tested.

(g) *Oral fluid testing.* If the licensee or other entity elects to use oral fluid for drug or alcohol testing, the collection, packaging, and temporary storage of the drug or alcohol test device, and shipment of an oral fluid specimen to an HHS-certified laboratory or the collection of an oral fluid specimen for alcohol testing must be performed in accordance with licensee- or other entity-established procedures based either on the requirements in part 26 or the procedures in HHS Guidelines identified by the licensee or other entity in § 26.606(b)(1)(iv). The device must have received premarket approval from the FDA and must not expire before laboratory testing. The drugs, drug metabolites, initial and confirmatory testing cutoffs, and biological markers, if applicable, must be those established by HHS for oral fluid testing and the alcohol cutoffs in this part or, if not established by HHS or the NRC for the panel of drugs and drug metabolites to be tested, as determined and documented by a forensic toxicologist review conducted pursuant to § 26.31(d)(1)(i)(D).

(h) *Point of collection testing and assessment*. (1) If the licensee or other entity elects to use a POCTA device, then it may only be used for pre-access and random drug and alcohol initial testing in § 26.607(b), the alcohol testing process in § 26.607(c)(3), and the portal area screening process in § 26.607(j). Before the licensee or other entity uses a POCTA device, a forensic toxicologist must review and document their evaluation that the validity and accuracy of the device for alcohol and/or the drugs and drug metabolites listed in § 26.31(d) are comparable to the performance achieved by initial testing conducted using a similar technology at an HHS-certified laboratory. For initial testing of drugs and drug metabolites using a POCTA device, this review must include a documented evaluation of POCTA device performance against the requirements in §

26.161(b) for a urine specimen or the procedures in the HHS Guidelines for urine or oral fluid, as implemented by the licensee or other entity through its procedures.

(2) If the performance of the POCTA device is not comparable to that achieved from initial testing conducted by an HHS-certified laboratory as determined by the forensic toxicologist, then the licensee or other entity must implement a mitigating strategy to maintain program effectiveness under § 26.603(e)(2), as applicable.

(3) The licensee and other entity must implement procedures for the use of a POCTA that ensures the effectiveness of the collection process, assessment of the screening results, and prevention of subversion attempts.

(4) If the use of a POCTA device indicates a discrepant biological marker or that a test result exceeds the initial test cutoff, the specimen is invalid, or the individual subverted the drug or alcohol test, then the individual must be immediately removed from duties, responsibilities, and access making the individual subject to this subpart.

(i) The individual must be subject to an immediate drug and alcohol test using the alcohol testing process in § 26.607(c)(3) for a positive alcohol screen and either oral fluid or urine by a collection kit that is not a POCTA device, but of the same type of biological specimen collected by the POCTA, for validity, if required, and initial and confirmatory testing by an HHS-certified laboratory.

(ii) If this individual shows any signs of impairment, the individual's authorization must be temporarily removed until the MRO reviews the laboratory test result(s), interviews the individual, and performs a determination of fitness under § 26.189 or § 26.619, as applicable, that enables the restoration of authorization.

(i) *Hair testing*. The testing of hair specimens may only be used to inform a licensee's or other entity's determination of whether the individual is trustworthy and reliable under the test condition in § 26.607(b)(1) to supplement the information gained

from a pre-access test using oral fluid or urine as the test specimen and must be conducted at an HHS-certified laboratory certified for hair specimens.

(1) If used, this process must be described in the licensee's or other entity's FFD policy and described in detail in its procedure. The panel of drugs and drug metabolites to be evaluated must only include those listed as Schedule I or II of section 202 of the Controlled Substances Act [21 U.S.C. 812]. The collection, packaging, and temporary storage of a hair specimen and shipment of the specimen to an HHS-certified laboratory must be conducted in accordance with the HHS Guidelines. The test kit must be FDA cleared, and licensee- or other entity-designated FFD program personnel must conduct the collection, packaging, temporary storage, shipping, and custody and control of the specimen.

(2) Before the licensee or other entity begins to conduct hair testing, the initial and confirmatory testing cutoffs must be the cutoffs established by HHS for hair testing or, if not established by HHS or the NRC, as determined by a forensic toxicologist review conducted pursuant to § 26.31(d)(1)(i)(D).

(3) Confirmed positive test results must be considered potentially disqualifying FFD information until proven otherwise by a review under § 26.613. Sanctions under this subpart must not be issued for any FFD policy violation involving a drug test using a hair specimen unless the licensee or other entity determines that the individual subverted, as defined in § 26.5, the hair test.

(j) *Portal area screening*. A non-invasive point of collection testing instrument may be used to screen individuals for drugs, drug metabolites, and alcohol before the individuals' entry into or exit from a protected or vital area.

(1) If a licensee or other entity uses such an instrument, then before such use, a forensic toxicologist must review the instrument and document an evaluation that the

instrument and setpoints used in the instrument are acceptable for use for the detection and screening of the drugs and drug metabolites selected for screening from the panel of drugs and drug metabolites to be tested under the FFD program and alcohol and its metabolites.

(2) The instrument must be operated in accordance with the manufacturer's specifications. If screening detects the presence of drugs, drug metabolites, or alcohol at or above the instrument set point(s) , the individual screened by the instrument must be subject to a POCTA screening test using the process described in § 26.607(h) or an oral fluid or urine test that is sent to an HHS-certified laboratory.

(3) A part 26 sanction may not be issued to an individual based solely on a portal area screening instrument detection that drugs or alcohol exceed the instrument's established setpoint.

(k) *Blood testing*. The testing of blood specimens may only be conducted under the order of the licensee- or other entity-designated MRO for a valid medical reason as confirmed by the MRO pursuant to § 26.31(d)(5). This testing must be subject to testing by a laboratory that satisfies quality control requirements that are comparable to those required for certification by the HHS.

(l) *Custody-and-control form*. For the collection and packaging of urine, oral fluid, and hair specimens, the licensee or other entity must use a custody-and-control form approved by the U.S. Office of Management and Budget. For the use of a POCTA device, the licensee or other entity must implement a licensee- or other entity-approved and -maintained procedure that ensures the reliability of the tracking, handling, and storage of a specimen from the point of specimen collection to the final disposition of the specimen and the reliability of an identification system to uniquely assign the specimen to the donor.

(m) *Medical Review Officer.* Licensees or other entities must—

(1) Require their designated MRO to review positive, adulterated, substituted, and dilute confirmatory drug and validity test results and test results of questionable validity to determine whether the donor has violated the FFD policy for urine and oral fluid specimens. The review must be completed before reporting the results to the individual designated by the licensee or other entity to assess authorization or perform the suitability and fitness determinations required under § 26.619, or, if required, that are described in subpart H of this part.

(2) Require their MRO to satisfy the requirements in § 26.183 and, prior to conducting any activities under this part, attend and pass a medical- or clinical-based training session to improve his/her knowledge of MRO duties and responsibilities, drug and alcohol testing processes and procedures, and evaluation of drug testing results. This training session must be conducted by a nationally recognized MRO training and certification organization that has been assessed by the licensee's or other entity's FFD program personnel to include the technical elements an MRO must implement under § 26.185. An MRO who performed the duties and responsibilities in §§ 26.185 and 26.187 for at least 3 continuous years in the last 10 years prior to being hired or contracted by the licensee or other entity satisfies the requirements in this paragraph.

(3) Require their MRO to attend a medical- or clinical-based training session on a triennial basis to improve his/her knowledge of changes in drug and alcohol testing processes and procedures and evaluation of drug testing results.

(4) Require their MRO to determine whether a biological specimen is positive, adulterated, substituted, dilute or of questionable validity by implementing the requirements in § 26.185 or the HHS Guidelines through the licensee's or other entity's procedures.

(i) If § 26.185 or the HHS Guidelines, as used by the licensee or other entity in its procedures, are insufficient to make this determination, then guidance issued by a State agency in the state in which the NRC-licensed facility is located, Federal agencies, or nationally recognized MRO training and certification organizations may be used to inform an MRO determination.

(ii) An MRO need not review a confirmed alcohol positive test result determined by an evidentiary breath testing device under § 26.607(c)(3)(vi) and (vii).

(5) Require their MRO to determine and approve the use of oral fluid or urine as an alternative biological specimen when the donor cannot provide a specimen for testing. This determination and the retest must be documented and completed as soon as reasonably practicable.

(6) Require the MRO to review all specimens screened and tested associated with a drug-related FFD policy violation. This review includes POCTA, split specimens, and all specimens taken to resolve a discrepant condition, such as a possible subversion attempt, impairment without a known cause, or a donor-requested or MRO-directed re-test. To resolve a discrepant condition, the MRO is authorized to test a specimen for a biological marker, adulterants, or additional drugs.

(n) *Limitations of screening and testing*. Specimens collected under NRC regulations may only be designated or approved for screening and testing as described in this part and may not be used to conduct any other analysis or test without the written permission of the donor. Analyses, screens, and tests that may not be conducted include, but are not limited to, DNA testing, serological typing, or any other medical or genetic test used for diagnostic or specimen identification purposes. No biological specimens may be passively sampled and analyzed in a manner different than described in this subpart.

(o) All onsite specimen collections, except a collection by a portal area screening instrument in § 26.607(j), must be conducted by licensee- or other entity-designated and -trained personnel.

§ 26.608 FFD program training.

(a) *FFD program training.* (1) Individuals must be trained in the FFD policy and procedure, including fatigue management, and their FFD program responsibilities. Individuals who collect specimens for testing or screening must also be trained in specimen collector duties and responsibilities, including, at a minimum, specimen collection, custody and control, identification and response to subversion attempts, and privacy. For licensees and other entities of commercial nuclear plants, the FFD program training program must use a systems approach to training as defined in § 53.020 of this chapter and described in § 53.830 of this chapter for those individuals in § 26.4.

(2) FFD program training must include training on the behavioral observation program (BOP). The BOP training must include the detection of physiological or physiological behaviors or conditions that may indicate—

(i) Possible use, sale, or possession of illegal drugs or illicit drugs, or substance abuse on- or offsite;

(ii) Use or possession of alcohol onsite or use while on duty offsite;

(iii) Impairment from fatigue or any cause that, if left unattended, could result in inattentiveness or human errors; and

(iv) Any individual’s inability to safely and competently perform assigned duties and responsibilities or act in a trustworthy and reliable manner while having access to protected areas, SNM, or sensitive information.

(3) Training must explain that an individual’s FFD policy violation will—

(i) Subject the individual to an FFD program-required sanction designed to preclude recurrence of an FFD policy violation;

(ii) Contribute to the licensee's or other entity's assessment of whether the individual can be trusted and relied upon to safely and competently perform the assigned duties and responsibilities making the individual subject to this subpart;

(iii) Be used to inform the licensee's or other entity's insider mitigation and access authorization programs under § 73.55, § 73.56, § 73.100 or § 73.120 of this chapter; and,

(iv) Be used to inform other NRC licensees and other entities subject to part 26 when FFD program information is requested to support authorization determinations under subpart C of part 26; § 73.56; or § 73.120 of this chapter.

(b) *Training and assessments*. Training and a trainee assessment must be conducted before pre-access testing, and refresher training and trainee assessments must be conducted periodically thereafter.

(c) *Training program review*. The licensee or other entity must periodically evaluate its FFD training program and revise it as appropriate to reflect industry experience as well as applicable changes to the regulations in this part, the HHS Guidelines, if used, and specimen collection and testing processes implemented by the licensee or other entity.

§ 26.609 Behavioral observation.

(a) Licensees and other entities must ensure that the individuals who are subject to this subpart are subject to behavioral observation and that behavioral observation is performed by all individuals subject to this subpart.

(b) Licensees and other entities must require all individuals subject to the FFD program to report to the licensee- or other entity-designated representative any onsite or

offsite behaviors or activities by individuals subject to this part that may constitute an unreasonable risk to the safety or security of the NRC-licensed facility or SNM, or may cause harm to others. This reporting must include any information relating to character or reputation of the individual indicating that the individual cannot be trusted or relied upon to perform those duties and responsibilities or maintain access to NRC-licensed facilities, SNM, or sensitive information that makes them subject to part 26.

(c) Behavioral observation must be performed visually, in-person, and, when necessary, remotely by live video and audible streaming and capture, to observe the behavior of individuals in the workforce subject to the requirements in this subpart.

(d) Not withstanding § 26.609(c), for a reactor facility where individual task loading does not allow for the effective conduct of behavior observation in addition to assigned operational tasks, the licensee or other entity must implement a live video and audible streaming and capture system to conduct behavioral observation of NRC-licensed operators who manipulate the controls of any commercial nuclear plant licensed under part 53 of this chapter.

§ 26.610 Sanctions.

Licensees and other entities that implement an FFD program under this subpart must establish sanctions for FFD policy violations that, at a minimum, prohibit the individuals specified in § 26.4 from being assigned to perform or direct those duties and responsibilities or maintaining authorization making them subject to this subpart. The severity of the sanction must escalate with the number of occurrences and severity of the FFD policy violation. The sanction must be long enough to act as a deterrent and, if the individual is retained as a licensee employee or contractor/vendor, facilitate the individual to complete counseling or treatment. The sanctions must include a minimum 5-year denial of access to the NRC-licensed facility for any individual who is determined

to have been involved in the sale, use, or possession of illegal drugs or the consumption of alcohol within a protected area of any facility licensed under part 53 of this chapter or within a transporter's facility or vehicle used in the conveyance of formula quantities of strategic SNM while the individual is subject to this subpart, and a permanent denial of access to the NRC-licensed facility for three FFD policy violations or any subversion attempt of any drug or alcohol test or screening process, including subversion attempts at any licensee or other entity subject to part 26.

§ 26.611 Protection of information.

(a) Licensees and other entities that collect personal information about an individual for the purpose of complying with this subpart must establish and maintain a system of files and procedures to prevent unauthorized disclosure.

(b) Licensees and other entities must obtain a signed consent that documents the individual’s acceptance of being subject to the FFD program and authorizes the disclosure of the personal information collected and maintained under this subpart, except for disclosures to the individuals and entities specified in § 26.37(b)(1) through (b)(6), (b)(8), and persons deciding matters under review in § 26.613. This signed and dated consent must be obtained before making the individual subject to the FFD program.

§ 26.613 Appeals process.

Licensees and other entities that implement an FFD program under this subpart must establish and implement procedures for the review of a determination that an individual in § 26.4 has violated the FFD policy. The procedure must provide for an objective and impartial review of the facts related to the determination that the individual has violated the FFD policy and a schedule for the completion of the review.

§ 26.615 Audits.

(a) Licensees and other entities that implement an FFD program under this subpart must audit their programs at a frequency that ensures the continuing effectiveness of their FFD program, FFD program elements that are provided by C/Vs, and the FFD programs of C/Vs that are accepted by the licensee or other entity. Corrective actions must be as soon as reasonably practicable to resolve any problems identified in an audit and preclude recurrence.

(b) The subject matter, scope, and frequency of audits must be revised as necessary to improve or maintain program performance based on findings resulting from licensee or other entity implementation of its FFD PMRP in § 26.603(d).

(c) Licensees and other entities may conduct joint audits or accept audits of C/Vs so long as the audit addresses the relevant services of the C/Vs.

(d) Licensees and other entities must audit HHS-certified laboratories unless the licensee's or other entity's panel of drugs and drug metabolites to be tested is equivalent to the panel by which the laboratory is certified by HHS or is subject to the standards and procedures for drug testing and evaluation used by the laboratory under the HHS Guidelines. Licensees and other entities must audit any hospital or other facility licensed by the State (or State-designated entity) if used to conduct specimen collections and perform alcohol testing under this part on a biennial basis to confirm that the facility procedures are comparable to those described in subpart E of this part, for urine and oral fluid.

§ 26.617 Recordkeeping and reporting.

(a) Licensees and other entities that implement FFD programs under this subpart must ensure that records pertaining to the administration of their program, which may be stored and archived electronically, are maintained so that they are available for NRC inspection purposes and for any legal proceedings resulting from the administration of

the program. Records pertaining to the administration of the FFD program and FFD performance data required by § 26.717 must be retained until license termination.

(b) Licensees and other entities must make the following reports:

(1) Reports to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers any intentional act that casts doubt on the integrity of the FFD program and any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by individuals who are subject to this subpart. These events must be reported under this subpart, rather than under the provisions of § 73.71 of this chapter; and

(2) Annual program performance reports for the FFD program, including the FFD program performance data listed in § 26.717(b), as applicable. Licensees and other entities must submit FFD program performance data (for January through December) to the NRC annually, before March 1 of the following year and must use unexpired NRC-provided forms for the electronic submission of FFD information to the NRC.

(c) Licensees and other entities subject to this subpart must describe in sufficient detail to support an authorization determination, an individual's FFD policy violation (while protecting privacy information under § 26.611) and FFD program weakness to NRC, licensees, and other entities subject to part 26 when requested to support authorization determinations under subpart C of part 26 or § 73.120 of this chapter, as applicable, or to support licensee or other entity performance monitoring.

§ 26.619 Suitability and fitness determinations.

Licensees and other entities that implement FFD programs under this subpart must develop, implement, and maintain procedures for evaluating whether to assign individuals to perform or direct those duties and responsibilities making them subject to this subpart. A suitability or fitness determination conducted for cause must be

performed face to face. A suitability or fitness determination conducted for cause may be performed remotely using electronic communications only when supported by someone who is present in-person with the individual being assessed, and that supporting person must be trained in accordance with the requirements of either § 26.29 or § 26.608.

94. In § 26.709, redesignate the introductory text as new paragraph (a), revise and add new paragraph (b) to read as follows:

§ 26.709 Applicability.

(a) The requirements of this subpart apply to the FFD programs of licensees and other entities specified in § 26.3(a) through (d), except for FFD programs that are implemented under subpart K of this part.

(b) The requirements in this subpart apply to the FFD programs of licensees and other entities specified in § 26.3(f) that elect not to implement the requirements in subpart M or elect to implement the requirements in § 26.605(b).

§ 26.711 [Amended]

95. In § 26.711, add “, (d) and (f)” after “as applicable, (c)”, wherever it may appear.

§ 26.825 [Amended]

96. In § 26.825, revise paragraph (b) to read as follows:

(b) The regulations in Part 26 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 26.1, 26.3, 26.5, 26.7, 26.8, 26.9, 26.11, 26.51, 26.81, 26.121, 26.151, 26.181, 26.201, 26.601, 26.823, and 26.825.

PART 30 – RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

97. The authority citation for part 30 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 81, 161, 181, 182, 183, 184, 186, 187, 223, 234, 274 (42 U.S.C. 2014, 2111, 2201, 2231, 2232, 2233, 2234, 2236,

2237, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 44 U.S.C. 3504 note.

§ 30.4 [Amended]

98. In § 30.4, in the definition for "*Utilization facility",* add "or part 53" after "in part 50".

99. In § 30.50, revise paragraph (c)(3) to read as follows:

§ 30.50 Reporting requirements.

* * * * *

(c) * * *

(3) The provisions of § 30.50 do not apply to licensees subject to the notification requirements in § 50.72 or § 53.1630. They do apply to those part 50, 52 and 53 licensees possessing material licensed under part 30, who are not subject to the notification requirements in § 50.72 or § 53.1630.

PART 40 – DOMESTIC LICENSING OF SOURCE MATERIAL

100. The authority citation for part 40 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 62, 63, 64, 65, 69, 81, 83, 84, 122, 161, 181, 182, 183, 184, 186, 187, 193, 223, 234, 274, 275 (42 U.S.C. 2092, 2093, 2094, 2095, 2099, 2111, 2113, 2114, 2152, 2201, 2231, 2232, 2233, 2234, 2236, 2237, 2243, 2273, 2282, 2021, 2022); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Uranium Mill Tailings Radiation Control Act of 1978, sec. 104 (42 U.S.C. 7914); 44 U.S.C. 3504 note.

101. In § 40.60, revise paragraph (c)(3) to read as follows:

§ 40.60 Reporting requirements.

*** * * * ***

(c) * * *

(3) The provisions of § 40.60 do not apply to licensees subject to the notification requirements in § 50.72 or § 53.1630. They do apply to those part 50, 52, and 53 licensees possessing material licensed under part 40 who are not subject to the notification requirements in § 50.72 or § 53.1630.

PART 50 – DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

102. The authority citation for part 50 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 62, 63, 64, 65, 69, 81, 83, 84, 122, 161, 181, 182, 183, 184, 186, 187, 193, 223, 234, 274, 275 (42 U.S.C. 2092, 2093, 2094, 2095, 2099, 2111, 2113, 2114, 2152, 2201, 2231, 2232, 2233, 2234, 2236, 2237, 2243, 2273, 2282, 2021, 2022); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Uranium Mill Tailings Radiation Control Act of 1978, sec. 104 (42 U.S.C. 7914); 44 U.S.C. 3504 note.

103. In § 50.11, revise the introductory text to read as follows:

§ 50.11 Exceptions and exemptions from licensing requirements.

Nothing in this part or parts 52, 53, or 54 of this chapter will be deemed to require a license for:

* * * * *

104. In § 50.47, revise paragraphs (a)(1) to read as follows:

§ 50.47 Emergency plans.

(a)(1)(i) Except as provided in paragraph (d) of this section, no initial operating license for a nuclear power reactor will be issued under this part or under part 53 of this chapter unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. No finding under this section is necessary for issuance of a renewed nuclear power reactor operating license.

(ii) No initial combined license under part 52 or part 53 of this chapter will be issued unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. No finding under this section is necessary for issuance of a renewed combined license.

(iii) If an application for an early site permit under subpart A of part 52 or subpart H of part 53 of this chapter includes complete and integrated emergency plans under 10 CFR 52.17(b)(2)(ii) or § 53.1146(b)(2)(ii), respectively, no early site permit will be issued unless a finding is made by the NRC that the emergency plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

(iv) If an application for an early site permit proposes major features of the emergency plans under § 52.17(b)(2)(i) or § 53.1146(b)(2)(i) of this chapter, no early site permit will be issued unless a finding is made by the NRC that the major features are acceptable in accordance with the applicable standards of 10 CFR 50.47 and 10 CFR part 50, appendix E, within the scope of emergency preparedness matters addressed in the major features.

* * * * *

105. In Appendix B to part 50, revise the first paragraph in the Introduction section, the first paragraph of section III. Design Control, and the first paragraph of section IV. Procurement Document Control, to read as follows:

Appendix B to Part 50—Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

Introduction. Every applicant for a construction permit is required by the provisions of § 50.34 or § 53.1309 of this chapter to include in its preliminary safety analysis report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Every applicant for an operating license is required to include, in its final safety analysis report, information pertaining to the managerial and administrative controls to be used to

assure safe operation. Every applicant for a combined license is required by the provisions of §§ 52.79 or 53.1416 of this chapter to include in its final safety analysis report a description of the quality assurance applied to the design, and to be applied to the fabrication, construction, and testing of the structures, systems, and components of the facility and to the managerial and administrative controls to be used to assure safe operation. For applications submitted after September 27, 2007, every applicant for an early site permit is required by the provisions of §§ 52.17 or 53.1146 of this chapter to include in its site safety analysis report a description of the quality assurance program applied to site activities related to the design, fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site. Every applicant for a design approval is required by the provisions of §§ 52.137 or 53.1209 of this chapter to include in its final safety analysis report a description of the quality assurance program applied to the design of the structures, systems, and components of the facility. Every applicant for a design certification is required by the provisions of §§ 52.47 or 53.1239 of this chapter to include in its final safety analysis report a description of the quality assurance program applied to the design of the structures, systems, and components of the facility. Every applicant for a manufacturing license is required by the provisions of §§ 52.157 or 53.1279 of this chapter to include in its final safety analysis report a description of the quality assurance program applied to the design, and to be applied to the manufacture of, the structures, systems, and components of the reactor. Nuclear power plants and fuel reprocessing plants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of those structures, systems, and components. The pertinent

requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

* * * * *

III. Design Control

Measures shall be established to assure that applicable regulatory requirements and the design bases, as defined in § 50.2 and as specified in the license application, or the functional design criteria, as defined in § 53.020 of this chapter and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components.

* * * * *

IV. Procurement Document Control

Measures shall be established to assure that applicable regulatory requirements, design bases, functional design criteria and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix.

* * * * *

PART 51 – ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

107. The authority citation for part 51 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 161, 193 (42 U.S.C. 2201, 2243); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); National Environmental Policy Act of 1969 (42 U.S.C. 4332, 4334, 4335); Nuclear Waste Policy Act of 1982, secs. 144(f), 121, 135, 141, 148 (42 U.S.C. 10134(f), 10141, 10155, 10161, 10168); 44 U.S.C. 3504 note.

108. In § 51.20, revise paragraphs (b)(1) and (2) to read as follows:

§ 51.20 Criteria for and identification of licensing and regulatory actions requiring environmental impact statements.

* * * * *

(b) * * *

(1) Issuance of a limited work authorization or a permit to construct a nuclear power reactor, testing facility, or fuel reprocessing plant under part 50 of this chapter, issuance of an early site permit under part 52 of this chapter, or issuance of a limited work authorization, construction permit, or early site permit under part 53 of this chapter.

(2) Issuance or renewal of a full power or design capacity license to operate a nuclear power reactor, testing facility, or fuel reprocessing plant under parts 50 or 53 of this chapter, or a combined license under parts 52 or 53 of this chapter.

* * * * *

109. In § 51.22, revise paragraphs (c)(3) introductory text, (c)(9) introductory text, (c)(12) introductory text, (c)(17), and (c)(22) and (23) to read as follows:

§ 51.22 Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.

* * * * *

(c) * * *

(3) Amendments to parts 20, 30, 31, 32, 33, 34, 35, 37, 39, 40, 50, 51, 52, 53, 54, 60, 61, 63, 70, 71, 72, 73, 74, 81, and 100 of this chapter which relate to—

* * *

(9) Issuance of an amendment to a permit or license for a reactor under parts 50, 52, or 53 of this chapter that changes a requirement or issuance of an exemption from a requirement, with respect to installation or use of a facility component located within the restricted area, as defined in part 20 of this chapter; or the issuance of an amendment to a permit or license for a reactor under parts 50, 52, or 53 of this chapter that changes an inspection or a surveillance requirement; provided that:

* * * * *

(12) Issuance of an amendment to a license under parts 50, 52, 53, 60, 61, 63, 70, 72, or 75 of this chapter relating solely to safeguards matters (i.e., protection against sabotage or loss or diversion of special nuclear material) or issuance of an approval of a safeguards plan submitted under parts 50, 52, 53, 70, 72, and 73 of this chapter, provided that the amendment or approval does not involve any significant construction impacts. These amendments and approvals are confined to—

* * * * *

(17) Issuance of an amendment to a permit or license under parts 30, 40, 50, 52, 53, or part 70 of this chapter which deletes any limiting condition of operation or

monitoring requirement based on or applicable to any matter subject to the provisions of the Federal Water Pollution Control Act.

* * * * *

(22) Issuance of a standard design approval under parts 52 or 53 of this chapter.

(23) The Commission finding for a combined license under § 52.103(g) or § 53.1452(g) of this chapter.

* * * * *

§ 51.26 [Amended]

110. In § 51.26(d), remove “under part 52” and add in its place “under 10 CFR parts 52 or 53,”.

111. In § 51.30, revise paragraph (a) introductory text and paragraphs (d) and (e) to read as follows:

§ 51.30 Environmental assessment.

(a) An environmental assessment for proposed actions, other than those for a standard design certification under 10 CFR parts 52 or 53, or a manufacturing license under parts 52 or 53, shall identify the proposed action and include:

* * * * *

(d) An environmental assessment for a standard design certification under subpart B of part 52 or under subpart H of part 53 of this chapter must identify the proposed action and will be limited to the consideration of the costs and benefits of severe accident mitigation design alternatives and the bases for not incorporating severe accident mitigation design alternatives in the design certification. An environmental assessment for an amendment to a design certification will be limited to the consideration of whether the design change which is the subject of the proposed amendment renders a severe accident mitigation design alternative previously rejected

in the earlier environmental assessment to become cost beneficial, or results in the identification of new severe accident mitigation design alternatives, in which case the costs and benefits of new severe accident mitigation design alternatives and the bases for not incorporating new severe accident mitigation design alternatives in the design certification must be addressed.

(e) An environmental assessment for a manufacturing license under subpart F of part 52 of this chapter or under subpart H of part 53 of this chapter must identify the proposed action and will be limited to the consideration of the costs and benefits of severe accident mitigation design alternatives and the bases for not incorporating severe accident mitigation design alternatives in the manufacturing license. An environmental assessment for an amendment to a manufacturing license will be limited to consideration of whether the design change which is the subject of the proposed amendment either renders a severe accident mitigation design alternative previously rejected in an environmental assessment to become cost beneficial, or results in the identification of new severe accident mitigation design alternatives, in which case the costs and benefits of new severe accident mitigation design alternatives and the bases for not incorporating new severe accident mitigation design alternatives in the manufacturing license must be addressed. In either case, the environmental assessment will not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

§ 51.31 [Amended]

112. In § 51.31(a), remove “part 52” and add in its place “parts 52 or 53”.

§ 51.32 [Amended]

113. In § 51.32, in paragraphs (b)(1) and (3) after “of this chapter” add “or under subpart H f part 53 of this chapter”.

§ 51.49 [Amended]

114. In § 51.49(c) introductory text, add “or under subpart H of part 53 of this chapter” after “part 52 of this chapter”.

§ 51.50 [Amended]

115. In § 51.50, in (a), (b)(4), and (c) introductory text add “or § 53.1112” after “§ 50.36b”.

§ 51.53 [Amended]

116. In § 51.53(d), add “, § 52.110 or § 53.1080” after “§ 50.82”.

§ 51.54 [Amended]

117. In § 51.54(a), add “or under subpart H of part 53” after “of part 52”.

§ 51.55 [Amended]

118. In § 51.55(a), add “or under subpart H of part 53” after “of part 52”.

119. In § 51.58, revise paragraph (b) to read as follows:

§ 51.58 Environmental report – number of copies; distribution.

* * * * *

(b) Each applicant for a license to manufacture a nuclear power reactor, or for an amendment to a license to manufacture, seeking approval of the final design of the nuclear power reactor under subpart F of part 52 or under subpart H of part 53 of this chapter, shall submit to the Commission an environmental report or any supplement to an environmental report in the manner specified in § 52.3 or § 53.040 of this chapter. The applicant shall maintain the capability to generate additional copies of the environmental report or any supplement to the environmental report for subsequent distribution to parties and Boards in the NRC proceeding; Federal, State, and local officials; and any affected Indian Tribes, in accordance with written instructions issued by the Director, Office of Nuclear Reactor Regulation.

§ 51.77 [Amended]

120. In § 51.77(a) introductory text, insert the word “impact” after the word “environmental” and remove “, except an action authorizing issuance, amendment or renewal of a license to manufacture a nuclear power reactor pursuant to 10 CFR part 52, appendix M”.

§ 51.92 [Amended]

121. In § 51.92(b), remove “part 52”, wherever it may appear and add in its place “parts 52 or 53”.

§ 51.95 [Amended]

122. In § 51.95(c) introductory text, remove “under 10 CFR parts 52 or 54” and add in its place “under parts 50, 52, 53, or 54”.

123. In § 51.101, revise paragraph (a)(2) to read as follows:

§ 51.101 Limitations on actions.

(a) * * *

(2) Any action concerning the proposal taken by an applicant which would—

(i) Have an adverse environmental impact, or

(ii) Limit the choice of reasonable alternatives that may be grounds for denial of the license. In the case of an application covered by § 30.32(f), § 40.31(f), § 50.10(d), § 53.1130, § 70.21(f), or §§ 72.16 and 72.34 of this chapter, the provisions of this paragraph will be applied in accordance with § 30.33(a)(5), § 40.32(e), § 50.10(d) and (e), § 53.1130, § 70.23(a)(7), or §§ 72.40(b) of this chapter, as appropriate.

* * * * *

§ 51.103 [Amended]

124. In § 51.103(a)(6), remove “10 CFR 50.10” and add in its place “§ 50.10 or § 53.1130of this chapter".

125. In § 51.105, revise paragraph (c)(1) to read as follows:

§ 51.105 Public hearings in proceedings for issuance of construction permits or early site permits; limited work authorizations.

* * * * *

(c)(1) In addition to complying with the applicable provisions of § 51.104, in any proceeding for the issuance of a construction permit for a nuclear power plant or an early site permit under parts 52 or 53 of this chapter, where the applicant requests a limited work authorization under § 50.10(d) or § 53.1130of this chapter, the presiding officer will—

* * * * *

126. In § 51.107, revise paragraphs (a) introductory text, (b) introductory text, and paragraph (d)(1) to read as follows:

§ 51.107 Public hearings in proceedings for issuance of combined licenses; limited work authorizations.

(a) In addition to complying with the applicable requirements of § 51.104, in a proceeding for the issuance of a combined license for a nuclear power reactor under parts 52 or 53 of this chapter, the presiding officer will:

* * * * *

(b) If a combined license application references an early site permit, then the presiding officer in the combined license hearing must not admit any contention proffered by any party on environmental issues that have been accorded finality under § 52.39 or § 53.1188 of this chapter, unless the contention:

* * * * *

(d)(1) In any proceeding for the issuance of a combined license where the applicant requests a limited work authorization under § 50.10(d) or § 53.1130(a) of this

chapter, the presiding officer, in addition to complying with any applicable provision of § 51.104, will:

* * * * *

127. Revise § 51.108 to read as follows:

§ 51.108 Public hearings on Commission findings that inspections, tests, analyses, and acceptance criteria of combined licenses are met.

In any public hearing requested under § 52.103(b) or § 53.1452(b), the Commission will not admit any contentions on environmental issues, the adequacy of the environmental impact statement for the combined license issued under subpart C of part 52 or under subpart H of part 53 of this chapter, or the adequacy of any other environmental impact statement or environmental assessment referenced in the combined license application. The Commission will not make any environmental findings in connection with the finding under § 52.103(g) or § 53.1452(g).

1286. Part 53 is added to read as follows:

PART 53—RISK-INFORMED, TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK FOR COMMERCIAL NUCLEAR PLANTS

Subpart I — Maintaining and Revising Licensing Basis Information

Authority: Atomic Energy Act of 1954, secs. 11, 101, 103, 108, 122, 147, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note; Sec. 109, Pub. L. 96-295, 94 Stat. 783; Pub. L. 115-439, 132 Stat. 5571.

§ 53.000 Purpose.

This part provides optional a technology-inclusive, performance-based frameworks for the issuance, amendment, renewal, and termination of licenses, permits, certifications, and approvals for commercial nuclear plants licensed under Section 103 of the Atomic Energy Act of 1954, as amended (AEA) (68 Stat. 919), and Title II of the Energy Reorganization Act of 1974, as amended (ERA) (88 Stat. 1242). Also, this part gives notice to all persons who knowingly provide to any holder of or applicant for an approval, certification, permit, or license, or to a contractor, subcontractor, or consultant of any of them, components, equipment, materials, or other goods or services that relate to the activities of a holder of or applicant for an approval, certification, permit, or license,

subject to this part, that they may be individually subject to U.S. Nuclear Regulatory Commission (NRC) enforcement action for violation of the provisions in § 53.050.

Subpart A — General Provisions

§ 53.020 Definitions.

For the purpose of this part:

Act means the Atomic Energy Act of 1954 (68 Stat. 919) including any amendments thereto.

Anticipated event sequence means event sequences expected to occur one or more times during the life of a commercial nuclear plant. Anticipated event sequences take into account the expected response of all SSCs within the plant, regardless of safety classification.

Applicant means a person applying for a license, permit, or other form of Commission permission or approval under this part.

Certified fuel handler means, for a commercial nuclear plant, either—

(1) A non-licensed operator who has qualified in accordance with a fuel handler training program approved by the Commission; or

(2) A non-licensed operator who demonstrates compliance with the following criteria:

(i) Has qualified in accordance with a fuel handler training program that demonstrates compliance with the same requirements as training programs for non-licensed operators required by § 53.830, and

(ii) Is responsible for decisions on—

(A) Safe conduct of decommissioning activities,

(B) Safe handling and storage of spent fuel, and

(C) Appropriate response to plant emergencies.

Combined license means a combined construction permit and operating license with conditions for a commercial nuclear plant issued under this part.

Commercial nuclear plant means a commercial utilization facility consisting of one or more nuclear reactors and associated co-located support facilities, including the collection of buildings, radionuclide sources, and structures, systems, and components for which a license(s) is being sought under this part, that is used for producing power for commercial electric power or other commercial purposes. For the purposes of requirements in this part that reference requirements in part 50 of this chapter, a commercial nuclear plant is equivalent to a nuclear power plant.

Commission means the NRC or its duly authorized representatives.

Consensus code or standard means any technical standard that is—

(1) Developed or adopted by a voluntary consensus standard body under procedures that assure that persons having interests within the scope of the standard that are affected by the provisions of the standard have reached substantial agreement on its adoption;

(2) Formulated in a manner that afforded an opportunity for diverse views to be considered; and

(3) Designated by the standards body as a consensus code or standard.

Construction means the activities in paragraph (1) below and does not mean the activities in paragraph (2) below.

(1) Activities constituting construction are those activities credited or relied upon for demonstrating compliance with the safety criteria defined in subpart B of this part that are conducted on-site to build the commercial nuclear plant, including the driving of piles; subsurface preparation; placement of backfill, concrete, or permanent retaining

walls within an excavation; installation of foundations; or in-place assembly, erection, fabrication, or testing, which are for—

(i) Safety-related (SR) and non-safety-related but safety-significant (NSRSS) structures, systems, and components (SSCs) of a facility;

(ii) SSCs necessary to comply with 10 CFR part 73; or

(iii) Onsite emergency facilities necessary to comply with § 53.855.

(2) Construction does not include—

(i) Changes for temporary use of the land for public recreational purposes;

(ii) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(iii) Preparation of a site for construction of a facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(iv) Erection of fences and other access control measures;

(v) Excavation;

(vi) Erection of support buildings (such as construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(vii) Building of service facilities (such as paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewage treatment facilities, and transmission lines);

(viii) Procurement or fabrication of components or portions of the proposed facility occurring at locations other than the final, in-place location at the facility; or

(ix) Manufacture of a nuclear power reactor under a manufacturing license under subpart H of this part to be installed at the proposed site and to be part of the proposed facility.

Custom combined license (custom COL) means a COL that does not reference a standard design certification or design certification.

Decommission or *decommissioning* means to remove a plant or site safely from service and reduce residual radioactivity to a level that permits—

(1) Release of the property for unrestricted use and termination of the license; or

(2) Release of the property under restricted conditions and termination of the license.

Defense in depth means inclusion of two or more independent and redundant layers of defense in the design of a facility and its operating procedures to compensate for uncertainties such that no single layer of defense, no matter how robust, is exclusively relied upon. Defense in depth includes, but is not limited to, the use of access controls, physical barriers, redundant and diverse safety functions, and emergency response measures.

Design-basis accidents (DBAs) means postulated event sequences that are used to set functional design criteria and performance objectives for the design of safety-related (SR) structures, systems, and components (SSCs) through deterministic analyses. DBAs are a type of licensing-basis event and are based on the capabilities and reliabilities of SR SSCs needed to mitigate and prevent event sequences, respectively.

Design-basis external hazard level means the level of severity or intensity of an external hazard for which the safety-related structures, systems, and components are

designed to withstand with no adverse impact on their capability to perform their safety functions.

Design features means the active and passive structures, systems, and components (SSCs) and the inherent characteristics of those SSCs that contribute to limiting the total effective dose equivalent to individual members of the public during normal operations and prevent or mitigate the consequences of event sequences.

Electric utility means any entity that generates or distributes electricity and that recovers the cost of this electricity, either directly or indirectly, through rates established by the entity itself or by a separate regulatory authority. Investor-owned utilities, including generation or distribution subsidiaries, public utility districts, municipalities, rural electric cooperatives, and State and Federal agencies, including associations of any of the foregoing, are included within the meaning of "electric utility."

Event sequence means a postulated initiating event defined for a set of initial plant conditions followed by system, safety function, and operator successes or failures, and terminating in a specified end state depending on the system, safety function, and operator successes and failures (e.g., prevention of release of radioactive material or release in one of the reactor-specific release categories). An event sequence may include many unique variations of events that are similar in terms of results or end states.

Exclusion area means that area surrounding the reactor, in which the reactor licensee has the authority to determine all activities including exclusion or removal of personnel and property from the area. This area may be traversed by a highway, railroad, or waterway, provided these are not so close to the facility as to interfere with normal operations of the facility and provided appropriate and effective arrangements are made to control traffic on the highway, railroad, or waterway, in case of emergency,

to protect the public health and safety. Residence within the exclusion area must normally be prohibited. In any event, residents must be subject to ready removal in case of necessity. Activities unrelated to operation of the reactor may be permitted in an exclusion area under appropriate limitations, provided that no significant hazards to the public health and safety will result.

Fission product release means the amount and composition of radioactive material released to the environment, after accounting for any retention of radionuclides provided by reactor design features.

Functional design criteria means metrics for the performance of structures, systems, and components (SSCs). For safety-related SSCs, these criteria define performance metrics necessary to demonstrate compliance with safety criteria in § 53.210. For non-safety-related but safety-significant SSCs, these criteria define performance metrics necessary to demonstrate compliance with the safety criteria in § 53.220.

Fuel means special nuclear material (SNM) or source material, discrete elements that physically contain SNM or source material, and homogeneous mixtures that contain SNM or source material, intended to or used to create power from nuclear fission in a self-supporting chain reaction in a nuclear reactor.

Generally licensed reactor operator means any individual licensed under the provisions of § 53.810 to manipulate controls of a self-reliant-mitigation facility and to direct the licensed activities of generally licensed reactor operators.

Interaction-dependent-mitigation facility means a commercial nuclear plant design other than one that demonstrates compliance with the operating and technical characteristics defined under § 53.800.

License, when used in the context of a facility, means a limited work authorization, construction permit, operating license, early site permit, combined license, or manufacturing license under this part, or a renewed license issued by the Commission under this part. When used in the context of an operator license, *license* means a license issued by the Commission to perform the function of an operator, senior operator, or generally licensed reactor operator as defined in this part.

Licensee means a person who is authorized to conduct activities under a license issued under this part by the Commission.

Licensing-basis events (LBEs) means a collection of event sequences considered in the design and licensing of the commercial nuclear plant. LBEs are unplanned events and include anticipated event sequences, unlikely event sequences, very unlikely event sequences, and design basis accidents.

Licensing basis information means the information contained in regulations, orders, licenses, certifications, or approvals issued by the NRC for a commercial nuclear plant licensed under this part and that information submitted to the NRC by an applicant or licensee in a Safety Analysis Report, program description, or other licensing-related document required under this part.

Load following means operation of a commercial nuclear plant to automatically changing its output to match expected demand in response to externally originated instructions or signals.

Low population zone means the area immediately surrounding the exclusion area which contains residents, the total number and density of which are such that there is a reasonable probability that appropriate protective measures could be taken on their behalf in the event of a serious accident. A permissible population density or total population within this zone is not included in this definition because the situation may

vary from case to case. Whether a specific number of people can, for example, be evacuated from a specific area or instructed to take shelter on a timely basis, will depend on many factors such as location, number and size of highways, scope and extent of advance planning, and actual distribution of residents within the area.

Major decommissioning activity means, for a commercial nuclear plant, any activity that results in permanent removal of major radioactive components, permanently modifies the structure of the containment, if applicable, or results in dismantling components for shipment containing greater than class C waste in accordance with § 61.55 of this chapter.

Manufactured reactor means the essential portions of a nuclear reactor that are manufactured under a manufacturing license and subsequently transported and incorporated into a commercial nuclear plant under a combined license.

Manufacturing license means a license issued under this part that authorizes the manufacture of a manufactured reactor but not its construction, installation, or operation.

Non-safety-related but safety-significant (NSRSS) structures, systems, and components (SSCs) means those SSCs that are not SR but are relied on to achieve adequate defense in depth or perform risk-significant functions.

Non-safety-significant structures, systems, and components (SSCs) means those SSCs that are not safety-related or non-safety-related but safety-significant, are not relied on to achieve adequate defense in depth or to perform risk-significant functions, and do not warrant special treatment.

Nuclear reactor means an apparatus, other than an atomic weapon, designed or used to sustain nuclear fission.

Person means—

(1) any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, government agency other than the Commission or the Department, except that the Department shall be considered a person to the extent that its facilities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974, any State or any political subdivision of, or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and

(2) any legal successor, representative, agent, or agency of the foregoing.

Population center distance means the distance from the reactor to the nearest boundary of a densely populated center containing more than about 25,000 residents.

Probabilistic risk assessment means a quantitative assessment of the risk associated with plant operation and maintenance that is measured in terms of event sequence occurrence frequencies and consequences.

Programmatic controls means administrative procedures that govern human action in implementing programs and operating, monitoring, and maintaining SSCs and equipment of a commercial nuclear plant.

Prototype plant means a nuclear reactor that is used to test design features. A prototype plant is similar to a first-of-a-kind or standard plant design in all features and size but may include additional safety features to protect the public and the plant staff from the possible consequences of accidents during the testing period.

Quality assurance (QA) means all those planned and systematic actions necessary to ensure that an structure, system, or component will perform satisfactorily in service. QA includes quality control, which comprises those QA actions related to the physical characteristics of a material, structure, component, or system which provide a

means to control the quality of the material, structure, component, or system to predetermined requirements.

Reference plant means the specific commercial nuclear plant on which a simulation facility's configuration, system control arrangement, and design data are based. The reference plant may or may not be constructed.

Safety criteria means performance-based metrics that establish a level of safety provided in requirements in §§ 53.210 and 53.220.

Safety function means a purpose served by a design feature, human action, or programmatic control to prevent or mitigate unplanned events and thereby demonstrate compliance with requirements in this part for limiting risks to public health and safety. Safety functions can be performed by any combination of the elements listed above and can be specified at the plant level or at the level of a particular barrier or system.

Safety-related structures, systems, and components means those structures, systems, and components that are relied upon to meet the safety criteria in § 53.210.

Self-reliant-mitigation facility means a commercial nuclear plant design that demonstrates compliance with the operating and technical characteristics of § 53.800.

Severe accident means those events that progress beyond design basis accidents in which substantial damage is done to the reactor core or to any other structure, vessel, or retention system that contains a significant inventory of radiological material, whether or not there are serious offsite consequences.

Simulation facility means an interface designed to provide a realistic imitation of the operation of a commercial nuclear plant used for the administration of examinations, for training, and/or to demonstrate compliance with experience requirements for applicants or licensees. A simulation facility may rely, in whole or part, upon the physical utilization of the reference plant itself.

Site characteristics means the actual physical, environmental, and demographic features of a site. Site characteristics are specified in an early site permit or in a Preliminary or Final Safety Analysis Report for an limited work authorization, construction permit, or combined license, as applicable.

Site parameters are the postulated physical, environmental, and demographic features of an assumed site. Site parameters are specified in a standard design approval, standard design certification, or manufacturing license.

Source material means source material as defined in subsection 11z. of the Act and in the regulations contained in part 40 of this chapter.

Special nuclear material (SNM) means: (1) plutonium, uranium-233, uranium enriched in the isotope-233 or in the isotope-235, and any other material which the Commission, pursuant to the provisions of Section 51 of the Act, determines to be SNM, but does not include source material; or (2) any material artificially enriched by any of the foregoing, but does not include source material.

Special treatments means those items, such as quality assurance and programmatic controls, that ensure that safety-related and non-safety-related but safety-significant structures, systems, and components (SSCs) will provide defense in depth or perform risk-significant functions. The special treatments also ensure that the SSCs will perform under the service conditions and with the reliability assumed in the analysis performed under § 53.450 to demonstrate compliance with the safety criteria in §§ 53.210 and 53.220.

Standard design means a design which is sufficiently detailed and complete to support certification or approval in accordance with subpart H of this part, and which is usable under this part for a multiple number of units or at a multiple number of sites without reopening or repeating the review.

Standard design approval or *design approval* means an NRC staff approval, issued under subpart H of this part, of a final standard design for a commercial nuclear plant. The approval may be for either the final design for the entire reactor facility or the final design of major portions thereof.

Standard design certification or *design certification* means a Commission approval, issued under subpart H of this part, of a final standard design for a nuclear power facility. This design may be referred to as a certified standard design.

Systems approach to training means a training program that includes the following five elements:

(1) Systematic analysis of the jobs to be performed.

(2) Learning objectives derived from the analysis which describe desired performance after training.

(3) Training design and implementation based on the learning objectives.

(4) Evaluation of trainee mastery of the objectives during training.

(5) Evaluation and revision of the training based on the performance of trained personnel in the job setting.

Total effective dose equivalent means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Unlikely event sequences means event sequences that are not expected to occur in the life of a commercial nuclear plant and are therefore less likely than anticipated event sequences, but are infrequent rather than rare. Unlikely event sequences take into account the expected response of all structures, systems, and components within the plant regardless of safety classification.

Utilization facility means any nuclear reactor other than one designed or used primarily for the formation of plutonium or uranium–233 or a fueled manufactured reactor with at least two independent mechanisms each of which is sufficient to prevent criticality assuming maximum reactivity of the fissile material would be attained from possible fuel configurations, neutron moderation, and neutron reflection from the manufactured reactor and surrounding materials.

Very unlikely event sequences means rare event sequences that are less likely than unlikely event sequences. Very unlikely event sequences take into account the expected response of all structures, systems, and components within the plant regardless of safety classification.

§ 53.040 Written communications.

(a) *General requirements.* All correspondence, reports, applications, and other written communications from the applicant or licensee to the NRC concerning the regulations in this part or individual license conditions must be sent either by mail addressed: ATTN: Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland, between the hours of 8:15 a.m. and 4 p.m. eastern time; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, e-mail, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC’s Web site at *http://www.nrc.gov/site-help/e-submittals.html;* by e-mail to *MSHD.Resource@nrc.gov;* or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The guidance

discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. If the communication is on paper, the signed original must be sent. If a submission due date falls on a Saturday, Sunday, or Federal holiday, the next Federal working day becomes the official due date.

(b) *Distribution requirements.* Copies of all correspondence, reports, and other written communications concerning the regulations in this part or individual license conditions, or the terms and conditions of an early site permit or standard design approval, must be submitted to the persons listed below (addresses for the NRC Regional Offices are listed in appendix D to 10 CFR part 20).

(1) *Applications for amendment of permits and licenses, reports, and other communications.* All written communications (including responses to generic letters, bulletins, information notices, regulatory information summaries, inspection reports, and miscellaneous requests for additional information) that are required of or requested from holders of licenses, permits, and design approvals issued pursuant to this part, must be submitted as follows, except as otherwise specified in paragraphs (b)(2) through (7) of this section: to the NRC's Document Control Desk (if on paper, the signed original), with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector, if one has been assigned to the site of the facility or the place of manufacture of a reactor licensed under this part.

(2) *Applications for permits and licenses, and amendments to applications.* Applications for licenses, permits, and design approvals and amendments to any of these types of applications must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector, if one has been assigned to the facility or the place of manufacture of a reactor licensed under this part, except as otherwise specified in paragraphs (b)(3)

through (9) of this section. If the application or amendment is on paper, the submission to the Document Control Desk must be the signed original.

(3) *Acceptance review application.* Written communications required for an application for determination of suitability for docketing must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office. If the communication is on paper, the submission to the Document Control Desk must be the signed original.

(4) *Security plan and related submissions.* Written communications, as defined in paragraphs (b)(4)(i) through (v) of this section, must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office. If the communication is on paper, the submission to the Document Control Desk must be the signed original. Submissions should include the following as appropriate:

(i) Physical security plan;

(ii) Safeguards contingency plan;

(iii) Cyber security plan;

(iv) Change to security plan, guard training and qualification plan, safeguards contingency plan, or cyber security plan made without prior Commission approval under § 53.1565; and

(v) Application for amendment of physical security plan, guard training and qualification plan, safeguards contingency plan, or cyber security plan under § 53.1510.

(5) *Emergency plan and related submissions.* Written communications as defined in paragraphs (b)(5)(i) through (iii) of this section must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector, if one has been assigned to the site of the

facility. If the communication is on paper, the submission to the Document Control Desk must be the signed original. Submissions should include the following as appropriate:

(i) Emergency plan;

(ii) Change to an emergency plan under § 53.1565; and

(iii) Emergency implementing procedures under § 53.855.

(6) *Updated Final Safety Analysis Report.* An Updated Final Safety Analysis Report (UFSAR) or replacement pages under § 53.1545 must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector, if one has been assigned to the site of the facility or the place of manufacture of a reactor licensed under this part. Paper copy submissions may be made using replacement pages; however, if a licensee chooses to use electronic submission, all subsequent updates or submissions must be performed electronically on a total replacement basis. If the communication is on paper, the submission to the Document Control Desk must be the signed original. If the communications are submitted electronically, see Guidance for Electronic Submissions to the Commission.

(7) *Quality assurance related submissions.* (i) A change to the Safety Analysis Report quality assurance program (QAP) description under § 53.1565, or a change to a licensee's NRC-accepted QA topical report under § 53.1565, must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector, if one has been assigned to the site of the facility or the place of manufacture of a reactor licensed under this part. If the communication is on paper, the submission to the Document Control Desk must be the signed original.

(ii) A change to an NRC-accepted QA topical report from non-licensees (i.e., architect/engineers, nuclear steam supply system (NSSS) suppliers, fuel suppliers, constructors, etc.) must be submitted to the NRC's Document Control Desk. If the communication is on paper, the signed original must be sent.

(8) *Certification of permanent cessation of operations.* The licensee's certification of permanent cessation of operations, under subpart G or subpart Q of this part, must state the date on which operations have ceased or will cease, and must be submitted to the NRC's Document Control Desk. This submission must be under oath or affirmation.

(9) *Certification of permanent fuel removal.* The licensee's certification of permanent fuel removal, under subpart G or subpart Q of this part, must state the date on which the fuel was removed from the reactor vessel and the disposition of the fuel, and must be submitted to the NRC's Document Control Desk. This submission must be under oath or affirmation.

(c) *Form of communications.* All paper copies submitted to demonstrate compliance with the requirements set forth in paragraph (b) of this section must be typewritten, printed, or otherwise reproduced in permanent form on unglazed paper. Exceptions to these requirements imposed on paper submissions may be granted for the submission of micrographic, photographic, or similar forms.

(d) *Regulation governing submission.* Licensees, applicants, and holders of standard design approvals submitting correspondence, reports, and other written communications under the regulations of this part are requested but not required to cite whenever practical, in the upper right corner of the first page of the submission, the specific regulation or other basis requiring submission.

§ 53.050 Deliberate misconduct.

(a) Any licensee, holder of a standard design approval, applicant for a standard design certification, applicant for a license, applicant for a standard design approval, employee of a licensee or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or applicant for a license, who knowingly provides to any licensee, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities in this part, may not—

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or

(2) Deliberately submit to the NRC, a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

(b) A person who violates paragraph (a)(1) or (2) of this section may be subject to enforcement action in accordance with the procedures in subpart B of 10 CFR part 2.

(c) For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows—

(1) Would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

§ 53.060 Employee protection.

(a) Discrimination by a Commission licensee, holder of a standard design approval, an applicant for a license, standard design certification, or standard design

approval, a contractor or subcontractor of a Commission licensee, holder of a standard design approval, applicant for a license, standard design certification, or standard design approval, against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in Section 211 of the ERA and in general are related to the administration or enforcement of a requirement imposed under the Act or the ERA.

(1) The protected activities include but are not limited to—

(i) Providing the Commission or his or her employer information about alleged violations of either of the statutes named in paragraph (a) of this section or possible violations of requirements imposed under either of those statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) of this section or under these requirements if the employee has identified the alleged illegality to the employer;

(iii) Requesting the NRC to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in paragraph (a) of this section; and

(v) Assisting or participating in, or being about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(3) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the

employer's agent), deliberately causes a violation of any requirement of the ERA or the Act.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraph (a), (e), or (f) of this section by a Commission licensee, a holder of a standard design approval, an applicant for a Commission license, standard design certification, or a standard design approval, or a contractor or subcontractor of a Commission licensee, holder of a standard design approval, or any applicant may be grounds for—

(1) Denial, revocation, or suspension of the license or standard design approval;

(2) Withdrawal or revocation of a proposed or final standard design certification;

(3) Imposition of a civil penalty on the licensee, holder of a standard design approval, or applicant (including an applicant for a standard design certification under this part following Commission adoption of final design certification rule) or a contractor or subcontractor of the licensee, holder of a standard design approval, or applicant; or

(4) Other enforcement action.

(d) Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An

employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each holder or applicant for a license or design approval, must prominently post the revision of NRC Form 3, "Notice to Employees," referenced in § 19.11(e)(1) of this chapter. This form must be posted at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted no later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, and for 30 days following license termination.

(2) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate NRC Regional Office listed in appendix D to 10 CFR part 20, via email to *Forms.Resource@nrc.gov*, or by visiting the NRC's online library at *http://www.nrc.gov/reading-rm/doc-collections/forms/*.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to Section 211 of the ERA, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in paragraph (a)(1) of this section including, but not limited to, providing information to the NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

(g) Part 19 of 10 CFR sets forth requirements and regulatory provisions applicable to licensees, holders of a standard design approval, applicants for a license, standard design certification, or standard design approval, and contractors or

subcontractors of a Commission licensee, or holder of a standard design approval, and are in addition to the requirements in this section.

§ 53.070 Completeness and accuracy of information.

(a) Information provided to the Commission by a holder of a license, permit, design certification, or standard design approval under this part or an applicant for a license, permit, design certification, or standard design approval under this part, and information required by statute or by the Commission's regulations, orders, license conditions, or terms and conditions of a standard design approval to be maintained by the applicant or the licensee must be complete and accurate in all material respects.

(b) Each applicant for or licensee of a commercial nuclear plant under this part, each holder of a standard design approval under this part, and each applicant for a standard design certification under this part following Commission adoption of a final design certification regulation, must notify the Commission of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or common defense and security. An applicant, licensee, or holder violates this paragraph only if the applicant, licensee, or holder fails to notify the Commission of information that the applicant, licensee, or holder has identified as having a significant implication for public health and safety or common defense and security. Notification must be provided to the Administrator of the appropriate Regional Office within 2 working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements.

§ 53.080 Specific exemptions.

(a) The Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of the regulations of this part,

which are authorized by law, will not present an undue risk to the public health and safety, and are consistent with the common defense and security.

(b) The Commission will not consider granting an exemption unless special circumstances are present. Special circumstances are present whenever —

(1) Application of the regulation in the particular circumstances conflicts with other rules or requirements of the Commission;

(2) Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule;

(3) Compliance would result in undue hardship or other costs that are significantly in excess of those contemplated when the regulation was adopted, or that are significantly in excess of those incurred by others similarly situated;

(4) The exemption would result in benefit to the public health and safety that compensates for any decrease in safety that may result from the grant of the exemption;

(5) The exemption would provide only temporary relief from the applicable regulation and the licensee or applicant has made good faith efforts to comply with the regulation; or

(6) There is present any other material circumstance not considered when the regulation was adopted for which it would be in the public interest to grant an exemption. If such condition is relied on exclusively for demonstrating compliance with paragraph (b) of this section, the exemption may not be granted until the Executive Director for Operations has consulted with the Commission.

(c) Any person may request an exemption permitting the conduct of construction activities prohibited by § 53.610 prior to the issuance of a CP. The Commission may grant such an exemption upon considering and balancing the following factors:

(1) Whether conduct of the proposed activities will give rise to a significant adverse impact on the environment and the nature and extent of such impact, if any;

(2) Whether redress of any adverse environment impact from conduct of the proposed activities can reasonably be effective should such redress be necessary;

(3) Whether conduct of the proposed activities would foreclose subsequent adoption of alternatives; and

(4) The effect of delay in conducting such activities on the public interest, including whether the power needs to be used by the proposed facility, the availability of alternative sources, if any, to meet those needs on a timely basis and delay costs to the applicant and to consumers.

(d) Issuance of such an exemption must not be deemed to constitute a commitment to issue a CP. During the period of any exemption granted pursuant to paragraph (c) of this section, any activities conducted must be carried out in such a manner as will minimize or reduce their environmental impact.

(e) The Commission’s consideration of requests for exemptions from requirements of the regulations of other parts in this chapter that are applicable by virtue of this part must be governed by the exemption requirements of those parts.

§ 53.090 Standards for review.

(a) *Common standards*. In determining that a construction permit (CP), operating license (OL), early site permit, combined license (COL), or manufacturing license (ML) under this part will be issued to an applicant, the Commission will be guided by the following considerations:

(1) Except for an early site permit or ML, the processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other technical specifications, or the proposals, in regard to any of the foregoing, collectively

provide reasonable assurance that the applicant will comply with the regulations in this chapter, including the regulations in 10 CFR part 20, and that the health and safety of the public will not be endangered.

(2) The applicant for a CP, OL, COL, or ML is technically and financially qualified to engage in the proposed activities in accordance with the regulations in this chapter. However, no consideration of financial qualification is necessary for an electric utility applicant for an OL for a utilization facility of the type described in paragraph (d) of this section or for an applicant for an ML.

(3) The issuance of a CP, OL, early site permit, COL, or ML to the applicant will not, in the opinion of the Commission, be inimical to the common defense and security or to the health and safety of the public.

(4) Any applicable requirements of subpart A of 10 CFR part 51 have been satisfied.

(b) *Additional standards for licenses*. In determining whether a license will be issued to an applicant, the Commission will, in addition to applying the standards set forth in paragraph (a) of this section, consider whether the proposed activities will serve a useful purpose proportionate to the quantities of special nuclear material or source material to be utilized.

(c) *Additional standards and provisions affecting licenses for commercial power*. In addition to applying the standards set forth in paragraphs (a) and (b) of this section, paragraphs (c)(1) through (c)(4) of this section apply in the case of a license for a facility for the generation of commercial power.

(1) The NRC will—

(i) Give notice in writing of each application to the regulatory agency or State as may have jurisdiction over the rates and services incident to the proposed activity;

(ii) Publish notice of the application in trade or news publications as it deems appropriate to give reasonable notice to municipalities, private utilities, public bodies, and cooperatives which might have a potential interest in the utilization facility; and

(iii) Publish notice of the application once each week for four consecutive weeks in the *Federal Register*. No license will be issued by the NRC prior to the giving of these notices and until four weeks after the last notice is published in the *Federal Register*.

(2) If there are conflicting applications for a limited opportunity for such license, the Commission will give preferred consideration in the following order: first, to applications submitted by public or cooperative bodies for facilities to be located in high cost power areas in the United States; second, to applications submitted by others for facilities to be located in such areas; third, to applications submitted by public or cooperative bodies for facilities to be located in areas other than high cost power areas; and, fourth, to all other applicants.

(3) The licensee who transmits electric energy in interstate commerce, or sells it at wholesale in interstate commerce, must be subject to the regulatory provisions of the Federal Power Act.

(4) Nothing shall preclude any government agency, now or hereafter authorized by law to engage in the production, marketing, or distribution of electric energy, if otherwise qualified, from obtaining a CP, OL, or COL under this part for a utilization facility for the primary purpose of producing electric energy for disposition for ultimate public consumption.

(d) Applications for a design certification, COL, ML, OL, or standard design approval that propose nuclear reactor designs which differ significantly from light-water reactor designs that were licensed before 1997, or use simplified, inherent, passive, or other innovative means to accomplish their safety functions, will be approved only if—

(i)(A) The performance of each safety feature of the design has been demonstrated through either analysis, appropriate test programs, experience, or a combination thereof;

(B) Interdependent effects among the safety features of the design are acceptable, as demonstrated by analysis, appropriate test programs, experience, or a combination thereof; and

(C) Sufficient data exist on the safety features of the design to assess the analytical tools used for safety analyses over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions; or

(ii) There has been acceptable testing of a prototype plant over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions. If a prototype plant is used to comply with the testing requirements, then the NRC may impose additional requirements on siting, safety features, or operational conditions for the prototype plant to protect the public and the plant staff from the possible consequences of accidents during the testing period.

(de) *Licenses for commercial nuclear plants*. A license will be issued, to an applicant who qualifies, for any one or more of the following: to transfer or receive in interstate commerce, or manufacture, produce, transfer, acquire, possess, or use a utilization facility for commercial purposes.

§ 53.100 Jurisdictional limits.

No permit, license, standard design approval, or standard design certification under this part shall be deemed to have been issued for activities that are not under or within the jurisdiction of the United States.

§ 53.110 Attacks and destructive acts.

Licensees, applicants for licenses, permits, certifications, and design approvals, and applicants for an amendment to any license, permit, certification, or design approval under this part are not required to provide for design features or other measures for the specific purpose of protection against the effects of—

(a) Attacks and destructive acts, including sabotage, directed against the facility by an enemy of the United States, whether a foreign government or other person; or

(b) Use or deployment of weapons incident to U.S. defense activities.

§ 53.115 Rights related to special nuclear material.

(a) No right to the SNM will be conferred by a license issued under this part except as may be defined by the license.

(b) Neither a license issued under this part, nor any right thereunder, nor any right to utilize or produce SNM may be transferred, assigned, or disposed of in any manner, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission, after securing full information, finds that the transfer is in accordance with the provisions of the Act and gives its consent in writing.

§ 53.117 License suspension and rights of recapture.

Any license issued under this part must be subject to suspension and to the rights of recapture of the material or control of the facility reserved to the Commission under Section 108 of the Act in a state of war or national emergency declared by Congress.

§ 53.120 Information collection requirements: OMB approval.

(a) The NRC has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). The NRC may not conduct or

sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-XXXX.

(b) The approved information collection requirements contained in this part appear in §§ 53.070, 53.080, 53.240, 53.410, 53.420, 53.425, 53.430, 53.440, 53.450, 53.480, 53.500, 53.540, 53.605, 53.610, 53.620, 53.700, 53.710, 53.715, 53.720, 53.730, 53.780, 53.805, 53.810, 53.815, 53.830, 53.850, 53.855, 53.865, 53.875, 53.880, 53.910, 53.1010, 53.1020, 53.1030, 53.1045, 53.1060, 53.1070, 53.1075, 53.1080, 53.1100, 53.1109, 53.1115, 53.1130, 53.1140, 53.1144, 53.1146, 53.1173, 53. 1182, 53.1188, 53.1200, 53.1206, 53.1209, 53.1210, 53.1221, 53.1230, 53.1236, 53.1239, 53.1241, 53.1254, 53.1257, 53,1263, 53.1270, 53.1276, 53.1279, 53.1282, 53.1288, 53.1295, 53.1300, 53.1306, 53.1309, 53.1312, 53.1327, 53.1330, 53.1333, 53.1336, 53.1348, 53.1360, 53.1366, 53.1369, 53.1372, 53.1384, 53.1410, 53.1413, 53.1416, 53.1419, 53.1437, 53.1449, 53.1452, 53.1458, 53.1470, 53.1505, 53.1510, 53.1515, 53.1525, 53.1530, 53.1535, 53.1540, 53.1545, 53.1550, 53.1560, 53.1565, 53.1570, 53.1575, 53.1580, 53.1620, 53.1630, 53.1645, 53.1680, 53.1690, and 53.1720.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. The information collection requirement and the control numbers under which it is approved are as follows:

(1) In § 53.1640, NRC Form 366 is approved under control number 3150-0104.

(2) In § 53.1630, NRC Form 361 is approved under control number 3150-0238.

(3) In § 53.1650, IAEA Design Information Questionnaire forms are approved under control number 3150–0056.

(4) In § 53.1650, DOC/NRC Form AP–A and associated forms are approved under control numbers 0694–0135.

Subpart B — Technology-Inclusive Safety Requirements

§ 53.210 Safety criteria for design-basis accidents.

The analyses under § 53.450 of the performance of a commercial nuclear plant for design basis accidents identified under § 53.240 must demonstrate the following:

(a) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release would not receive a radiation dose in excess of 25 rem (250 millisieverts (mSv)) total effective dose equivalent (TEDE); and

(b) An individual located at any point on the outer boundary of the low population zone who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (250 mSv) TEDE.[1]

[1] The use of 25 rem TEDE is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

§ 53.220 Safety criteria for licensing-basis events other than design-basis accidents.

(a) The applicant or licensee must identify evaluation criteria for each event or specific category of licensing basis event to determine the acceptability of plant response to the challenges posed by internal and external hazards to provide an appropriate level of safety.

(b) The analyses under § 53.450 of the performance of a commercial nuclear plant for licensing-basis events (LBEs) other than design basis accidents (DBAs) identified under § 53.240 demonstrate that plant structures, systems, and components,

personnel, and programs provide the necessary capabilities and maintain the necessary reliability to meet the acceptance criteria identified in paragraph (a) of this section.

§ 53.230 Safety functions.

(a) The primary safety function is limiting the release of radioactive materials from the facility. The holder of a license to operate a commercial nuclear plant under this part must maintain the capability of the plant to perform the primary safety function during normal operation and for licensing-basis events (LBEs) identified under § 53.240 until the Commission terminates the license.

(b) The applicant or licensee for a commercial nuclear plant must identify additional safety functions to support the retention of radioactive materials during LBEs. The additional safety functions may include controlling reactivity, heat generation, heat removal, and chemical interactions as appropriate to the design.

(c) The primary and additional safety functions necessary to satisfy the safety criteria defined in §§ 53.210 and 53.220 must be fulfilled by the design features, human actions, and programmatic controls specified throughout this part.

§ 53.240 Licensing-basis events.

(a) The applicant or licensee for a commercial nuclear plant must identify Licensing-basis events (LBEs) for analysis under § 53.450 to demonstrate that the safety requirements in this subpart have been satisfied. The LBEs must be identified using insights from the risk evaluation performed under § 53.450 in combination with other generally accepted approaches that have been endorsed or otherwise found acceptable by the NRC for systematically evaluating engineered systems to identify and analyze equipment failures and human errors.

(b) The identified LBEs, ranging from anticipated event sequences to very unlikely event sequences, must collectively address combinations of malfunctions of

plant structures, systems, and components (SSCs), human errors, facility hazards, and the effects of external hazards.

(c) The analysis of LBEs must—

(1) Include analysis of one or more design basis accidents under § 53.450(f);

(2) Confirm the adequacy of design features and programmatic controls needed to satisfy the safety criteria defined in §§ 53.210 and 53.220, and

(3) Establish related functional requirements for plant SSCs, personnel, and programs.

(d) The methodology used to identify, categorize, and analyze LBEs must include a means to identify event sequences that are significant for controlling the risks posed to public health and safety.

§ 53.250 Defense in depth.

(a) Measures must be taken for each commercial nuclear plant to ensure appropriate defense in depth is provided to compensate for uncertainties in the analysis of the safety criteria such that there is reasonable assurance that the safety criteria in this subpart are met over the life of the plant.

(b) The uncertainties that must be addressed under paragraph (a) of this section include those related to the state of knowledge and modeling capabilities, the ability of barriers to limit the release of radioactive materials from the facility during LBEs other than DBAs, the reliability and performance of plant SSCs and personnel, and the effectiveness of programmatic controls.

(c) The safety analysis may not rely upon a single engineered design feature, human action, or programmatic control, no matter how robust, to address the range of LBEs other than DBAs.

§ 53.260 Normal operations.

Holders of licenses to operate commercial nuclear plants under this part must control public doses and dose rates in unrestricted areas from normal plant operations to meet the requirements in part 20 of this chapter.

§ 53.270 Protection of plant workers.

Holders of licenses to operate commercial nuclear plants under this part must control the radiological dose to plant workers to meet the requirements in part 20 of this chapter.

Subpart C — Design and Analysis Requirements

§ 53.400 Design features for licensing-basis events.

Design features must be provided for each commercial nuclear plant such that, when combined with corresponding human actions and programmatic controls, the plant will satisfy the safety criteria defined in §§ 53.210 and 53.220 and fulfill the safety functions identified in § 53.230 during licensing-basis events identified under § 53.240.

§ 53.410 Functional design criteria for design-basis accidents.

The applicant or licensee for a commercial nuclear plant must define functional design criteria for each design feature required by § 53.400 and relied upon to demonstrate compliance with the safety criteria defined in § 53.210.

§ 53.415 Protection against external hazards.

Structures, systems, and components (SSCs) categorized as safety-related SSCs under § 53.460 must be protected against or must be designed to withstand the effects of natural phenomena (e.g., earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches) and man-related hazards (e.g., dams, transportation routes, military and industrial facilities) considering an event severity up to the design-basis external hazard levels as determined under § 53.510 without losing the capability to perform the safety

functions identified under § 53.230. Specific requirements for earthquake engineering are included in § 53.480.

§ 53.420 Functional design criteria for licensing-basis events other than design-basis accidents.

The applicant or licensee for a commercial nuclear plant must define functional design criteria for each design feature required by § 53.400 and relied upon to demonstrate compliance with the evaluation criteria in § 53.450(e).

§ 53.425 Design features and functional design criteria for normal operations.

(a) Design features must be provided for each commercial nuclear to support the Radiation Protection Program required in § 53.850.

(b) Functional design criteria must be defined for each design feature relied upon to demonstrate compliance with § 53.850.

(c) Functional design criteria, including design objectives for dose to the maximally exposed member of the public, must be defined for design features to show that plant design features and corresponding programmatic controls, including monitoring programs, control liquid, gaseous, and solid wastes as required under part 20 of this chapter. A guide for keeping doses to the public as low as is reasonably achievable is that the estimated annual dose to the maximally exposed member of the public does not exceed 10 mrem total effective dose equivalent. A design objective of maintaining doses below 10 mrem/year should not be construed as a radiation protection standard.

§ 53.430 Design features and functional design criteria for protection of plant workers.

(a) Design features must be provided for each commercial nuclear plant such that, when combined with corresponding programmatic controls, the requirements in § 53.270 can be met.

(b) Functional design criteria must be defined for each design feature relied upon to demonstrate compliance with § 53.270.

§ 53.440 Design requirements.

(a) [Reserved]

(b) [Reserved]

(c) The materials used for safety-related (SR) and non-safety-related but safety significant (NSRSS) structures, systems, and components (SSCs) must be qualified for their service conditions over the plant lifetime.

(d) Possible degradation mechanisms related to aging, fatigue, chemical interactions, operating temperatures, effects of irradiation, and other environmental factors that may affect the performance of SR and NSRSS SSCs must be evaluated and used to inform the design

(e)(1) SR and NSRSS SSCs must be designed and located to minimize, consistent with other safety requirements in this part, the probability and effect of fires and explosions.

(2) Noncombustible and fire-resistant materials must be used wherever practical throughout the facility, particularly in locations with SR and NSRSS SSCs.

(3) Fire detection and fire suppression systems of appropriate capacity and capability must be provided and designed to minimize the adverse effects of fires on SR and NSRSS SSCs.

(4) Fire suppression systems must be designed to ensure that their rupture or inadvertent operation does not significantly impair the ability of SR and NSRSS SSCs to perform their safety functions identified under § 53.230.

(f) Safety and security must be considered together in the design process such that, where possible, security issues are effectively resolved through design and engineered security features.

(g) The reactor system and waste stores for each commercial nuclear plant must be capable of reliably controlling reactivity during normal operations and following any LBE identified in accordance with § 53.240.

(h) Each commercial nuclear plant must have a capability to provide long-term cooling of the reactor fuel and waste stores during normal operations or following any licensing-basis event (LBE) identified in accordance with § 53.240.

(i) The design, analysis, staffing, and programmatic controls for each commercial nuclear plant must consider the number of reactors, waste stores, and other significant inventories of radioactive materials and the associated operating configurations, common systems, system interfaces, and system interactions.

(j)(1) Design features must be provided and related functional design criteria defined such that, with limited use of operator actions, one or more physical barriers are maintained to limit the release of radionuclides from reactor systems, waste stores, or other significant inventories of radioactive materials assuming the impact of a large, commercial aircraft.

(2) The functional design criteria for those design features provided to address the requirements in paragraph (j)(1) of this section must be based on an assessment of the impact of a large, commercial aircraft used for long distance flights in the United States, with aviation fuel loading typically used in such flights, and an impact speed and

angle of impact considering the ability of both experienced and inexperienced pilots to control large, commercial aircraft at low altitude representative of a commercial nuclear plant's low profile.[1]

(k) Design features and related functional design criteria must be defined such that analyses demonstrate a low risk of permanent injury to the public due to the health effects of the chemical hazards of licensed material.

(l) Measures must be taken during the design of commercial nuclear plants to minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste in accordance with § 20.1406 of this chapter.

(m)(1) Each commercial nuclear plant must include criticality monitoring capabilities meeting the requirements of either § 70.24 of this chapter or paragraph (m)(2) of this section.

(2) In lieu of maintaining a monitoring system capable of detecting criticality as described in § 70.24 of this chapter, criticality accident requirements may be satisfied by—

(i) Demonstrating the sub-criticality of SNM, except when it is inside the reactor and the reactor is being operated, by maintaining k-effective below 0.95 at a 95 percent probability, 95 percent confidence level, under conditions that maximize reactivity for the applicable storage and handling configurations, and

(ii) Providing radiation monitors for fuel storage and associated handling areas when fuel is present to detect excessive radiation levels and to support initiating appropriate safety actions.

(3) While a spent fuel transportation package approved under 10 CFR part 71 of this chapter or spent fuel storage cask approved under 10 CFR part 72 is in the SNM

handing or storage area, the requirements in 10 CFR parts 71 or 72, as applicable, and the requirements of the certificate of compliance for that package or cask, are the applicable requirements for the fuel within that package or cask.

(n) *Human factors engineering*

(1) The design of each commercial nuclear plant must reflect state-of-the-art human factors principles for safe and reliable performance in all locations that human activities are expected for performing or supporting the continued availability of plant safety or emergency response functions.

(2) In order to ensure the plant staff are able to monitor plant conditions and respond to events, the design must provide for the following capabilities.:

(i) Features for displaying to operating personnel a minimum set of parameters that define the safety status of the plant and are capable of displaying both the full range of important plant parameters and data trends on demand, as well as indicating when process limits are being approached or exceeded;

(ii) Automatic indication of the bypassed and operable status of safety systems;

(iii) Direct indication of SSC status that relates to the ability of the SSC to perform its safety function, such as relief and safety valve position (i.e., open or closed) for barriers important to fulfilling safety functions of with such devices, and ultimate heat sink and cooling system status and availability;

(iv) Instrumentation to measure, record, and display key plant parameters related to the performance of SSCs and the integrity of barriers important to fulfilling safety functions to support operators in monitoring plant conditions and responding to plant events. Examples include temperatures and pressures within important systems or structures, core or fuel system conditions (including possible damage states), temperatures and levels associated with cooling functions, combustible gas

concentrations, radiation levels in systems and within structures, and radioactive effluent releases;

(v) Leakage control and detection in the design of systems that pass through barriers important to fulfilling safety functions for the release of radionuclides. An example is an SSC that penetrates a containment structure that might contain radioactive materials that could contribute to the source term during an accident;

(vi) Monitoring of in-plant radiation and airborne radioactivity as appropriate for a broad range of normal operating and accident conditions

(3) The means by which the design and human actions together will achieve the safety requirements of subpart B of this part must be evaluated and used to inform the design and the development of the concept of operations required by § 53.730(c).

(4) A functional requirements analysis and function allocation must be used to ensure that plant design features address how safety functions and functional safety criteria are satisfied, and how the safety functions will be assigned to appropriate combinations of human action, automation, active safety features, passive safety features, or inherent safety characteristics.

(o) *Load following*. The design of a commercial nuclear plant that will operate in a load following mode must include one of the following features capable of immediately refusing demands that could challenge the safe operation of the plant or are otherwise precluded by the plant equipment conditions:

(i) An automatic protection system that utilizes setpoints more conservative than those otherwise credited for the purposes of reactor protection; or

(ii) An automated control system; or

(iii) Provisions to allow operator or senior operator or a generally licensed reactor operator, as appropriate to refuse the demand.

(p) The configuration of structures, systems, and components must provide sufficient access for personnel and equipment to perform inservice inspection and inservice testing under § 53.880. Shielding must be provided to support the radiation protection of plant personnel when accomplishing the inspections and testing as needed under the radiation protection program required by part 20 of this Chapter.

[1] Changes to the detailed parameters on aircraft impact characteristics set forth in guidance must be approved by the Commission.

§ 53.450 Analysis requirements.

(a) *Requirement to have a risk evaluation.* An applicant or licensee of a commercial nuclear plant must perform a risk evaluation to identify potential failures, susceptibility to internal and external hazards, and other contributing factors to event sequences that might challenge the safety functions identified in § 53.230 and to support demonstrating that the commercial nuclear plant meets the safety criteria of § 53.220.

(b) *Specific uses of analyses*. The risk evaluation in combination with other generally accepted approaches for systematically evaluating engineered systems must be used—

(1) To inform the selection of the licensing basis events (LBEs)under § 53.240, which must be considered in the design to achieve compliance with the safety criteria in Subpart B of this part.

(2) To inform the classification of structures, systems, and components (SSCs) under § 53.460 and to identify the environmental conditions under which the SSCs and operating staff must perform their safety functions.

(3) To evaluate the adequacy of defense-in-depth measures under § 53.250.

(4) To identify and assess all plant operating states where there is the potential for the uncontrolled release of radioactive material to the environment.

(5) To identify and assess events that challenge plant control and safety systems whose failure could lead to the uncontrolled release of radioactive material to the environment. These include internal events, such as human errors and equipment failures, and external events identified in accordance with Subpart D of this part.

(c) *Maintenance and upgrade of risk evaluation*. The holder of a license to operate a commercial nuclear plant under this part must maintain the risk evaluation until the license no longer authorizes operation of the reactor under § 53.1070. The licensee must upgrade the risk evaluation as appropriate to its technical adequacy in order to assure that it properly reflects the as-built, as-operated plant.

(d) *Qualification of analytical codes*. The analytical codes used in modeling plant behavior in analyses of licensing basis events must be qualified over the range of conditions for which they are to be used.

(e) *Analyses of licensing-basis events other than design-basis accidents*. (1) The applicant or licensee for a commercial nuclear power plant must perform analyses for LBEs other than design basis accidents (DBAs).

(2) [Reserved].

(3) The analyses of LBEs other than DBAs must address event sequences from initiation to a defined end state and be used in combination with other engineering analyses to demonstrate that the functional design criteria required by § 53.420 provide sufficient barriers to the unplanned release of radionuclides to satisfy the evaluation criteria defined for each LBE other than DBAs of § 53.220 and provide defense in depth as required by § 53.250.

(f) *Analysis of design-basis accidents*. (1) The analysis of LBEs required by § 53.240 must include analysis of DBAs that address possible challenges to the safety

functions identified under § 53.230. The events selected as DBAs must be those that, if not terminated, have the potential for exceeding the safety criteria in § 53.210.

(2) The DBAs selected must be analyzed using deterministic methods that address event sequences from initiation to a safe stable end state and assume only the SR SSCs identified under § 53.460 and human actions addressed by the requirements of subpart F of this part are available to perform the safety functions identified in accordance with § 53.230.

(3) The analysis must demonstrate compliance with the safety criteria in § 53.210.

(g) *Other required analyses*. Analyses must be performed to assess—

(1) *Fire protection.* Fire protection measures to demonstrate, through inclusion of fires in the analysis of LBEs or by separate analyses, that a fire or explosion in any plant area would not—

(i) Prevent equipment from fulfilling the safety functions identified in accordance with § 53.230, or

(ii) Challenge the safety criteria in §§ 53.210 and 53.220.

(2) *Aircraft impact.* The need for measures to protect against aircraft impacts under § 53.440(j).

(3) *Dose to members of the public.* Measures taken under § 53.425, including estimating—

(i) The quantity of each of the principal radionuclides expected to be released annually to unrestricted areas in liquid effluents produced during normal reactor operations and the dose to the maximally exposed member of the public in unrestricted areas.

(ii) The quantities of each of the principal radionuclides of the gases, halides, and particulates expected to be released annually to unrestricted areas in gaseous effluents produced during normal reactor operations and the dose to the maximally exposed member of the public in unrestricted areas.

(iii) The annual external radiation dose in unrestricted areas and the maximally exposed member of the public in unrestricted areas due to direct radiation from contained radiation sources from the commercial nuclear plant during normal reactor operations.

§ 53.460 Safety categorization and special treatments.

(a) Structures, systems, and components (SSCs) must be classified according to their safety significance. The SSC categories must include “Safety-Related” (SR), “Non-Safety-Related but Safety-Significant” (NSRSS), and “Non-Safety-Significant” (NSS), as defined in subpart A of this part.

(b) For SR and NSRSS SSCs, the conditions under which they must perform their safety function in § 53.230 must be identified. Special treatments must be established to provide confidence that the SSCs will perform under the identified conditions and with reliability consistent with the analysis performed under § 53.450 to demonstrate meeting the safety criteria in §§ 53.210 and 53.220.

(1) The special treatments for SR SSCs must include meeting the applicable QA requirements.

(2) The special treatments for NSRSS SSCs may include meeting selected QA requirements when such treatment is needed to address performance requirements, equipment reliability, or uncertainties.

§ 53.480 Earthquake engineering.

(a) Structures, systems, and components (SSCs) classified as safety-related (SR) or non-safety-related but safety significant (NSRSS) must be able to withstand the effects of earthquakes, commensurate with the safety significance of the SSC, without loss of capability to perform their role in fulfilling the safety functions required by § 53.230.

(b) For the purpose of this section—

Design-Basis Ground Motions (DBGMs) are the vibratory ground motions for which certain SSCs must be designed to remain functional.

Operating basis earthquake (OBE) ground motion is the vibratory ground motion for which those features of the commercial nuclear plant necessary for continued operation without undue risk to the health and safety of the public are designed to remain functional. The OBE ground motion is used in § 53.720.

Response spectrum is a plot of the maximum responses (acceleration, velocity, or displacement) of idealized single-degree-of-freedom oscillators as a function of the natural frequencies of the oscillators for a given damping value. The response spectrum is calculated for a specified vibratory motion input at the oscillators' supports.

Surface deformation is the distortion of geologic strata on or near the ground surface that occurs by the processes of folding or faulting as a result of various earth forces. Tectonic surface deformation is associated with earthquakes.

(c)(1) *Design-Basis Ground Motions.*

(i) The DBGMs must be derived from the Site Ground Motion Response Spectra (GMRS) developed in accordance with § 53.510(c), by taking into consideration the functional design criteria of SSCs in accordance with §§ 53.410 and 53.420. The horizontal component of the DBGM(s) in the free-field at the foundation level of the structures must be an appropriate response spectrum that is determined based on the

risk-significance of SSCs and their safety functions. In view of the limited data available on vibratory ground motion of strong earthquakes, it is acceptable that the design response spectra be smoothed spectra.

(ii) The commercial nuclear plant must be designed so that, if the DBGMs occur, the following SSCs remain functional and within applicable stress, strain, and deformation limits:

(A) SSCs for which functional design criteria are established in accordance with § 53.410 or § 53.420; and

(B) SSCs classified as SR or NSRSS commensurate with safety significance in accordance with § 53.460.

(iii) In addition to seismic loads, applicable concurrent normal operating, functional, and accident-induced loads must be taken into account in the design of the SR SSCs and, taken into account commensurate with the safety significance of NSRSS SSCs in their design.

(iv) The design of the commercial nuclear plant must take into account the possible effects of seismic-induced ground disruption, such as fissuring, lateral spreads, differential settlement, liquefaction, and landsliding, on the facility foundations.

(v) The SSCs fulfilling the safety functions required by § 53.230 must be able to fulfill those safety functions during and after the vibratory ground motion associated with the DBGMs as demonstrated through analytical, testing, or qualification methods.

(vi) The evaluation of SSCs required by this section to show they are able to function during and after earthquake ground motion must take into account soil-structure interaction effects and the expected duration of vibratory motion. It is permissible to design for strain limits in excess of yield strain in some of these SSCs for the DBGMs

and under the postulated concurrent loads, provided the necessary safety functions are maintained.

(2) *Operating Basis Earthquake Ground Motion.* The OBE Ground Motion must be characterized by response spectra. The value of the OBE Ground Motion must be set to one-third or less of the DBGMs response spectra.

(3) [Reserved]

(4) *Required Seismic Instrumentation.* Suitable instrumentation must be provided so that the seismic response of commercial nuclear plant SR SSCs or NSRSS SSCs can be evaluated promptly after an earthquake.

(d) *Surface Deformation.*

(1) The potential for surface deformation must be taken into account in the design of the commercial nuclear plant by providing reasonable assurance that in the event of deformation, SSCs classified as SR or NSRSS under § 53.460 will remain functional.

(2) In addition to surface deformation induced loads, the design of SSCs must take into account, commensurate with safety significance, seismic loads and applicable concurrent functional and accident-induced loads.

(3) The design provisions for surface deformation must be based on its postulated occurrence in any direction and azimuth and under any part of the commercial nuclear plant, unless evidence indicates this assumption is not appropriate, and must take into account the estimated rate at which the surface deformation may occur.

(e) *Seismically Induced Floods and Water Waves and Other Design Conditions.* Seismically induced floods and water waves from either locally or distantly generated seismic activity and other design conditions determined pursuant to Subpart D must be

taken into account in the design of the commercial nuclear plant so as to prevent undue risk to the health and safety of the public.

Subpart D — Siting Requirements

§ 53.500 General siting and siting assessment.

(a) The siting of each commercial nuclear plant must be supported by assessments of proposed sites such that the design, including design features and programmatic controls corresponding to the site characteristics, satisfies the safety criteria defined in §§ 53.210 and 53.220. The siting assessment must ensure that site characteristics that might contribute to the initiation, progression, or consequences of licensing-basis events (LBEs) analyzed under §§ 53.450 and 53.480 are identified and mitigated by design features or programmatic controls. The siting assessment must take into consideration the potential adverse impacts that a commercial nuclear plant may have on nearby populations as a result of normal operations or LBEs.

(b) Activities performed to identify site characteristics or otherwise needed to determine site-specific contributors to functional design criteria or analysis assumptions under subpart C of this part must be performed under a quality assurance program that satisfies the applicable special treatment requirements of § 53.460, including, where applicable, the QA requirements from appendix B to part 50 of this chapter.

§ 53.510 External hazards.

(a) *General external hazard requirements.* The design-basis external hazard level for the relevant external hazards for a site must be identified and characterized based on site-specific assessments of natural and man-related hazards with the potential to adversely affect plant functions. The external hazard frequencies and magnitudes determined from the site-specific assessments must take into account

uncertainties and variabilities in data, models, and methods relied on to characterize the external hazards.

(b) *Definitions.* For the purpose of this section, the following terms mean:

Geological Siting Factors are geological and seismic factors that may affect the design and operation of the proposed commercial nuclear plant.

Ground Motion Response Spectra (GMRS) are the site-specific GMRS resulting from the geologic investigations and evaluations of the site vicinity and region and used to determine design-basis ground motions (DBGMs) for SSCs under § 53.480.

Probabilistic Seismic Hazard Analysis (PSHA) is an analytical methodology that incorporates uncertainty into estimates of an annual frequency of exceedance for a certain ground motion parameter (e.g., peak ground acceleration, peak ground velocity, response spectral values) at a site.

(c) *Geological, seismological, and engineering Investigations*. The investigations required in this paragraph are not considered “construction” as defined in § 53.020. The GMRS for the site must be determined based on the results of investigations of the geological, seismological, and engineering characteristics of the site and its environs and must be characterized by both horizontal and vertical free-field GMRS at the free ground surface. The size of the region to be investigated and the type of data pertinent to the investigations must be determined based on the nature of the region surrounding the site. Data on vibratory ground motion, earthquake recurrence rates, fault geometry and slip rates, and site subsurface material properties must be obtained by reviewing pertinent literature and carrying out field investigations. Uncertainties are inherent in the parameters and models used to estimate the GMRS for the site. The site assessment must reflect these uncertainties through an appropriate analysis, such as a probabilistic seismic hazard analysis. Each applicant must investigate all geologic and seismic

factors (for example, volcanic activity) that may affect the design and operation of the proposed commercial nuclear plant irrespective of whether such factors are explicitly included in this section.

(d) *Geologic Siting Factors*. The geologic and seismic siting factors considered for design under §§ 53.415 and 53.480 must include determination of the potential for surface tectonic and nontectonic deformations, the size and character of seismically induced floods and water waves that could affect a site from either locally or distantly generated seismic activity, soil and rock stability, liquefaction potential, and natural and artificial slope stability.

§ 53.520 Site characteristics.

Site characteristics that might contribute to the initiation, progression, or consequences of licensing-basis events analyzed under § 53.450 must be identified, assessed, and considered in the design and analyses required by subpart C of this part.

§ 53.530 Population-related considerations.

Every site must have an exclusion area, a low population zone, and a population center distance as defined in § 53.020.

(a) The offsite radiological consequences estimated by the analyses required by § 53.450(f) must be used in selecting the boundaries of the exclusion area and low population zone.

(b) The population center distance must be at least one and one-third times the distance from the reactor to the outer boundary of the low population zone. The boundary of the population center must be determined upon consideration of population distribution. Political boundaries are not controlling in the calculation of population center distance.

(c) Reactor sites should be located away from very densely populated centers. Areas of low population density are, generally, preferred. However, in determining the acceptability of a particular site located away from a very densely populated center but not in an area of low population density, consideration will be given to safety, environmental, economic, or other factors, which may result in the site being found acceptable.

§ 53.540 Siting interfaces.

Site characteristics must be addressed by the design features, programmatic controls, and supporting analyses used to demonstrate that the safety criteria in §§ 53.210 and 53.220 are met for each commercial nuclear plant. Site characteristics must be such that adequate emergency plans and security plans can be developed and maintained.

Subpart E — Construction and Manufacturing Requirements

§ 53.600 Construction and manufacturing – scope and purpose.

This subpart applies to those construction and manufacturing activities authorized by a construction permit, combined license, manufacturing license, or limited work authorization issued under this part.

§ 53.605 Reporting of defects and noncompliance.

Each construction permit (CP) and manufacturing license (ML) issued under this part is subject to the terms and conditions in this section, and each combined license (COL) issued under this part is subject to the terms and conditions in this section until the date that the Commission makes the finding under § 53.1452(g).

(a) *Definitions*. The definitions in § 21.3 of this chapter apply to this section.

(b) *Posting requirements*.(1) The holder of a CP, COL, or ML subject to the regulations in this section must post current copies of this section and the regulations in

10 CFR part 21; Section 206 of the ERA; and procedures adopted under these regulations. These documents must be posted in a conspicuous position on any premises within the United States where the activities subject to the license are conducted.

(2) If posting of these regulations or the procedures adopted under them is not practical, the licensee may, in addition to posting Section 206 of the ERA, post a notice that describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

(c) *Procedures*. The holder of a CP, COL, or ML subject to this section must adopt appropriate procedures to –

(1) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (c)(2) of this section, in all cases within 60 days of discovery, to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected.

(2) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from the discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer, or designated person as discussed in paragraph (d)(5) of this section. The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.

(3) Ensure that a director or responsible officer of the holder of a CP, COL, or ML subject to this section is informed as soon as practicable, and, in all cases, within the 5

working days after completion of the evaluation described in paragraph (c)(1) or (c)(2) of this section, if the construction or manufacture of a facility or activity, or a manufactured reactor, or a basic component supplied for such a facility or activity –

(i) Fails to comply with the Act or any applicable regulation, order, or license of the Commission relating to a substantial safety hazard;

(ii) Contains a defect; or

(iii) Underwent any significant breakdown in any portion of the quality assurance program (QAP) conducted under the requirements of appendix B to part 50 of this chapter that could have produced a defect in a basic component or manufactured reactor. These breakdowns in the QAP are reportable whether or not the breakdown actually resulted in a defect in a design approved and released for construction, installation, or manufacture.

(d) R*eporting defects and noncompliance.*

(1) The holder of a CP, COL, or ML subject to this section that obtains information reasonably indicating that the facility or manufactured reactors fails to comply with the Act or any applicable regulation, order, or license of the Commission relating to a substantial safety hazard must notify the Commission of the failure to comply through a director, responsible officer, or designated person as discussed in paragraph (d)(5) of this section.

(2) The holder of a CP, COL, or ML subject to this section that obtains information reasonably indicating the existence of any defect found in the construction or manufacture, or any defect found in the final design of a facility or manufactured reactor as approved and released for construction or manufacture, must notify the Commission of the defect through a director, responsible officer, or designated person as discussed in paragraph (d)(5) of this section.

(3) The holder of a CP, COL, or ML subject to this section, who obtains information reasonably indicating that the QAP has undergone any significant breakdown discussed in paragraph (c)(3)(iii) of this section must notify the Commission of the breakdown in the QAP through a director, responsible officer, or designated person as discussed in paragraph (d)(5) of this section.

(4) When acting as a dedicating entity, the holder of a CP, COL, or ML subject to this section is responsible for identifying and evaluating deviations; reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and maintaining auditable records for the dedication process.

(5) The notification requirements of this paragraph apply to all defects and failures to comply associated with a substantial safety hazard regardless of whether extensive evaluation, redesign, or repair is required to conform to the criteria and bases stated in the Safety Analysis Report, CP, COL, or ML. Evaluation of potential defects and failures to comply and reporting of defects and failures to comply under this section satisfies the CP holder's, COL holder's, and ML holder's evaluation and notification obligations under 10 CFR part 21, and satisfies the responsibility of individual directors or responsible officers or holders of a CP, COL, or ML subject to this section to report defects, and failures to comply associated with substantial safety hazards under Section 206 of the ERA. The director or responsible officer may authorize an individual to provide the notification required by this section. However, this does not relieve the director or responsible officer of his or her responsibility under this section.

(e) *Notification – timing and where sent*. The notification required by paragraph (d) of this section must consist of –

(1) Initial notification by telephone, facsimile, or e-mail identified in Appendix D to 10 CFR part 20 to the NRC Operations Center within 2 days following receipt of

information by the director or responsible officer under paragraph (c)(3) of this section, on the identification of a defect or a failure to comply. If the CP, COL, or ML holder elects to use facsimile, verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in paragraph (c)(2) of this section.

(2) Written notification submitted to the NRC Document Control Desk by an appropriate method listed in § 53.040, with a copy to the appropriate NRC Regional Administrator at the address specified in appendix D to 10 CFR part 20 and a copy to the appropriate NRC resident inspector, if applicable, within 30 days following receipt of information by the director or responsible officer under paragraph (c)(3) of this section, on the identification of a defect or failure to comply.

(f) *Content of notification*. The written notification required by paragraph (e)(2) of this section must clearly indicate that the written notification is being submitted under this section and include the following information, to the extent known.

(1) Name and address of the individual or individuals informing the Commission.

(2) Identification of the facility, the activity, manufactured reactor, or the basic component supplied for the facility or the activity within the United States which contains a defect or fails to comply.

(3) Identification of the firm constructing or manufacturing the facility or manufactured reactor or supplying the basic component which fails to comply or contains a defect.

(4) Nature of the defect or failure to comply and the safety hazard which is created or could be created by the defect or failure to comply.

(5) The date on which the information of a defect or failure to comply was obtained.

(6) In the case of a basic component that contains a defect or failure to comply, the number and location of these components in use at the facility subject to the regulations in this part.

(7) In the case of a manufactured reactor under this part, the entities to which the reactor was supplied.

(8) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(9) Any advice related to the defect or failure to comply about the facility, activity, manufactured reactor, or basic component that has been, is being, or will be given to other entities.

(g) *Procurement documents*. Each holder of a CP, COL, or ML subject to this section must ensure that each procurement document for a facility or a basic component specifies the provisions of 10 CFR part 21 or this section that apply, as applicable.

(h) *Coordination with 10 CFR part 21*. The requirements of this section are satisfied when the defect or failure to comply associated with a substantial safety hazard has been previously reported under 10 CFR part 21, under § 73.71 of this chapter, under this section, or under § 53.1640.

(i) *Records retention*. The holder of a CP, COL, or ML subject to this section must prepare and maintain records necessary to accomplish the purposes of this section, specifically –

(1) Retain procurement documents, which define the requirements that facilities, manufactured reactors, or basic components must satisfy in order to be considered acceptable, for the lifetime of the facility, manufactured reactor, or basic component.

(2) Retain records of evaluations of all deviations and failures to comply under paragraph (c)(1) of this section for the longest of—

(i) Ten years from the date of the evaluation;

(ii) Five years from the date that an early site permit is referenced in an application for a COL; or

(iii) Five years from the date of delivery of a manufactured reactor.

(3) Retain records of all interim reports to the Commission made under paragraph (c)(2) of this section, or notifications to the Commission made under paragraph (d) of this section for the minimum time periods stated in paragraph (i)(2) of this section;

(4) [Reserved]

(5) Maintaining reports in accordance with this section satisfies the recordkeeping obligations under 10 CFR part 21 of the entities, including directors or responsible officers thereof, subject to this section.

§ 53.610 Construction.

(a) *Construction experience*. Licensees authorized to construct a commercial nuclear plant must develop and implement procedures to evaluate the applicability of other national and international construction experience to the planned and ongoing construction activities and to ensure the applicable experience will be provided to those constructing the plant.

(b) *Construction activities.* No person may begin the construction of a commercial nuclear plant on a site on which the facility is to be operated under this part until that person has been issued either a construction permit (CP) or combined license (COL), an early site permit authorizing activities under § 53.1130, or a limited work authorization (LWA) under this part.

(1) Licensees must satisfy the following requirements:

(i) [Reserved].

(ii) For construction of a commercial nuclear plant involving multiple reactor units, plans and procedures must be in place to prevent or mitigate potential hazards to the structures, systems, and components of operating units resulting from construction activities, including the managerial and administrative controls to be used to provide assurance that the limiting conditions for operation of the operating units are not exceeded as a result of construction activities.

(iii) Procedures must be in place prior to the start of construction activities that describe how construction will be controlled so as not to impact other features important to the design, such as dewatering, slope stability, backfill, compaction, and seepage.

(iv) For LWA holders, a plan must be developed for redress of activities performed under the LWA should one of the following situations arise:

(A) LWA work activities are terminated by the holder of the LWA;

(B) The LWA is revoked by the NRC; or

(C) The Commission denies the associated CP or COL application.

(2) Fire protection measures must be implemented for work and storage areas (including adjacent fire areas that could affect the work or storage area) before initial receipt of byproduct, source, or non-fuel special nuclear material (excluding exempt quantities as described in § 30.18 of this chapter). The fire protection measures for areas associated with new fuel (including all fuel handling, fuel storage, and adjacent fire areas that could affect the new fuel) must be implemented before receipt of fuel.

(c) *Acceptance of a manufactured reactor for construction of a commercial nuclear plant*. Upon delivery to the site, a manufactured reactor may not be used in the construction of a commercial nuclear plant until the COL holder verifies it is in

acceptable condition in compliance with the manufacturing license using inspections and tests under its program. These inspections must confirm that all necessary interface requirements between the manufactured reactor and the remaining portions of the commercial nuclear plant are met.

§ 53.615 Application for operating licenses.

(a) *Updating of application*. At or about the time of completion of the construction or modification of the facility, the applicant will file any additional information needed to bring the original application for license up to date and will file an application for an operating license as specified in paragraph (b) of this section.

(b) Application for operating licenses. The holder of a construction permit for a commercial nuclear plant must, at the time of submission of the final safety analysis report, file an application for an operating license. The application must state the name of the applicant, the name, location and power level, if any, of the facility and the time when the facility is expected to be ready for operation and may incorporate by reference any pertinent information submitted under § 53.1109 with the application for a construction permit.

§ 53.620 Manufacturing.

(a) *Management and control*. Holders of manufacturing licenses (MLs) must ensure that the following plans, programs, and organizational units are developed and implemented to manage and control the manufacturing activities within the scope of the ML:

(1) A program to evaluate the applicability of other national and international design and manufacturing experience to the planned and ongoing manufacturing activities.

(2) A quality assurance program (QAP) meeting the requirements of appendix B to part 50 of this chapter, to be applied to the design, fabrication, and testing of the structures, systems, and components (SSCs) of the manufactured reactor.

(b) *Loading fuel into a manufactured reactor at the factory*

(1) (i) An ML may include authorization for the loading of fuel into a manufactured reactor at the factory only if the manufactured reactor is configured during its loading and storage to provide at least two independent mechanisms each of which is sufficient to prevent criticality assuming maximum reactivity of the fissile material would be attained from possible fuel configurations, neutron moderation, and neutron reflection from the manufactured reactor and surrounding materials. The Commission has determined that any such fueled manufactured reactor in which these mechanisms have been installed is not a utilization facility as defined in section 11cc. of the Act or § 53.020 until it is installed in its final place of use and the Commission has found that the inspections, tests, and analyses of the ML have been performed and the ML acceptance criteria have been met under § 53.620(f) and the inspections, tests, and analyses in the combined license (COL) that authorized reactor construction have been performed and the COL acceptance criteria have been met under § 53.1452(g); and

(ii) The Commission has determined that, upon a Commission finding with respect to a particular fueled manufactured reactor that the inspections, tests, and analyses in the COL that authorized reactor construction have been performed and the COL acceptance criteria have been are met under § 53.1452(g) that the fueled manufactured reactor is part of a utilization facility and all COL provisions and regulations applicable to the type of commercial nuclear plant for which the Commission has made the finding apply to that fueled manufactured reactor.

(2) If the ML authorizes fuel loading into a manufactured reactor at the factory, the following must be in place prior to the receipt of SNM:

(i) Procedures to receive, transfer, possess, and use source, byproduct, and SNM in accordance with the applicable portions of 10 CFR parts 30, 40 and 70;

(ii) A fire protection program before the initial receipt of byproduct, source, or non-fuel SNM (excluding exempt quantities as described in § 30.18 of this chapter). The fire protection measures for areas associated with fueling a manufactured reactor (including all fuel handling, fuel storage and adjacent areas where a fire could affect the fresh fuel) must be implemented before receipt of fresh fuel at the manufacturer's facility. Prior to the receipt of fuel at the manufacturer's facility, a formal letter of agreement must be in place with the local fire department specifying the nature of arrangements in support of the fire protection program;

(iii) An emergency plan appropriate for responding to the facility-specific hazards of an accidental release of radioactive material and to limit the health effects of the associated chemical hazards of licensed material must be approved and implemented prior to the receipt of byproduct, source, or SNM (excluding exempt quantities as described in § 30.18 of this chapter);

(iv) A plant staff training program associated with the receipt of radioactive material must be approved and implemented before initial receipt of byproduct, source, or SNM (excluding exempt quantities as described in § 30.18 of this chapter).

(v) Security requirements must be implemented for the protection of SNM based on the type, enrichment, and quantity in accordance with 10 CFR part 73, as applicable, and for the protection of Category 1 and Category 2 quantities of radioactive material in accordance with 10 CFR part 37, as applicable.

(vi) Radiation monitoring instrumentation and alarms.

(vii) Measures to prevent criticality accidents under §§ 70.61 and 70.64 of this chapter and to detect potential criticality accidents in accordance with § 53.440(m).

(viii) Procedures, equipment, and personnel qualified to handle fresh fuel, load it into the reactor, monitor the reactivity, and secure the fuel and reactor assembly for shipment.

(ix) A physical security program for the storage of fresh fuel under 10 CFR 73.67.

(x) An MC&A program under 10 CFR part 74.

(3) The storage, movement, and loading of fresh fuel into the manufactured reactor within the manufacturing facility must comply with the requirements of §§ 70.61, 70.62 and 70.64 of this chapter.

(4) The loading or unloading of fresh fuel into or from a manufactured reactor and any changes to the configuration of reactivity-related systems for the manufactured reactor module must be performed by a certified fuel handler meeting the requirements in subpart F.

(c) *Transportation.*

(1) A holder of an ML may not transport or allow to be removed from the places of manufacture the manufactured reactor except to the site of a licensee with a COL. The COL must authorize the construction of a commercial nuclear plant using the manufactured reactor(s).

(2) A holder of an ML must include, in any contract governing the transport of a manufactured reactor from the places of manufacture to any other location, a provision requiring that the person or entity transporting the manufactured reactor comply with all NRC-approved shipping requirements in the ML.

(3) Procedures governing the preparation of the manufactured for transport and the conduct of the transport must be implemented prior to transport.

(4) The packaging and shipping of any fueled manufactured reactor module must be done in compliance with 10 CFR parts 71 and 73.

Subpart F — Requirements for Operation

§ 53.710 Technical specifications and programmatic controls.

(a) Each operating license or combined license for a commercial nuclear plant under this part must include technical specifications that define conditions or limitations on plant operations that are necessary to ensure that safety-related (SR) structures, systems, and components (SSCs) can fulfill the safety functions identified under § 53.230 and support meeting the safety criteria of § 53.210. The technical specifications must describe include the following items:

(1) *Inventory Limits* on radioactive materials within the reactor system and supporting systems to prevent exceeding the safety criteria in § 53.210 in the event of a design-basis accident (DBA). These limits must be determined based on potential collective releases from the systems.

(2) *Operating limits* for the facility that if exceeded could lead to a failure to perform a required safety function necessary to demonstrate compliance with the safety criteria in § 53.210.

(3) For each SR SSC, technical specifications must define—

(i) *Limiting conditions for operation*. Limiting conditions for operation are the lowest functional capability or performance levels of SR SSCs required to prevent exceeding the safety criteria of § 53.210 in the event of a DBA. When a limiting condition for operation is not met, the licensee must shut down the plant or follow any remedial action permitted by the technical specifications until the condition can be met.

(ii) *Surveillance requirements.* Surveillance requirements are requirements relating to test, calibration, or inspection to assure that the necessary quality of systems and components is maintained and that the limiting conditions for operation will be met.

(4) *Design elements*. Design elements to be included are those elements of the plant such as materials of construction and geometric arrangements, which, if altered or modified, would have a significant effect on the capability of the commercial nuclear plant to prevent exceeding the safety criteria of § 53.210 and are not covered in categories described in paragraphs (a)(1) through (3) of this section.

(5) *Administrative Controls*. Administrative controls are the provisions relating to organization and management, procedures, recordkeeping, review and audit, and reporting necessary to assure operation of the plant in a safe manner. Administrative controls for commercial nuclear plants subject to §§ 53.800 through 53.820 must address the requirements of § 53.805. Each licensee must submit any reports to the Commission pursuant to approved technical specifications under § 53.040.

(b) Controls on plant operations, including availability controls, must be developed and implemented to ensure that the configurations and special treatments for NSRSS SSCs provide the capabilities, availability, and reliability required to demonstrate compliance with the criteria of §§ 53.220 and 53.450(e). The controls must—

(1)(i) Identify who within the commercial nuclear plant has authority to make configuration changes;

(ii) Establish processes to make configuration changes to NSRSS SSCs; and

(iii) Establish processes to ensure that all departments of the staff of the commercial nuclear plant affected by the configuration changes are formally notified and approve of the change.

(2) Describe how the special treatments for each NSRSS SSC will be established and maintained over the operating life of the commercial nuclear plant.

§ 53.715 Maintenance, repair, and inspection programs.

(a) Each holder of a license to operate a commercial nuclear plant under this part must develop, implement, and maintain a program to control maintenance activities and monitor the performance or condition of safety-related (SR) and non-safety-related but safety-significant (NSRSS) structures, systems, and components (SSCs) to ensure that the safety criteria defined in §§ 53.210 and 53.220 will be met.

(b) Whenever a licensee determines through activities related to maintenance, repair, and inspection of SSCs, the activities under § 53.710, or otherwise that the performance or condition of an NSRSS SSC does not demonstrate compliance with established special treatments or performance goals related to capabilities, availability, or reliability, the licensee must take appropriate corrective action.

(c) Performance and condition monitoring activities and associated goals and preventive maintenance activities must be evaluated at least every 24 months. The evaluations must take into account, where practical, industry-wide operating experience. Adjustments must be made where necessary to ensure that the objective of preventing failures of SSCs through maintenance is appropriately balanced against the objective of minimizing unavailability of SSCs due to monitoring or preventive maintenance.

(d) Before performing maintenance activities (including but not limited to surveillance, post-maintenance testing, and corrective and preventive maintenance), the licensee must assess and manage the increase in risk that may result from the proposed

maintenance activities. The scope of the assessment may be limited to SSCs that a risk-informed evaluation process determines are necessary to ensure that the criteria defined in §§ 53.210, 53.220, and 53.450(e) will be met.

§ 53.720 Response to seismic events.

If vibratory ground motion exceeding that of the operating basis earthquake Ground Motion determined under § 53.480 or significant plant damage due to vibratory ground motion occurs at a commercial nuclear plant, the licensee must shut down the plant. If structures, systems, or components necessary for the safe shutdown of the plant are not available after the occurrence of this vibratory ground motion, the licensee must consult with the Commission and must propose a plan for the timely, safe shutdown of the plant. Prior to resuming operations, the licensee must demonstrate to the Commission that those features necessary for continued operation without undue risk to the health and safety of the public or necessary to maintain the licensing basis of the plant were either not functionally damaged or have been repaired.

§ 53.725 General staffing, training, personnel qualifications, and human factors requirements.

(a) *Two classes of commercial nuclear plants.* Commercial nuclear plants licensed under this part are either of the class, based upon the similarity of operating and technical characteristics of the plants in the class, of self-reliant-mitigation facilities or of interaction-dependent-mitigation facilities. A commercial nuclear plant is a self-reliant-mitigation facility if the NRC determined as part of its approval of the operating license (OL) or combined license (COL) for that plant that its design demonstrates compliance with the criteria of either § 53.800(a)(1) through (a)(4). Otherwise, the commercial nuclear plant is an interaction-dependent-mitigation facility.

(b) *Purpose and applicability*. The regulations in §§ 53.725 through 53.830 address areas related to staffing, training, personnel qualifications, and human factors engineering for applicants for or holders of OLs or COLs under this part. These regulations are organized as follows:

(1) Sections 53.725 through 53.745 address general requirements for staffing, training, personnel qualifications, and human factors engineering. The regulations within these sections are applicable to all applicants for or holders of OLs or COLs under this part, except where specifically stated otherwise.

(2) Sections 53.760 through 53.780 address operator and senior operator licensing requirements. The regulations within these sections are applicable to those applicants for or holders of OLs or COLs under this part for interaction-dependent-mitigation facilities that have not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070.

(3) Sections 53.800 through 53.820 address generally licensed reactor operator requirements. The regulations within these sections are in lieu of §§ 53.760 through 53.780 for by those applicants for or holders of OLs or COLs under this part for self-reliant-mitigation facilities that have not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070.

(4) Section 53.830 provides general personnel training requirements. The regulations within this section are applicable to all applicants for or holders of OLs or COLs under this part.

(c) *Definitions*.. As used in §§ 53.725 through 53.830—

Automation means a device or system that accomplishes (partially or fully) a function or task.

Auxiliary operator means any individual who operates components of a commercial nuclear plant but does not manipulate controls or direct the manipulation of controls of the plant and is not required to be licensed under the provisions of this part.

Controls when used with respect to a nuclear reactor means apparatus and mechanisms, the manipulation of which directly affects the reactivity or power level of the reactor.

Operator means any individual licensed under the provisions of §§ 53.760 through 53.780 to manipulate controls of an interaction-dependent-mitigation facility.

Performance testing means testing conducted to verify a simulation facility's performance as compared to actual or predicted reference plant performance.

Senior operator means any individual licensed under the provisions of §§ 53.760 through 53.780 to manipulate controls of an interaction-dependent-mitigation facility and to direct the licensed activities of operators.

(d) Scope. The regulations in §§ 53.725 through 53.830 apply to:

(1) Any individual who manipulates the controls of any commercial nuclear plant licensed under this part,

(2) Any individual designated to be responsible for directing any licensed activity of a senior operator, operator, or generally licensed reactor operator by the holder of a license to operate a commercial nuclear plant under this part.

(c) Any operating license or combined license issued under this part.

§ 53.726 Communications.

Each licensee that is required to comply with the requirements of §§ 53.760 through 53.780 (i.e., interaction-dependent-mitigation facilities) must notify the

appropriate NRC contact within 30 days of the following in regard to a licensed operator or senior operator:

(1) Permanent reassignment from the position for which the licensee has certified the need for a licensed operator or senior operator under § 55.31(a)(3) of this chapter;

(2) Termination of any operator or senior operator; or

(3) Permanent disability or illness as required under § 55.25 of this chapter.

§ 53.730 Defining, fulfilling, and maintaining the role of personnel in ensuring safe operations.

Each applicant for or holder of an OL or COL for a commercial nuclear plant under this part must comply with the following:

(a) [Reserved].

(b) [Reserved].

(c) *Concept of operations.* A concept of operations that is of sufficient scope and detail to address the following must be provided:

(1) Plant goals;

(2) The roles and responsibilities of operating personnel and automation (or any combination thereof) that are responsible for completing plant functions;

(3) Staffing, qualifications, and training;

(4) The management of normal operations;

(5) The management of off-normal conditions and emergencies;

(6) The management of maintenance and modifications; and

(7) The management of tests, inspections, and surveillances.

(d) *Functional requirements analysis and function allocation*. A functional requirements analysis and a function allocation must be provided that are sufficient to demonstrate compliance with the following:

(1) The functional requirements analysis must address how safety functions and functional safety criteria are satisfied, and

(2) The function allocation must describe how the safety functions will be assigned to human action, automation, active safety features, passive safety features, and/or inherent safety characteristics.

(e) *Operating experience*. A program, during construction and during operation, as applicable, for evaluating and applying operating experience must be developed, implemented, and maintained.

(f) *Staffing plan.* A staffing plan must be developed, implemented and maintained until such time as the permanent cessation of operations and permanent removal of fuel from the reactor vessel has been certified as described under § 53.1070. The staffing plan is subject to the requirements of § 53.1565and the following:

(1) The staffing plan must include a description of how engineering expertise will be available to the on-shift operating personnel during all plant conditions, to assist if they encounter a situation not covered by procedures or training. Engineering expertise includes familiarity with the operation of the plant for which the expertise is provided and one of the following:

(i) A bachelor’s degree in engineering, engineering technology, or physical science from an institution accredited by a U.S. Government recognized accrediting body or equivalent; or

(ii) A Professional Engineer’s license from a U.S. State or territory.

(2) Applicants for or holders of OLs or COLs for interaction-dependent-mitigation facilities must include within their staffing plans a description of how the proposed numbers, positions, and qualifications of operators and senior operators across all modes of plant operations will be sufficient to ensure that plant safety functions will be

maintained. This description must be supported by human factors engineering analyses and assessments.

(3) Applicants for or holders of OLs or COLs for self-reliant-mitigation facilities must include within their staffing plans a description of how generally licensed reactor operator staffing that is both sufficient to continually monitor the operations of fueled reactors and to provide for a continuity of responsibility for facility operations at all times during the operating phase will be maintained.

(4) Applicants for or holders of OLs or COLs under this part must include within their staffing plans a description of how the numbers, positions, and responsibilities of personnel contained within those plans will adequately support all necessary functions within areas such as plant operations, equipment surveillance and maintenance, radiological protection, chemistry control, fire brigades, engineering, security, and emergency response.

(5) The staffing plan must be approved by the NRC as part of its approval of the OL or COL for the plant. The approved staffing plan is subject to the requirements of § 53.1565applicable.

(g) *Training, examination, and proficiency programs*. Develop, implement, and maintain programs that comply with the following requirements. These programs must be approved by the NRC as part of its approval of the OL or COL for the plant:

(1) For those applicants for or holders of OLs or COLs for interaction-dependent-mitigation facilities:

(i) The operator licensing initial training program required under § 53.780(a);

(ii) The operator licensing initial examination program required under § 53.780(b);

(iii) The operator licensing requalification program required under § 53.780(c); and

(iv) The operator proficiency program required under § 53.780(g).

(2) For those applicants for or holders of OLs or COLs for self-reliant-mitigation facilities, the generally licensed reactor operator training, examination, and proficiency programs required under § 53.815.

(3) The operator licensing requalification programs required under § 53.780(c) or § 53.815(b) must be implemented upon commencing the administration of initial examinations under the operator licensing examination program required under § 53.780(b) or § 53.815(b), respectively.

§ 53.735 General exemptions.

The regulations in §§ 53.725 through 53.830 do not require a license for an individual who –

(a) Under the direction and in the presence of an operator or senior operator or a generally licensed reactor operator, as appropriate, manipulates the controls of a commercial nuclear plant as a part of the individual's training in the training program for the commercial nuclear plant as approved by the Commission to qualify for an operator or senior operator license or a generally licensed reactor operator license there, as appropriate, under these regulations; or

(b) Under the direction and in the presence of a senior operator or generally licensed reactor operator, as appropriate, manipulates the controls of a commercial nuclear plant to load or unload the fuel into, out of, or within the reactor vessel while the reactor is not operating.

§ 53.740 Conditions on Operating and Combined Licenses.

(a) [Reserved].

(b) [Reserved].

(c) Except as provided under § 53.735, the holder of a license to operate a commercial nuclear plant may not permit the manipulation of the controls of the plant by anyone who is not an operator or senior operator or generally licensed reactor operator at that plant, as appropriate.

(d) Holders of licenses for interaction-dependent-mitigation facilities that have not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070 must designate senior operators to be responsible for supervising the licensed activities of operators.

(e) Apparatus and mechanisms other than controls, the operation of which may affect the reactivity or power level of a reactor, must be manipulated only while plant conditions are being monitored by an individual who is an operator or senior operator or a generally licensed reactor operator, as appropriate.

(f)(1) Load following is permitted if—

(i) The actuation of an automatic protection system provided under 53.440(o) is operable; or

(ii) An operator or senior operator or a generally licensed reactor operator, as appropriate, is immediately capable of refusing demands that could challenge the safe operation of the plant or are otherwise precluded by the plant equipment conditions.

(2) The provisions of paragraph (e) of this section do not apply to the externally generated instructions or signals during load following operations.

(g) Holders of licenses allowing the operation of commercial nuclear plants must have present during alteration of the core (including fuel loading or transfer) a senior operator or a senior operator with a license limited to fuel handling or a generally licensed reactor operator to directly supervise the activity. The individual supervising the alteration of the core must not be assigned other duties. The provisions of this paragraph

do not apply to core alterations performed as part of refueling operations while a facility that is capable of online refueling is operating at power.

(h) A licensee may take reasonable action that departs from a license condition or a technical specification (contained in a license issued under this part) in an emergency when this action is immediately needed to protect the public health and safety and no action consistent with license conditions and technical specifications that can provide adequate or equivalent protection is immediately apparent. Such licensee action must be approved, as a minimum, by a senior operator or a generally licensed reactor operator, as applicable, or, at a commercial nuclear plant for which the certifications of permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070 have been submitted, by a certified fuel handler, senior operator, or generally licensed reactor operator, as applicable, prior to taking the action.

§ 53.745 Operator license requirements.

A person must be authorized by a license issued by the Commission to perform the function of an operator, senior operator, or generally licensed reactor operator as defined in this part.

§ 53.760 Operator licensing for interaction-dependent mitigation facilities.

(a) *Applicability*. Part 55 of this chapter addresses operator and senior operator licensing requirements for interaction-dependent mitigation facilities.

(b) The Commission and licensees of interaction-dependent mitigation facilities will use the training, examination, and proficiency programs developed under §§ 53.730(g) and 53.780 in lieu of those specified in part 55.

§ 53.780 Training, examination, and proficiency program.

(a) *Operator licensing initial training program*. (1) A program that is based upon a systems approach to training, as defined by § 53.020, may be utilized to provide applicants for operator and senior operator licenses with the knowledge, skills, and abilities necessary to protect the public health and maintain those plant safety functions specific to the facility design. The program must be approved by the Commission prior to its use for training applicants, as described under § 53.730(g). The approved operator licensing initial training program is subject to the requirements of § 53.1565.

(2) The operator licensing initial training program documentation must include the following:

(i) The holder of the operating license or combined license must maintain records documenting the initial operator licensing training administered and completed by each applicant. The holder of the operating license or combined license must retain these records during the period in which any trainees subsequently remain licensed as operators or senior operators at the facility.

(ii) [Reserved].

(b) *Operator licensing initial examination program*. (1) The holder of the operating license or combined license must establish and implement an examination program for testing a representative sample of the knowledge, skills, and abilities needed to safely perform operator and senior operator duties, as appropriate, to include both the examination methods and criteria to be used to assess passing performance. The program must provide for valid and reliable examinations and be approved by the Commission prior to its use for examining applicants, as described under § 53.730(g). The approved operator licensing initial examination program is subject to the requirements of § 53.1565.

(2) The holder of the operating license or combined license must submit prepared examinations to the Commission for review and approval in advance of their administration.

(3) The Commission will either administer an approved examination or allow the holder of the operating license or combined license to administer the examination. The holder of the operating license or combined license must ensure that sufficient advance notification is provided to the Commission to either administer the examination or allow for a representative of the Commission to be afforded the opportunity to be present when the holder of the operating license or combined license administers the examination.

(4) Graded examination documentation for each applicant must be promptly provided to the Commission for review in making operator licensing decisions.

(5) The operator licensing initial examination program documentation must include the following:

(i) The holder of the operating license or combined license must maintain records documenting the participation of each operator and senior operator applicant in a non-NRC-administered initial examination. The records must contain copies of examinations administered, the answers given by the applicant, documentation of the grading of examinations, and documentation of any additional training administered in areas in which an applicant exhibited deficiencies. The holder of the operating license or combined license must retain these records during the period in which the associated operators or senior operators remain licensed at the facility.

(ii) [Reserved].

(c) *Operator licensing requalification program.* (1) A program based upon a systems approach to training, as defined by § 53.020, must be utilized for the continuing training of operators and senior operators.

(i) The program must enable operators and senior operators at the facility to maintain the knowledge, skills, and abilities necessary to protect the public health and maintain those plant safety functions specific to the facility design. The program must be conducted for a continuous period not to exceed two years in duration.

(ii) The program must be approved by the Commission prior to its use for continuing training, as described under § 53.730(g). The approved operator licensing requalification program is subject to the requirements of § 53.1565.

(2) The following requirements apply to operator licensing requalification programs:

(i) The holder of the operating license or combined license must propose a requalification examination program for testing, for each requalification period, a sample of the topics included under the systems approach to training, to include both the examination methods and criteria to be used to assess passing performance. The program must provide for valid and reliable examinations and be approved by the Commission prior to its use for examining operators and senior operators, as described under § 53.730(g). The approved requalification examination program is subject to the requirements of § 53.1565.

(ii) The following requirements apply to the requalification examination program:

(A) The holder of the operating license or combined license must make prepared requalification examinations available to the Commission for review.

(B) The holder of the operating license or combined license must ensure that a representative of the Commission is afforded the opportunity to be present during requalification examination administration.

(C) The holder of the operating license or combined license must ensure that each operator and senior operator is administered a complete requalification examination on a periodicity not to exceed 24 months. Additionally, the holder of the operating license or combined license must ensure that any operator or senior operator who either demonstrates unsatisfactory performance on, or fails to complete, the biennial requalification examination is removed from the performance of operator and senior operator duties until such time that any necessary remedial training has been completed and a retake examination has been passed.

(D) The holder of the operating license or combined license must promptly provide a summary of examination results for each operator and senior operator following the completion of the requalification examination.

(3) The holder of the operating license or combined license must maintain records documenting the participation of each operator and senior operator in the requalification program. The records must contain copies of examinations administered, the answers given by the operator or senior operator, documentation of the grading of examinations, and documentation of any additional training administered in areas in which an operator or senior operator exhibited deficiencies. The holder of the operating license or combined license must retain these records until the operator's or senior operator's license is renewed.

(d) *Examination integrity*. Applicants, operators and senior operators, and holders of operating licenses or combined licenses must not engage in any activity that compromises the integrity of any application or examination required by §§ 53.760

through 53.780. The integrity of an examination is considered compromised if any activity, regardless of intent, affected, or, but for detection, could have affected the equitable and consistent administration of the examination. This includes activities related to the preparation and certification of applications and all activities related to the preparation, administration, and grading of examinations required by §§ 53.760 through 53.780.

(e) *Simulation facilities.* (1) This section addresses the use of a simulation facility for the administration of examinations, for training, or to demonstrate compliance with experience requirements for applicants for operator and senior operator licenses.

(2) Simulation facilities used for training purposes, for demonstrating compliance with experience requirements, or for the conduct of examinations under § 53.780(b) and (c) must demonstrate compliance with the following criteria as they relate to the reference plant:

(i) The simulation facility must be of sufficient scope and fidelity for individuals to acquire and demonstrate the necessary knowledge, skills, and abilities to safely perform operator and senior operator duties.

(ii) The simulation facility must utilize models relating to nuclear, thermal-hydraulic, and other applicable design-specific characteristics that either replicate the most recent fuel load in the reference plant or, prior to initial fuel load, replicate the intended initial fuel load for the reference plant, with the exception of those portions of the simulation facility that utilize the reference plant itself.

(iii) Simulation facility fidelity must be demonstrated so that significant control manipulations are completed without procedural exceptions, simulator performance exceptions, or deviation from the approved training scenario sequence.

(3) Holders of operating licenses or combined licenses that maintain a simulation facility that has been approved by the Commission for training purposes, demonstrating compliance with experience requirements, or the conduct of examinations under § 53.780(b) and (c) for the reference plant must:

(i) Conduct performance testing throughout the life of the simulation facility in a manner sufficient to ensure that paragraph (e)(2) of this section is met;

(ii) Retain the results of performance testing for 4 years after the completion of each performance test or until superseded by updated test results;

(iii) Promptly correct modeling and hardware discrepancies and discrepancies identified from scenario validation and from performance testing or provide justification as to why the presence of such discrepancies will not adversely affect simulator performance with respect to the criteria of paragraph (e)(2) of this section;

(iv) Make the results of any uncorrected performance test failures that may exist at the time of the initial license examination or requalification examination available for NRC review, prior to or concurrent with preparations for each initial license examination or requalification examination; and

(v) Maintain the provisions for license application and examination integrity consistent with § 53.780(d).

(4) A simulation facility must demonstrate compliance with the requirements of paragraphs (e)(2) and (e)(3) of this section for the Commission to accept the simulation facility for conducting initial examinations as described in § 53.780(b), requalification training as described in § 53.780(c), or performing control manipulations that affect reactivity to establish eligibility for an operator or senior operator license as described in § 53.775(a).

(f) *Waiver of examination requirement.* On application, the Commission may waive any or all of the requirements for an examination if it finds that the applicant has demonstrated the required knowledge, skills, and abilities to safely operate the plant, and is capable of continuing to do so. The Commission may make such a finding based on demonstration of the following:

(1) The applicant's actual operating experience at a comparable facility;

(2) The applicant's past competent and safe performance; and

(3) The applicant's current qualifications.

(g) *Proficiency.* The holder of an operating license or combined license must develop, implement, and maintain a proficiency program to ensure that operators and senior operators who actively perform the functions of an operator or senior operator, respectively, maintain proficiency with on-shift duties and familiarity with plant status. This program must include those steps to be taken by an operator or senior operator prior to performing the functions of an operator or senior operator to re-establish proficiency when proficiency cannot be maintained. This program must be approved by the Commission as part of its approval of the OL or COL for the plant. The approved proficiency program is subject to the requirements of § 53.1565.

(h) *Records*. Each record required by this section must be legible throughout the retention period specified by each Commission regulation. The record may be the original, a reproduced copy, or an electronic copy provided that the copy is authenticated by authorized personnel.

§ 53.800 Self-reliant-mitigation facilities.

(a) A commercial nuclear plant is a self-reliant-mitigation facility if the NRC determined as part of its approval of the OL or COL for that plant that its design demonstrates compliance with criteria (a)(1) though (a)(4) of this section. A self-reliant-

mitigation facility is of a class, based upon the similarity of operating and technical characteristics of the plants in the class, such that its licensee must comply with the requirements of §§ 53.800 through 53.820 in lieu of those in §§ 53.760 through 53.780.

(1) The results of the risk evaluation under § 53.450 must demonstrate that the evaluation criteria in §§ 53.210 and 53.220 will be met without reliance on human actions to achieve acceptable event mitigation.

(2) The functional requirements analysis and function allocation performed under § 53.730(d) must demonstrate that functions required for safety are not reliant upon credited human action.

(3) The plant response to events analyzed under § 53.450 in must rely exclusively on safety features and characteristics that will neither be rendered unavailable by credible human errors of commission or omission nor credibly require manual human operation in response to equipment failures. Compliance with this paragraph may be achieved through the use of structures, systems, and components that function through inherent characteristics or that have engineered protections against human failures.

(4) The plant design must provide for a layered defense-in-depth approach that is not dependent upon any single barrier or credited human action.

(b) [Reserved]

§ 53.805 Conditions of licenses for commercial nuclear plants related to generally licensed reactor operators.

(a) Holders of operating licenses or combined licenses for self-reliant-mitigation facilities that have not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070 must—

(1) Ensure that, in addition to being qualified to perform those items identified by the facility-specific systems approach to training conducted under § 53.815, generally licensed reactor operators are qualified to safely and competently—

(i) Perform administrative tasks, including compliance with technical specifications, and perform operability determinations;

(ii) Implement maintenance and configuration controls;

(iii) Comply with radioactive release limitations;

(iv) Understand plant operating data, including reactor parameters, and evaluate emergency conditions;

(v) Initiate a reactor shutdown from necessary locations;

(vi) Dispatch and direct operations and maintenance personnel;

(vii) Implement any applicable responsibilities under the facility emergency plan; and

(viii) Make required notifications to local, State, participating Tribal and Federal authorities.

(2) [Reserved]

(3) Develop, implement, and maintain the generally licensed reactor operator training, examination, and proficiency programs required under § 53.815.

(4) Ensure that generally licensed reactor operators are subject to the facility's generally licensed reactor operator training, examination, and proficiency programs required under § 53.815. Ensure that generally licensed reactor operators are subject to and comply with the applicable programmatic requirements for plant personnel required under 10 CFR parts 26 and 73. An individual that is not in compliance with any of these programs is not qualified to be in a position that may involve the manipulation of the controls of the commercial nuclear plant.

(5) Report annually to the NRC the identity of all generally licensed reactor operators at the commercial nuclear plant, including all additions and deletions since the previous report.

(6) Ensure that the commercial nuclear plant continues to meet the criteria of § 53.800.

(b) [Reserved]

§ 53.810 Generally licensed reactor operators.

(a) A general license to manipulate the controls of a self-reliant-mitigation facility and to direct the licensed activities of generally licensed reactor operators is hereby issued to any individual employed in a position that may involve the manipulation of the controls of that self-reliant-mitigation facility and who observes the restrictions of this section.

(b) A generally licensed reactor operator must comply with the operating procedures and other conditions specified in the license authorizing operation of the facility.

(c) The general license is limited to the commercial nuclear plant(s) at which the operator is employed.

(d) The Commission may require information from a generally licensed reactor operator to determine whether a general license should be revoked or suspended with respect to that operator.

(e) The generally licensed reactor operator must not consume or ingest alcoholic beverages within the protected area of commercial nuclear plants, or power reactors, or the controlled access area on non-power utilization facilities. The generally licensed reactor operator must not use, possess, or sell any illegal drugs. The generally licensed reactor operator must not perform activities requiring a general license while under the

influence of alcohol or any prescription, over-the-counter, or illegal substance that could adversely affect his or her ability to safely and competently perform these activities. For the purpose of this paragraph, with respect to alcoholic beverages and drugs, the term "under the influence" means the generally licensed reactor operator exceeded, as evidenced by a confirmed test result, the lower of the cutoff levels for drugs, drug metabolites, or alcohol contained in 10 CFR part 26, or as established by the holder of the operating license or combined license. The term "under the influence" also means the generally licensed reactor operator could be mentally or physically impaired as a result of substance use including prescription and over-the-counter drugs, as determined under the provisions, policies, and procedures established by the holder of the operating license or combined license for its fitness for duty program, in such a manner as to adversely affect his or her ability to safely and competently perform generally licensed reactor operator duties.

(f) The Commission will suspend the general license on an individual basis for violations of any provision of the Act or any rule or regulation issued thereunder whenever the Commission deems such suspension desirable, including—

(1) For willful violation of, or failure to observe, any of the terms and conditions of the Act or the general license, or of any rule, regulation, or order of the Commission;

(2) For any conduct determined by the Commission to be a hazard to safe operation of the commercial nuclear plant; or

(3) For the sale, use, or possession of illegal drugs, or refusal to participate in the facility drug and alcohol testing program, or a confirmed positive test for drugs, drug metabolites, or alcohol in violation of the conditions and cutoff levels established by § 53.810(f) or the consumption of alcoholic beverages within the protected area of commercial nuclear plants, or power reactors, or the controlled access area on non-

power utilization facilities, or a determination of unfitness for scheduled work as a result of the consumption of alcoholic beverages

(g) The generally licensed reactor operator must notify the Commission within 30 days about a conviction for a felony.

§ 53.815 Generally licensed reactor operator training, examination, and proficiency programs.

(a) *Applicability*. The requirements of this section apply to each holder of an operating license or combined license for a self-reliant-mitigation facility that has not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070 or § 53.4670, as applicable.

(b) *Requirements*. (1) The licensee must develop, implement, and maintain training and examination programs that demonstrate compliance with the requirements of paragraphs (b)(2) through (b)(3) of this section.

(2) The training program must provide for both the initial and continuing training of generally licensed reactor operators and be derived from a systems approach to training as defined in this part.

(3)(i) The training program must incorporate the instructional requirements necessary to provide qualified generally licensed reactor operators to operate and maintain the facility in a safe manner in all modes of operation. The training program must comply with the license for the commercial nuclear plant, including all technical specifications and applicable regulations. The holder of the operating license or combined license must periodically evaluate and revise the training program as appropriate to reflect industry experience and relevant changes, including changes to the commercial nuclear plant, procedures, regulations, and QA requirements. The holder

of the operating license or combined license must periodically review the training program for effectiveness.

(ii) The training program must enable the generally licensed reactor operators to acquire and maintain the necessary knowledge, skills, and abilities.

(iii) The training program must include the generally licensed reactor operator manipulating the controls of either the commercial nuclear plant or a simulation facility that demonstrates compliance with the requirements of § 53.815(e).

(iv) The training program must include an initial examination program for testing a representative sample of the knowledge, skills, and abilities needed to safely perform generally licensed reactor operator duties, to include both the examination methods and criteria to be used to assess passing performance. The holder of the operating license or combined license must provide the opportunity for a representative of the Commission to be present during initial examination administration.

(v) The training program must include a requalification examination program for testing a sample of the topics included under the systems approach to training, to include the examination methods and criteria to be used to assess passing performance. The requalification examination program must specify an appropriate periodicity for administering a complete requalification examination to each generally licensed reactor operator, and the holder of the operating license or combined license must provide the opportunity for a representative of the Commission to be present during requalification examination administration.

(A) The holder of the operating license or combined license must ensure that any generally licensed reactor operator who either demonstrates unsatisfactory performance on, or fails to complete, the requalification examination is removed from the performance

of generally licensed reactor operator duties until such time that any necessary remedial training has been completed and a retake examination has been passed.

(B) [Reserved]

(vi) The training program must be approved by the Commission prior to its use, as described under § 53.730(g). The examination program must provide for valid and reliable examinations and must be approved by the Commission prior to its use, as described under § 53.730(g). The approved programs are subject to the requirements of § 53.1565.

(c) *Records.* The following is required regarding the documentation of the generally licensed reactor operator training and examination programs:

(1) Sufficient records must be maintained by the holder of the operating license or combined license to maintain the integrity of the programs and kept available for NRC inspection to verify the adequacy of the programs.

(2) The holder of the operating license or combined license must maintain records documenting the participation of each generally licensed reactor operator in the training and examination programs. The records must contain copies of examinations administered, the answers given by the generally licensed reactor operator, documentation of the grading of examinations, and documentation of any additional training administered in areas in which a generally licensed reactor operator exhibited deficiencies. The holder of the operating license or combined license must retain these records while the associated generally licensed reactor operators remain employed at the facility.

(3) Each record required by this part must be legible throughout the retention period. The record may be the original, a reproduced copy, or an electronic copy provided that the copy is authenticated by authorized personnel.

(d) *Examination integrity.* Generally licensed reactor operators and holders of operating licenses and combined licenses must not engage in any activity that compromises the integrity of any examination conducted under the generally licensed reactor operator training and examination programs. The integrity of an examination is considered compromised if any activity, regardless of intent, affected, or, but for detection, could have affected the equitable and consistent administration of the examination. This includes all activities related to the preparation, administration, and grading of examinations.

(e) *Simulation facilities.* (1) Simulation facilities used for training purposes, for maintaining proficiency, or for the conduct of examinations must demonstrate compliance with the following criteria as they relate to the reference plant:

(i) The simulation facility must be of sufficient scope and fidelity for individuals to acquire and demonstrate the necessary knowledge, skills, and abilities to safely perform generally licensed reactor operator duties.

(ii) The simulation facility must utilize models relating to nuclear, thermal-hydraulic, and other applicable design-specific characteristics that either replicate the most recent fuel load in the reference plant or, prior to initial fuel load, replicate the intended initial fuel load for the reference plant, with the exception of those portions of the simulation facility that utilize the reference plant itself.

(iii) Simulator fidelity must be demonstrated so that significant control manipulations are completed without procedural exceptions, simulator performance exceptions, or deviation from the approved training scenario sequence.

(2) Holders of operating licenses and combined licenses that maintain a simulation facility for training purposes, for maintaining proficiency, or for the conduct of examinations must—

(i) Conduct performance testing throughout the life of the simulation facility in a manner sufficient to ensure that paragraph (e)(1) of this section is met;

(ii) Retain the results of performance testing for 4 years after the completion of each performance test or until superseded by updated test results;

(iii) Promptly correct modeling and hardware discrepancies and discrepancies identified from scenario validation and from performance testing or provide justification for why the presence of such discrepancies will not adversely affect the criteria of paragraph (e)(1) of this section;

(iv) Make the results of any uncorrected performance test failures that may exist at the time of an inspection available for NRC review; and

(v) Maintain the provisions for examination integrity consistent with § 53.815(d).

(f) *Waiver of examination requirement*. The holder of an operating license or combined license may waive any or all of the requirements for an examination in accordance with the facility licensee's Commission-approved generally licensed reactor operator training and examination programs.

(g) *Proficiency.* The holder of the operating license or combined license must develop, implement, and maintain a proficiency program to allow that generally licensed reactor operators to maintain proficiency regarding position functions and familiarity with plant status. This program must include those steps that will be taken in order to re-establish proficiency when it cannot be maintained.

§ 53.820 Cessation of individual applicability.

The general license ceases to be applicable on an individual basis once a generally licensed reactor operator is no longer being employed in a position that may involve the manipulation of the controls of the self-reliant mitigation facility.

§ 53.830 Training and qualification of commercial nuclear plant personnel.

(a) This section addresses personnel training requirements. The regulations within this section are applicable to all applicants for or holders of OLs or COLs under this part.

(b) Prior to fuel load, each holder of an operating or COL under this part must, with sufficient time to provide trained and qualified personnel to operate the commercial nuclear plant, establish, implement, and maintain a training program that demonstrates compliance with the requirements of paragraphs (c) and (d) of this section.

(c) The training program must be derived from a systems approach to training as defined in this part and must provide, at a minimum, for the training and qualification of the following categories of commercial nuclear plant personnel:

(1) Supervisors (e.g., shift supervisors);

(2) Technicians (e.g., maintenance, chemistry, and radiological); and

(3) Other appropriate operating personnel (e.g., auxiliary operators, certified fuel handlers, and individuals who provide engineering expertise to on-shift operating personnel).

(d) The training program must incorporate the instructional requirements necessary to provide qualified personnel to operate components of a commercial nuclear plant and maintain the commercial nuclear plant in a safe manner in all modes of operation. The training program must be developed to be in compliance with the facility license, including all technical specifications and applicable regulations.

(1) The training program must be periodically evaluated and revised as appropriate to reflect industry experience and relevant changes, including changes to the commercial nuclear plant, procedures, regulations, and QA requirements. The training program must be periodically reviewed for effectiveness.

(2) Sufficient records must be maintained by the holder of the operating license or combined license to maintain program integrity and kept available for NRC inspection to verify the adequacy of the training program.

§ 53.845 Programs.

(a) The required plant programs under this part include the programs described in the following sections of this subpart. Licensees may combine, separate, and otherwise organize programs and related documents as appropriate for the technologies and organizations associated with the commercial nuclear plant.

(b) [Reserved].

§ 53.850 Radiation protection.

Each holder of an operating license or combined license under this part must develop, implement, and maintain a program for the control of radioactive effluents and for keeping the doses to members of the public from radioactive effluents as low as is reasonably achievable. The program must be implemented by procedures and must include remedial actions to be taken whenever the program limits are exceeded.

§ 53.855 Emergency preparedness.

Each holder of an operating license or combined license under this part must have an emergency response plan under appendix E to 10 CFR part 50 and § 50.47 of this chapter.

§ 53.860 Security and fitness for duty programs.

(a) *Physical protection program.* Each holder of an operating license (OL) or combined license (COL) under this part must have a physical protection program under the following requirements:

(1) The licensee must implement security requirements for the protection of SNM based on the type, enrichment, and quantity in accordance with 10 CFR part 73,

as applicable, and implement security requirements for the protection of Category 1 and Category 2 quantities of radioactive material in accordance with 10 CFR part 37, as applicable; and

(2) The licensee must develop, implement, and maintain a physical protection program for SNM based on the type, enrichment, and quantity under either § 73.55 or § 73.100 of this chapter, unless the licensee performs a site-specific analysis, including identification of target sets, to show that the need for physical protection of SNM is met through design and engineered safety features under § 53.440(f) of this part by demonstrating that the radiological consequences from a design basis threat initiated event involving the loss of engineered systems for decay heat removal and possible breaches in physical structures surrounding the reactor, spent fuel, and other inventories of radioactive materials result in offsite doses below the values in § 53.210. The analysis must assume that licensee mitigation and recovery actions, including any operator actions, are unavailable or ineffective. The licensee must maintain the analysis until the permanent cessation of operations and permanent removal of fuel from the reactor vessel is certified as described under § 53.1070.

(b) *Fitness for duty*. Each holder of an OL or COL under this part must develop, implement, and maintain a fitness for duty program under 10 CFR part 26.

(c) *Access authorization*. Each holder of an OL or COL under this part must develop, implement, and maintain an access authorization program under § 73.120 of this chapter if the criterion in § 53.860(a)(2) is satisfied, or the requirements in § 73.56 of this chapter if the criterion is not satisfied.

(d) *Cyber security*. Each holder of an OL or COL under this part must develop, implement, and maintain a cyber security program under § 73.54 or § 73.110 of this chapter.

(e) *Information security*. Each holder of an OL or COL under this part must develop, implement, and maintain an information protection system under §§ 73.21, 73.22, and 73.23 of this chapter, as applicable.

§ 53.865 Quality assurance.

Each holder of an operating license or combined license under this part must develop, implement, and maintain a quality assurance program (QAP) under appendix B to part 50 of this chapter.

§ 53.875 Fire protection.

(a)(1) Each holder of an operating license (OL) or combined license (COL) under this part must have a fire protection plan that describes the overall fire protection program for the facility; identifies the various positions within the licensee's organization that are responsible for the program; states the authorities that are delegated to each of these positions to implement those responsibilities; and outlines the plans for fire protection, fire detection and suppression capability; and limitation of fire damage.

(2) The fire protection plan must also describe specific features necessary to implement the program described in paragraph (a)(1) of this section such as the following: administrative controls and personnel requirements for fire prevention and manual fire suppression activities; automatic and manually operated fire detection and suppression systems; and the means to limit fire damage to structures, systems, and components (SSCs) so that the capability to demonstrate compliance with the requirements of § 53.210 is ensured.

(b) Each holder of an OL or COL under this part must develop a performance-based or deterministic fire protection program that demonstrates compliance with the safety criteria outlined in §§ 53.210 and 53.220, related safety functions outlined in

§ 53.230, and defense in depth as outlined in § 53.250 with specific fire protection measures related to fire prevention, fire detection, and fire suppression.

§ 53.880 Inservice inspection and inservice testing.

(a) Each holder of an OL or COL under this part must develop, implement, and maintain a program for inservice inspection (ISI) and inservice testing (IST). The ISI/IST program must be supplemented by risk insights that identify the most important SSCs to plant safety. The types of testing and inspections and their frequency should be informed by risk insights to maintain the reliability and performance of SSCs consistent with the associated design and analyses activities involving those SSCs. Risk insights must also be used to determine when to conduct the inspections and tests (e.g., full power, shutdown, refueling) to minimize risk to the plant workers and the public.

(b) Prior to plant operation, baseline inspections and testing must be performed using the same techniques as will be used for future inspections and testing. The results of these inspections and testing must be used as benchmarks for evaluating the results of future inspections and testing. Acceptance criteria for determining whether corrective action is needed must be developed for evaluating the results of the inspections and testing. The ISI/IST results and corrective actions must be documented and the documentation retained until certification by the licensee of permanent cessation of operation and removal of fuel from the reactor vessel under § 53.1070.

Subpart G — Decommissioning Requirements

§ 53.1000 Scope and purpose.

This subpart defines the requirements related to decommissioning for applicants for, or holders of, an operating license or combined license under this part.

§ 53.1010 Financial assurance for decommissioning.

(a) This section establishes requirements for indicating to the NRC how an applicant for or holder of an operating license (OL) or combined license (COL) under this part will provide reasonable assurance that funds will be available for the decommissioning process. Reasonable assurance consists of a series of steps as provided in paragraph (b) of this section and §§ 53.1020, 53.1030 and 53.1040. Funding for the decommissioning of commercial nuclear plants may also be subject to the regulation of Federal or State government agencies (e.g., Federal Energy Regulatory Commission (FERC) and State Public Utility Commissions (PUCs)) that have jurisdiction over rate regulation. The requirements of this subpart, in particular § 53.1020, are in addition to, and not a substitution for, other requirements, and are not intended to be used by themselves or by other agencies to establish rates.

(b) Each applicant for an OL or COL under this part must prepare a decommissioning report that documents how adequate funding will be available to decommission the facility.

(1) Before the Commission issues an OL under this part, the applicant must submit an updated the decommissioning report to certify that it has provided financial assurance for decommissioning in the amount proposed in the application and approved by the NRC under § 53.1020.

(2) The amount of financial assurance for decommissioning to be provided must be based on a site-specific cost estimate for decommissioning the facility under § 53.1020.

(3) The amount of financial assurance for decommissioning to be provided must be adjusted annually using a rate at least equal to that stated in § 53.1030.

(4) The amount of financial assurance for decommissioning to be provided must be covered by one or more of the methods described in § 53.1040 as acceptable to the NRC.

§ 53.1020 Cost estimates for decommissioning.

Cost estimates for decommissioning must be site-specific. Site-specific decommissioning cost estimates (DCEs) must account for the engineering, labor, equipment, transportation, disposal, and related charges needed to support termination of the license. They must include the costs for decontaminating structures, systems, and components and the site environs; removal of contaminated components and materials from the plant and the site environs; disposal of removed components and materials in appropriate facilities; and any other activities supporting the release of the property and termination of the license. They must also address the approach to annual adjustments required by § 53.1030. Finally, site-specific DCEs must include plans for adjusting levels of funds assured for decommissioning to demonstrate that a reasonable level of assurance will be provided that funds will be available when needed to cover the cost of decommissioning.

§ 53.1030 Annual adjustments to cost estimates for decommissioning.

Each applicant for or holder of an OL or COL under this part must annually adjust the cost estimate for decommissioning to account for escalation in costs. Applicants or licensees may elect to use either a site-specific adjustment factor that addresses the estimated contributions and escalation of costs of decommissioning or a generic adjustment factor equal to 0.65 L + 0.13 E + 0.22 B, where L and E are escalation factors for labor and energy, respectively, and are to be taken from regional data of U.S. Department of Labor Bureau of Labor Statistics and B is an escalation factor for waste burial and is to be taken from NRC report NUREG-1307, "Report on Waste Burial

Charges." The site-specific adjustment factor must be approved as part of the decommissioning report required by § 53.1010, and must be at least equal to the generic adjustment factor.

§ 53.1040 Methods for providing financial assurance for decommissioning.

Financial assurance for decommissioning is to be provided by the following methods.

(a) *Prepayment*. Prepayment is the deposit made preceding the start of operation or the transfer of a license under § 53.1570 into an account segregated from licensee assets and outside the administrative control of the applicant or licensee and its subsidiaries or affiliates of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, or Government fund with payment by certificate of deposit, deposit of government or other securities, or other method acceptable to the NRC. This trust, escrow account, Government fund, or other type of agreement must be established in writing and maintained at all times in the United States with an entity that is an appropriate State or Federal government agency, or an entity whose operations in which the prepayment deposit is managed are regulated and examined by a Federal or State agency. An applicant or licensee that has prepaid funds may take credit for projected earnings on the prepaid decommissioning trust funds, using up to a 2 percent annual real rate of return through the time of termination of the license. An applicant or licensee may use a credit of greater than 2 percent if the licensee's rate-setting authority has specifically authorized a higher rate. Actual earnings on existing funds may be used to calculate future fund needs.

(b) *External sinking fund*. An external sinking fund is a fund established and maintained by setting funds aside periodically in an account segregated from licensee

assets and outside the administrative control of the applicant or licensee and its subsidiaries or affiliates in which the total amount of funds would be sufficient to pay decommissioning costs. An external sinking fund may be in the form of a trust, escrow account, or Government fund, with payment by certificate of deposit, deposit of Government or other securities, or other method acceptable to the NRC. This trust, escrow account, Government fund, or other type of agreement must be established in writing and maintained at all times in the United States with an entity that is an appropriate State or Federal government agency, or an entity whose operations in which the external sinking fund is managed are regulated and examined by a Federal or State agency. An applicant or licensee may take credit for projected earnings on the external sinking funds using up to a 2 percent annual real rate of return from the time of future funds' collection through the time of termination of the license. An applicant or licensee may use a credit of greater than 2 percent if the licensee's rate-setting authority has specifically authorized a higher rate. Actual earnings on existing funds may be used to calculate future fund needs. An applicant or licensee whose rates for decommissioning costs cover only a portion of these costs may make use of this method only for the portion of these costs that are collected in one of the manners described in this paragraph. This method may be used as the exclusive mechanism relied upon for providing financial assurance for decommissioning in the following circumstances:

(1) By an applicant or licensee that recovers, either directly or indirectly, the estimated total cost of decommissioning through rates established by "cost of service" or similar ratemaking regulation. Public utility districts, municipalities, rural electric cooperatives, and State and Federal agencies, including associations of any of the foregoing, that establish their own rates and are able to recover their cost of service allocable to decommissioning, are deemed to satisfy this condition.

(2) By an applicant or licensee whose source of revenues for its external sinking fund is a "non-bypassable charge," the total amount of which will provide funds estimated to be needed for decommissioning pursuant to § 53.1020, § 53.1060, or § 53.1575.

(c) *A surety method, insurance, or other guarantee method*.

(1) These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended, or, if written for a specified term, such as 5 years, must be renewed automatically, unless 90 days or more prior to the renewal day the issuer notifies the NRC, the beneficiary, and the applicant or licensee of its intention not to renew. The surety or insurance must also provide that the full- face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the applicant or licensee fails to provide a replacement acceptable to the NRC within 30 days after receipt of notification of cancellation.

(ii) The surety or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the NRC. An acceptable trustee includes an appropriate State or Federal government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(2) A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A to 10 CFR part 30.

(3) For commercial companies that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix C to 10 CFR part 30. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in appendix D to 10 CFR part 30. A guarantee by the applicant or licensee may not be used in any situation in which the applicant or licensee has a parent company holding majority control of voting stock of the company.

(d) *Funding method for Federal licensees*. For a Federal applicant or licensee, a statement of intent containing a cost estimate for decommissioning and indicating that funds for decommissioning will be obtained when necessary.

(e) *Contractual funding method*. Contractual obligation(s) on the part of an applicant’s or licensee's customer(s), the total amount of which over the duration of the contract(s) will provide the applicant’s or licensee's total share of uncollected funds estimated to be needed for decommissioning pursuant to § 53.1020, § 53.1060, or § 53.1575. To be acceptable to the NRC as a method of decommissioning funding assurance, the terms of the contract(s) must include provisions that the buyer(s) of electricity or other products will pay for the decommissioning obligations specified in the contract(s), notwithstanding the operational status either of the licensed plant to which the contract(s) pertains or force majeure provisions. All proceeds from the contract(s) for decommissioning funding will be deposited to the external sinking fund. The NRC reserves the right to evaluate the terms of any contract(s) and the financial qualifications of the contracting entity or entities offered as assurance for decommissioning funding.

(f) *Other funding mechanisms*. Any other mechanism, or combination of mechanisms, that provides, as determined by the NRC upon its evaluation of the specific

circumstances of each licensee submittal, assurance of decommissioning funding equivalent to that provided by the mechanisms specified in paragraphs (a) through (e) of this section. Applicants or licensees who do not have sources of funding described in paragraph (b) of this section may use an external sinking fund in combination with a guarantee mechanism, as specified in paragraph (c) of this section, provided that the total amount of funds estimated to be necessary for decommissioning is assured.

(g) Licensees that are not "electric utilities" as defined in § 53.020 that use prepayment or an external sinking fund to provide financial assurance must provide in the terms of the arrangements governing the trust, escrow account, or Government fund, used to segregate and manage the funds that—

(1) The trustee, manager, investment advisor, or other person directing investment of the funds—

(i) Is prohibited from investing the funds in securities or other obligations of the licensee or any other owner or operator of any commercial nuclear plant or their affiliates, subsidiaries, successors or assigns, or in a mutual fund in which at least 50 percent of the fund is invested in the securities of a licensee or parent company whose subsidiary is an owner or operator of a foreign or domestic commercial nuclear plant. However, the funds may be invested in securities tied to market indices or other non-nuclear sector collective, commingled, or mutual funds, provided that no more than 10 percent of trust assets may be indirectly invested in securities of any entity owning or operating one or more commercial nuclear plants.

(ii) Is obligated at all times to adhere to a standard of care set forth in the trust, which either shall be the standard of care, whether in investing or otherwise, required by State or Federal law or one or more State or Federal regulatory agencies with jurisdiction over the trust funds, or, in the absence of any such standard of care, whether

in investing or otherwise, that a prudent investor would use in the same circumstances. The term "prudent investor," shall have the same meaning as set forth in FERC's "Regulations Governing Nuclear Plant Decommissioning Trust Funds" at 18 CFR 35.32(a)(3), or any successor regulation.

(2) The licensee, its affiliates, and its subsidiaries are prohibited from being engaged as investment manager for the funds or from giving day-to-day management direction of the funds' investments or direction on individual investments by the funds, except in the case of passive fund management of trust funds where management is limited to investments tracking market indices.

(3) The trust, escrow account, Government fund, or other account used to segregate and manage the funds may not be amended in any material respect without written notification to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the proposed effective date of the amendment. The licensee must provide the text of the proposed amendment and a statement of the reason for the proposed amendment. The trust, escrow account, Government fund, or other account may not be amended if the person responsible for managing the trust, escrow account, Government fund, or other account receives written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period.

(4) Except for withdrawals being made under § 53.1045(a) or for payments of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, no disbursement or payment may be made from the trust, escrow account, Government fund, or other account used to segregate and manage the funds

until written notice of the intention to make a disbursement or payment has been given to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the date of the intended disbursement or payment. The disbursement or payment from the trust, escrow account, Government fund or other account may be made following the 30-working day notice period if the person responsible for managing the trust, escrow account, Government fund, or other account does not receive written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period. Disbursements or payments from the trust, escrow account, Government fund, or other account used to segregate and manage the funds, other than for payment of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, are restricted to decommissioning expenses or transfer to another financial assurance method acceptable under this section until final decommissioning has been completed. After decommissioning has begun and withdrawals from the decommissioning fund are made under paragraph (a) of this section, no further notification need be made to the NRC.

(h) Licensees that are "electric utilities" under § 53.020 that use prepayment or an external sinking fund to provide financial assurance must include a provision in the terms of the trust, escrow account, Government fund, or other account used to segregate and manage funds that except for withdrawals being made under § 53.1045 or for payments of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, no disbursement or payment may be made

from the trust, escrow account, Government fund, or other account used to segregate and manage the funds until written notice of the intention to make a disbursement or payment has been given the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the date of the intended disbursement or payment. The disbursement or payment from the trust, escrow account, Government fund or other account may be made following the 30-working day notice period if the person responsible for managing the trust, escrow account, Government fund, or other account does not receive written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period. Disbursements or payments from the trust, escrow account, Government fund, or other account used to segregate and manage the funds, other than for payment of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, are restricted to decommissioning expenses or transfer to another financial assurance method acceptable under this section until final decommissioning has been completed. After decommissioning has begun and withdrawals from the decommissioning fund are made under paragraph (a) of this section, no further notification need be made to the NRC.

(i) A licensee that is not an "electric utility" under § 53.020 and using a surety method, insurance, or other guarantee method to provide financial assurance must provide that the trust established for decommissioning costs to which the surety or insurance is payable contains in its terms the requirements in paragraphs (b)(1), (2), (3), and (4) of this section.

§ 53.1045 Limitations on the use of decommissioning trust funds.

(a)(1) Decommissioning trust funds may be used by licensees if—

(i) The withdrawals are for expenses for decommissioning activities consistent with the definition of decommission or decommissioning in § 53.020;

(ii) The expenditure would not reduce the value of the decommissioning trust below an amount necessary to place and maintain the reactor in a safe storage condition if unforeseen conditions or expenses arise; and

(iii) The withdrawals would not inhibit the ability of the licensee to complete funding of any shortfalls in the decommissioning trust needed to ensure the availability of funds to ultimately release the site and terminate the license.

(2) Initially, 3 percent of the amount determined in accordance with § 53.1020 may be used for decommissioning planning. For licensees that have submitted the certifications required under § 53.1070 and commencing 90 days after the NRC has received the post-shutdown decommissioning activities report (PSDAR) required by § 53.1060, an additional 20 percent may be used. An updated site-specific DCE must be submitted to the NRC prior to the licensee using any funding in excess of these amounts.

§ 53.1050 NRC oversight.

The NRC reserves the right to take the following steps in order to ensure a licensee's adequate accumulation of decommissioning funds: review, as needed, the rate of accumulation of decommissioning funds and, either independently or in cooperation with FERC and the licensee's State PUC, take additional actions as appropriate on a case-by-case basis, including modification of a licensee's schedule for the accumulation of decommissioning funds.

§ 53.1060 Reporting and recordkeeping requirements.

(a) Each holder of an operating license (OL) under this part or holder of a combined license (COL) under this part after the date that the Commission has made the finding under § 53.1452(g) must report, at least once every 2 years, by March 31, on the status of its certification of decommissioning funding for each commercial nuclear plant or part of a plant that it owns. The information in this report must include, at a minimum, the amount of decommissioning funds estimated to be required under §§ 53.1020 and 53.1030; the amount of decommissioning funds accumulated to the end of the calendar year preceding the date of the report; a schedule of the annual amounts remaining to be collected; the assumptions used regarding rates of escalation in decommissioning costs, rates of earnings on decommissioning funds, and rates of other factors used in funding projections; any contracts upon which the licensee is relying under § 53.1040(e); any modifications occurring to a licensee's method of providing financial assurance since the last submitted report; and any material changes to trust agreements. If any of the preceding items is not applicable, the licensee should so state in its report. Any licensee for a plant that is within 5 years of the projected end of its operation, or where conditions have changed such that it will close within 5 years (before the end of its licensed life), or that has already closed (before the end of its licensed life), or that is involved in a merger or an acquisition must submit this report annually.

(b) Each holder of a COL under this part must, 2 years before and 1 year before the scheduled date for initial loading of fuel, submit a report to the NRC containing a certification updating the decommissioning cost estimates (DCEs) and a copy of the financial instrument to be used to satisfy § 53.1040. No later than 30 days after the Commission publishes notice in the *Federal Register* under § 53.1452(a), the licensee must submit an updated decommissioning report , including a copy of the financial instrument obtained to satisfy § 53.1040.

(c) Each licensee must keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Commission. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Commission considers important to decommissioning consists of—

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when significant contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored and of locations of possible inaccessible contamination such as buried pipes that may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee must substitute appropriate records of available information concerning these areas and locations.

(3) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(4) Records of—

(i) The licensed site area, as originally licensed and any revisions, which must include a site map and any acquisition or use of property outside the originally licensed site area for the purpose of receiving, possessing, or using licensed materials;

(ii) The licensed activities carried out on the acquired or used property; and

(iii) The release and final disposition of any property recorded in paragraph (c)(4)(i) of this section, the historical site assessment performed for the release, radiation surveys performed to support release of the property, submittals to the NRC made under § 53.1070, and the methods employed to ensure that the property met the radiological criteria of subpart E of 10 CFR part 20 at the time the property was released.

(d) Each holder of an OL or COL under this part must at or about 5 years prior to the projected end of operations submit a preliminary DCE which includes an up-to-date assessment of the major factors that could affect the cost to decommission.

(e) Prior to or within 2 years following permanent cessation of operations, the licensee must submit a post shutdown decommissioning activities report (PSDAR) to the NRC, and a copy to the affected State(s). The PSDAR must contain a description of the planned decommissioning activities along with a schedule for their accomplishment, a discussion that provides the reasons for concluding that the environmental impacts associated with site-specific decommissioning activities will be bounded by appropriate previously issued environmental impact statements, and a site-specific DCE, including the projected cost of managing irradiated fuel.

(f) For decommissioning activities that delay completion of decommissioning by including a period of storage or surveillance, the licensee must provide a means of adjusting cost estimates and associated funding levels over the storage or surveillance period.

(g) After submitting its site-specific DCE required by paragraph (e) of this section, and until the licensee has completed its final radiation survey and demonstrated that residual radioactivity has been reduced to a level that permits termination of its license, the licensee must annually submit to the NRC, by March 31, a financial assurance status

report. The report must include the following information, current through the end of the previous calendar year:

(1) The amount spent on decommissioning, both cumulative and over the previous calendar year, the remaining balance of any decommissioning funds, and the amount provided by other financial assurance methods being relied upon;

(2) An estimate of the costs to complete decommissioning, reflecting any difference between actual and estimated costs for work performed during the year, and the decommissioning criteria upon which the estimate is based;

(3) Any modifications occurring to a licensee's current method of providing financial assurance since the last submitted report; and

(4) Any material changes to trust agreements or financial assurance contracts.

(5) If the sum of the balance of any remaining decommissioning funds, plus earnings on such funds calculated at not greater than a 2 percent real rate of return, together with the amount provided by other financial assurance methods being relied upon, does not cover the estimated cost to complete the decommissioning, the financial assurance status report must include additional financial assurance to cover the estimated cost of completion.

(h) After submitting its site-specific DCE required by paragraph (e) of this section, the licensee must annually submit to the NRC, by March 31, a report on the status of its funding for managing irradiated fuel. The report must include the following information, current through the end of the previous calendar year:

(1) The amount of funds accumulated to cover the cost of managing the irradiated fuel;

(2) The projected cost of managing irradiated fuel until title to the fuel and possession of the fuel is transferred to the Secretary of Energy; and

(3) If the funds accumulated do not cover the projected cost, a plan to obtain additional funds to cover the cost.

§ 53.1070 Termination of license.

For each holder of an operating license (OL) or combined license (COL) under this part—

(a)(1) When the licensee has determined to permanently cease operations the licensee must, within 30 days, submit a written certification to the NRC, consistent with the requirements of § 53.040(b)(8);

(2) Once fuel has been permanently removed from the reactor vessel, the licensee must submit a written certification to the NRC that meets the requirements of § 53.040(b)(9); and

(b) Upon docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessel, or when a final legally effective order to permanently cease operations has come into effect, the license issued under this part no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor vessel.

(c) Decommissioning will be completed within 60 years of permanent cessation of operations. Completion of decommissioning beyond 60 years will be approved by the Commission only when necessary to protect public health and safety. Factors that will be considered by the Commission in evaluating an alternative that provides for completion of decommissioning beyond 60 years of permanent cessation of operations include unavailability of waste disposal capacity and other site-specific factors affecting the licensee's capability to carry out decommissioning, including presence of other nuclear facilities at the site.

(d)(1) Following receipt of the post shutdown decommissioning activities report (PSDAR) submitted under § 53.1060(e), The NRC must make the PSDAR publicly available and publish notice of its availability for public comment in the *Federal Register*. The NRC must also schedule a public meeting readily accessible to individuals in the vicinity of the licensee's facility. The NRC must publish a notice in the *Federal Register* and in a forum, such as local newspapers, that is readily accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.

(e) Licensees must not perform any major decommissioning activities, as defined in § 53.020, until 90 days after the NRC has received the licensee's PSDAR submittal and until certifications of permanent cessation of operations and permanent removal of fuel from the reactor vessel, as required under paragraph (a) of this section, have been submitted.

(f) Licensees must not perform any activities that—

(1) Foreclose release of the site for possible unrestricted use;

(2) Result in significant environmental impacts not previously reviewed; or

(3) Result in there no longer being reasonable assurance that adequate funds will be available for decommissioning.

(g) In taking actions permitted under § 53.1540 following submittal of the PSDAR, the licensee must notify the NRC in writing, and send a copy to the affected State(s), before performing any decommissioning activity inconsistent with, or making any significant schedule change from, those actions and schedules described in the PSDAR, including changes that increase the decommissioning cost by more than 20 percent from the previously provided DCE.

(h) Licensees may use decommissioning trust funds consistent with the limitations of § 53.1045(a). Licensees must report on the status of decommissioning trust funds consistent with the requirements of § 53.1060.

(i) Licensees must submit an application for termination of license in accordance with § 53.1070. The application for termination of license must be accompanied or preceded by a license termination plan to be submitted for NRC approval.

(1) The license termination plan must be a supplement to the Final Safety Analysis Report (FSAR) or equivalent and must be submitted at least 2 years before termination of the license date.

(2) The license termination plan must include—

(i) A site characterization;

(ii) Identification of remaining dismantlement activities;

(iii) Plans for site remediation;

(iv) Detailed plans for the final radiation survey;

(v) A description of the end use of the site, if restricted;

(vi) An updated site-specific estimate of remaining decommissioning costs;

(vii) A supplement to the environmental report, pursuant to § 51.53 of this chapter, describing any new information or significant environmental change associated with the licensee's proposed termination activities; and

(viii) Identification of parts, if any, of the facility or site that were released for use before approval of the license termination plan.

(3) Following receipt of the license termination plan, the NRC must make the license termination plan publicly available and publish notice of its availability for public comment in the *Federal Register*. The NRC must also schedule a public meeting readily accessible to individuals in the vicinity of the licensee’s facility upon receipt of the license

termination plan. The NRC must publish a notice in the *Federal Register* and in a forum, such as local newspapers, that is readily accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.

(j) If the license termination plan demonstrates that the remainder of decommissioning activities will be performed in accordance with the regulations in this chapter, will not be inimical to the common defense and security or to the health and safety of the public, and will not have a significant effect on the quality of the environment and after notice to interested persons, the Commission will approve the plan, by license amendment, subject to such conditions and limitations as it deems appropriate and necessary and authorize implementation of the license termination plan.

(k) The Commission will terminate the license if it determines that—

(1) The remaining dismantlement has been performed in accordance with the approved license termination plan, and

(2) The final radiation survey and associated documentation, including an assessment of dose contributions associated with parts released for use before approval of the license termination plan, demonstrate that the facility and site have met the criteria for decommissioning in subpart E of 10 CFR part 20.

§ 53.1075 Program requirements during decommissioning.

(a) Licensees that have submitted the certifications required under § 53.1070 must maintain a decommissioning fire protection program to address the potential for fires that could cause the release or spread of radioactive materials.

(1) The objectives of the decommissioning fire protection program are to

(i) Reasonably prevent these fires from occurring;

(ii) Rapidly detect, control, and extinguish those fires that do occur and that could result in a radiological hazard; and

(iii) Ensure that the risk of fire-induced radiological hazards to the public, environment, and plant personnel is minimized.

(2) The licensee must assess the decommissioning fire protection program on a regular basis. The licensee must revise the decommissioning fire protection program documentation as appropriate throughout the various stages of facility decommissioning.

(3) The licensee may make changes to the decommissioning fire protection program without NRC approval if these changes do not reduce the effectiveness of fire protection for SSCs that could result in a radiological hazard, taking into account the decommissioning plant conditions and activities.

(b) The licensee must establish and maintain staffing consisting of certified fuel handlers, as defined under § 53.020, and other non-licensed personnel with appropriate qualifications, and in sufficient numbers, to ensure support for facility operations and radiological control activities. These personnel must be subject to the training requirements of § 53.830.

§ 53.1080 Release of part of a commercial nuclear plant or site for unrestricted use.

(a) Prior written NRC approval is required to release part of a commercial nuclear plant or site for unrestricted use at any time before receiving approval of a license termination plan. Section 53.1060 specifies recordkeeping requirements associated with partial release. Holders of an operating license or combined license under this part seeking NRC review and approval must—

(1) Evaluate the effect of releasing the property to ensure that—

(i) The dose to individual members of the public does not exceed the limits and standards of subpart D of 10 CFR part 20;

(ii) There is no reduction in the effectiveness of emergency planning or physical security;

(iii) Effluent releases remain within license conditions;

(iv) The environmental monitoring program and offsite dose calculation manual are revised to account for the changes;

(v) The siting criteria of subpart D of this part continue to be met; and

(vi) All other applicable statutory and regulatory requirements continue to be met.

(2) Perform a historical site assessment of the part of the commercial nuclear plant or site to be released; and

(3) Perform surveys adequate to demonstrate compliance with the radiological criteria for unrestricted use specified in § 20.1402 of this chapter for impacted areas.

(b) For release of non-impacted areas, the licensee may submit a written request for NRC review and approval of the release if a license amendment is not otherwise required. The request submittal must include—

(1) The results of the evaluations performed in accordance with paragraphs (a)(1) and (a)(2) of this section;

(2) A description of the part of the commercial nuclear plant or site to be released;

(3) The schedule for release of the property;

(4) The results of the evaluations performed in accordance with § 53.1540; and

(5) A discussion that provides the reasons for concluding that the environmental impacts associated with the licensee's proposed release of the property will be bounded by appropriate previously issued environmental impact statements.

(c) After receiving a request from the licensee for NRC approval of the release of a non-impacted area, the NRC must—

(1) Determine whether the licensee has adequately evaluated the effect of releasing the property as required by paragraph (a)(1) of this section;

(2) Determine whether the licensee's classification of any release areas as non-impacted is adequately justified; and

(3) If determining that the licensee's submittal is adequate, inform the licensee in writing that the release is approved.

(d) For release of impacted areas, the licensee must submit an application for amendment of its license for the release of the property. The application must include—

(1) The information specified in paragraphs (b)(1) through (b)(3) of this section;

(2) The methods used for and results obtained from the radiation surveys required to demonstrate compliance with the radiological criteria for unrestricted use specified in § 20.1402; and

(3) A supplement to the environmental report, under § 51.53 of this chapter, describing any new information or significant environmental change associated with the licensee's proposed release of the property.

(e) After receiving a license amendment application from the licensee for the release of an impacted area, the NRC must—

(1) Determine whether the licensee has adequately evaluated the effect of releasing the property as required by paragraph (a)(1) of this section;

(2) Determine whether the licensee's classification of any release areas as non-impacted is adequately justified;

(3) Determine whether the licensee's radiation survey for an impacted area is adequate; and

(4) If determining that the licensee's submittal is adequate, approve the licensee's amendment application.

(f) The NRC must publish notice receipt of the release approval request or license amendment application in the *Federal Register* and make the approval request or license amendment application available for public comment. Before acting on an approval request or license amendment application submitted in accordance with this section, the NRC must conduct a public meeting readily accessible to individuals in the vicinity of the licensee's facility for the purpose of obtaining public comments on the proposed release of part of the commercial nuclear plant or site. The NRC must publish a document in the *Federal Register* and in a forum, such as local newspapers, which is readily accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.

Subpart H — Licenses, Certifications, and Approvals

§ 53.1100 Filing of application for licenses, certifications, or approvals; oath or affirmation.

(a) *Serving of applications*.

(1) Each filing of an application for a standard design approval, standard design certification, or license under this part, and any amendments to the applications, must be submitted to the NRC under § 53.040, as applicable.

(2) Each applicant for a construction permit (CP), early site permit, combined license (COL), or manufacturing license (ML) under this part must, upon notification by the presiding officer designated to conduct the public hearing required by the Act, update the application and serve the updated copies of the application or parts of it, eliminating all superseded information, together with an index of the updated application, as directed by presiding officer. Any subsequent amendment to the application must be served on

those served copies of the application and must be submitted to the NRC as specified in § 53.040, as applicable.

(3) The applicant must make a copy of the updated application available at the public hearing for the use of any other parties to the proceeding and must certify that the updated copies of the application contain the current contents of the application submitted in accordance with the requirements under this part.

(4) At the time of filing an application, the Commission will make available at the NRC Web site, http://www.nrc.gov, a copy of the application, subsequent amendments, and other records pertinent to the matter that is the subject of the application for public inspection and copying.

(5) The serving of copies required by this section must not occur until the application has been docketed under § 2.101(a) of this chapter. Copies must be submitted to the Commission, as specified in § 53.040, as applicable, to enable the Director, Office of Nuclear Reactor Regulation to determine whether the application is sufficiently complete to permit docketing.

(b) *Oath or affirmation*. Each application for a standard design approval, standard design certification, or license, including, whenever appropriate, a CP or early site permit, or amendment of it, and each amendment of each application must be executed in a signed original by the applicant or duly authorized officer thereof under oath or affirmation.

(c) [Reserved]

(d) [Reserved]

(e) *Filing fees*. Each application for a standard design approval, standard design certification, or commercial nuclear plant license under this part, including, whenever appropriate, a CP, COL, OL, ML, or early site permit, other than a license exempted

from 10 CFR part 170, must be accompanied by the fee prescribed in 10 CFR part 170. No fee will be required to accompany an application for renewal, amendment, or termination of a CP, OL, COL, or ML, except as provided in § 170.21 of this chapter.

(f) *Environmental report*. An application for a CP, OL, early site permit, design certification, COL, or ML for a commercial nuclear plant must be accompanied by an environmental report required under subpart A of 10 CFR part 51.

§ 53.1101 Requirement for license.

Except as provided in § 50.11 of this chapter, no person within the United States may transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, or use any utilization facility except as authorized by a license issued by the Commission.

§ 53.1103 Combining applications and licenses.

(a) An applicant may combine more than one application in one application for different kinds of licenses under the regulations in this chapter.

(b) The Commission may combine in a single license the activities of an applicant which would otherwise be licensed separately.

§ 53.1106 Elimination of repetition.

An applicant may incorporate by reference in its application information contained in previous applications, statements, or reports filed with the Commission, provided, however, that such references are clear and specific.

§ 53.1109 Contents of applications; general information.

Each application must include, unless otherwise indicated in this subpart—

(a) Name of applicant;

(b) Address of applicant;

(c) Description of business or occupation of applicant;

(d)(1) If applicant is an individual, the citizenship of applicant;

(2) If applicant is a partnership, the name, citizenship and address of each partner and the principal location where the partnership does business;

(3) If applicant is a corporation or an unincorporated association, the following information:

(i) The State where it is incorporated or organized and the principal location where it does business;

(ii) The names, addresses and citizenship of its directors and of its principal officers; and

(iii) Whether it is owned, controlled, or dominated by an alien, a foreign corporation, or foreign government, and if so, give details; or

(4) If the applicant is acting as agent or representative of another person in filing the application, identify the principal and furnish information required under this paragraph with respect to such principal;

(e) The type of license applied for, the use to which the facility will be put, the period of time for which the license is sought, and a list of other licenses, except operator's licenses, issued or applied for in connection with the proposed facility;

(f) [Reserved]

(g)(1) If the application is for an operating license (OL) or combined license (COL) for a commercial nuclear plant, or if the application is for an early site permit for a commercial nuclear plant and contains plans for coping with emergencies under § 53.1146(b)(2)(ii), radiological emergency response plans of State, local, and participating Tribal governmental entities in the United States that are wholly or partially within the plume exposure pathway emergency planning zone (EPZ),[1] and the plans of State governments wholly or partially within the ingestion pathway EPZ. If the application

is for an early site permit that, under § 53.1146(b)(2)(i), proposes major features of the emergency plans describing the EPZs, then the descriptions of the EPZs must demonstrate compliance with the requirements of this paragraph. Generally, the plume exposure pathway EPZ for a commercial nuclear plant must consist of an area about 10 miles (16 km) in radius and the ingestion pathway EPZ must consist of an area about 50 miles (80 km) in radius. The exact size and configuration of the EPZs surrounding a particular commercial nuclear plant must be determined in relation to the local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. The size of the EPZs also may be determined on a case-by-case basis for gas-cooled reactors and for reactors with an authorized power level less than 250 megawatt (MW) thermal. The plans for the ingestion pathway must focus on such actions as are appropriate to protect the food ingestion pathway.

(2) [Reserved]

(h) [Reserved]

(i) A list of the names and addresses of such regulatory agencies as may have jurisdiction over the rates and services incident to the proposed activity, and a list of trade and news publications which circulate in the area where the proposed activity will be conducted and which are considered appropriate to give reasonable notice of the application to those municipalities, private utilities, public bodies, and cooperatives, which might have a potential interest in the facility; and

(j) If the application contains Restricted Data or classified National Security information, confirmation that all Restricted Data and classified National Security information are separated from the unclassified information.

(k) [Reserved]

[1] EPZs are discussed in NUREG–0396, EPA 520/1–78–016, "Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light-Water Nuclear Power Plants," December 1978.

§ 53.1112 Environmental conditions.

(a) Each construction permit (CP), early site permit, and combined license (COL) under this part may include conditions to protect the environment during construction. These conditions are to be set out in an attachment to the license, which is incorporated in and made a part of the license. These conditions will be derived from information contained in the environmental report submitted pursuant to § 51.50 of this chapter, as analyzed and evaluated in the NRC record of decision, and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirement for the protection of the nonaquatic environment.

(b) Each license authorizing operation of a commercial nuclear plant under this part, and each license for a commercial nuclear plant that no longer authorizes operation of the reactor under § 53.1070 submitted may include conditions to protect the environment during operation and decommissioning. These conditions are to be set out in an attachment to the license, which is incorporated in and made a part of the license. These conditions will be derived from information contained in the environmental report or the supplement to the environmental report submitted under §§ 51.50 and 51.53 of this chapter as analyzed and evaluated in the NRC record of decision, and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data and any conditions and monitoring requirement for the protection of the nonaquatic environment.

§ 53.1115 Agreement limiting access to classified information.

As part of its application and in any event before the receipt of Restricted Data or

classified National Security Information or the issuance of a license or standard design approval under this part, or before the Commission has adopted a final standard design certification rule under this part, the applicant must agree in writing that it will not permit any individual to have access to or any facility to possess Restricted Data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. The agreement of the applicant becomes part of the license or standard design approval.

§ 53.1118 Ineligibility of certain applicants.

Any person who is a citizen, national, or agent of a foreign country, or any corporation, or other entity which the Commission knows or has reason to believe is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government, will be ineligible to apply for and obtain a license.

§ 53.1121 Public inspection of applications.

Applications and documents submitted to the Commission in connection with applications may be made available for public inspection under the provisions of part 2 of this chapter.

§ 53.1124 Relationship between licenses, certifications, and approvals.

(a) *Standard design certifications and standard design approvals.* (1) An application for a standard design certification or standard design approval under this part may, but need not, reference an operating license (OL) or custom combined license (COL) under this part that is essentially the same as the information supporting the standard design for which certification or approval is being requested.

(2) An application for a construction permit (CP), OL, or COL may, but need not, reference a standard design certification or standard design approval issued under this

part. In the absence of a demonstration that an entity other than the one originally sponsoring and obtaining a standard design certification is qualified to supply a design, the Commission will entertain an application for a CP, OL, or COL that references a standard design certification issued under this part only if the entity that sponsored and obtained the certification supplies the design for the applicant's use.

(b) *Manufacturing licenses.* An application for a COL under this part may reference a manufactured reactor manufactured under a manufacturing license (ML) issued under this part may to be transported to and installed at a construction site for a commercial nuclear plant. An application for an OL under this part may not reference a manufactured reactor.

§ 53.1130 Limited work authorizations.

(a) *Request for limited work authorization*. (1) Any person to whom the Commission may otherwise issue either a license or permit related to a commercial nuclear plant may request a limited work authorization (LWA) allowing that person to perform the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, and installation of the foundation, including placement of concrete, any of which are for a structure, system, or component (SSC) of the facility for which either a construction permit (CP) or combined license (COL) is otherwise required under § 53.610 of this part.

(2) An application for an LWA may be submitted as part of a complete application for a CP or COL in accordance with § 2.101(a)(1) through (a)(5) of this chapter, or as a partial application in accordance with § 2.101(a)(9) of this chapter. An application for an LWA by the holder of an early site permit must be submitted as a complete application in accordance with § 2.101(a)(1) through (a)(4) of this chapter.

(3) The application must include—

(i) A Safety Analysis Report required by § 53.1146, § 53.1309 or § 53.1416, as applicable, a description of the activities requested to be performed, and the design and construction information otherwise required by the Commission's rules and regulations to be submitted for a CP or COL under this part but limited to those portions of the facility that are within the scope of the LWA. The Safety Analysis Report must demonstrate that activities conducted under the LWA will be conducted in compliance with the technically relevant Commission requirements in 10 CFR chapter I applicable to the design of those portions of the facility within the scope of the LWA;

(ii) An environmental report in accordance with § 51.49 of this chapter; and

(iii) A plan for redress of activities performed under the LWA, should limited work activities be terminated by the holder, or the LWA be revoked by the NRC or upon effectiveness of the Commission's final decision denying the associated CP or COL application, or the early site permit for the site is not referenced in an application for a CP or COL while the permit remains valid, as applicable.

(b) *Issuance of limited work authorization*. (1) The Director, Office of Nuclear Reactor Regulation may issue an LWA only after—

(i) The NRC staff issues the final environmental impact statement for the LWA under subpart A of part 51 of this chapter;

(ii) The presiding officer makes the finding in § 51.105(c) or § 51.107(d) of this chapter, as applicable;

(iii) The Director determines that the applicable standards and requirements of the Act, and the Commission's regulations applicable to the activities to be conducted under the LWA, have been met, the applicant is technically qualified to engage in the activities authorized, and that issuance of the LWA will provide reasonable assurance of adequate protection to public health and safety and will not be inimical to the common

defense and security; and

(iv) The presiding officer finds that there are no unresolved safety issues relating to the activities to be conducted under the LWA that would constitute good cause for withholding the authorization.

(2) Each LWA will specify the activities that the holder is authorized to perform.

(c) *Effect of limited work authorization*. Any activities undertaken under an LWA are entirely at the risk of the applicant and, except as to the matters determined under paragraph (b)(1) of this section, the issuance of the LWA has no bearing on the issuance of a CP or COL with respect to the requirements of the Act and rules, regulations, or orders issued under the Act. The environmental impact statement for a CP or COL application for which an LWA was previously issued will not address, and the presiding officer will not consider, the sunk costs of the holder of the LWA in determining whether the CP or COL should be issued, denied, or appropriately conditioned.

(d) *Implementation of redress plan*. If construction is terminated by the holder, the underlying application is withdrawn by the applicant or denied by the NRC, or the LWA is revoked by the NRC, then the holder must begin implementation of the redress plan in a reasonable time. The holder must also complete the redress of the site no later than 18 months after termination of construction, revocation of the LWA, or upon effectiveness of the Commission's final decision denying the associated CP application or the underlying COL application, as applicable.

§ 53.1140 Early site permits.

Sections 53.1140 through 53.1188 set out the requirements and procedures applicable to Commission issuance of an early site permit under this part for approval of a site for a commercial nuclear plant separate from the filing of an application for a construction permit or combined license for the facility.

§ 53.1143 Filing of applications.

Any person who may apply for a construction permit (CP) or for a combined license (COL) under this part, may file an application for an early site permit with the Director, Office of Nuclear Reactor Regulation. An application for an early site permit may be filed notwithstanding the fact that an application for a CP or a COL has not been filed in connection with the site for which a permit is sought.

§ 53.1144 Contents of applications for early site permits; general information.

The application must contain all of the information required by § 53.1109(a) through (d) and (j).

§ 53.1146 Contents of applications for early site permits; technical information.

(a) The application must contain—

(1) A Site Safety Analysis Report that must include the following:

(i) The specific number, type, and thermal power level of the facilities, or range of possible facilities, for which the site may be used;

(ii) The anticipated maximum levels of radiological and thermal effluents each facility will produce;

(iii) The type of cooling systems, including intakes and outflows, where appropriate, that may be associated with each facility;

(iv) The boundaries of the site;

(v) The proposed general location of each facility on the site;

(vi) The external hazards and site characteristics required by this part;

(vii) [Reserved];

(viii) The existing and projected future population profile of the area surrounding the site;

(ix) A description and assessment of the site on which a facility is to be located.

The assessment must address the requirements of subpart D of this part;

(x) Information demonstrating that site characteristics are such that adequate security plans and measures can be developed; and

(xi) A description of the quality assurance plan (QAP) applied to site-related activities for the future design, fabrication, construction, and testing of the SSCs of a facility or facilities that may be constructed on the site. Appendix B to part 50 of this chapter sets forth the requirements for QAPs for nuclear power plants. The description of the QAP for a commercial nuclear power plant site must include a discussion of how the applicable requirements of appendix B to part 50 of this chapter will be satisfied.

(2) A complete environmental report as required by § 51.50(b) of this chapter.

(b)(1) The Site Safety Analysis Report must identify physical characteristics of the proposed site, such as egress limitations from the area surrounding the site, that could pose a significant impediment to the development of emergency plans. If physical characteristics are identified that could pose a significant impediment to the development of emergency plans, the application must identify measures that would, when implemented, mitigate or eliminate the significant impediment.

(2) The Site Safety Analysis Report may also—

(i) Propose major features of the emergency plans, under the pertinent standards of § 53.855, such as the exact size and configuration of the emergency planning zones, for review and approval by the NRC, in consultation with the Federal Emergency Management Agency (FEMA), as applicable, in the absence of complete and integrated emergency plans; or

(ii) Propose complete and integrated emergency plans for review and approval by the NRC, in consultation with FEMA, as applicable, in accordance with the applicable standards of § 53.855. To the extent approval of emergency plans is sought, the

application must contain the information required by § 53.1109(g).

(3) Emergency plans submitted under paragraph (b)(2)(ii) of this section must include the proposed inspections, tests, and analyses that the holder of a combined license referencing the early site permit must perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will be operated in conformity with the emergency plans, the provisions of the Act, and the Commission's rules and regulations. Major features of an emergency plan submitted under paragraph (b)(2)(i) of this section may include proposed inspections, tests, analyses, and acceptance criteria.

(4) Under paragraphs (b)(1) and (b)(2)(i) of this section, the Site Safety Analysis Report must include, where appropriate, a description of contacts and arrangements made with Federal, State, participating Tribal, and local governmental agencies with emergency planning responsibilities. The Site Safety Analysis Report must contain any certifications that have been obtained. If these certifications, where appropriate, cannot be obtained, the Site Safety Analysis Report must contain information, including a utility plan, sufficient to show that the proposed plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site. Under the option set forth in paragraph (b)(2)(ii) of this section, the applicant must make good faith efforts, where appropriate, to obtain from the same governmental agencies certifications that—

(i) The proposed emergency plans are practicable;

(ii) These agencies are committed to participating in any further development of the plans, including any required field demonstrations; and

(iii) That these agencies are committed to executing their responsibilities under

the plans in the event of an emergency.

(c) An applicant may request that an LWA under § 53.1130 be issued in conjunction with the early site permit. The application must include the information otherwise required by § 53.1130.

§ 53.1149 Review of applications.

(a) *Standards for review of applications.* Applications filed under this part will be reviewed according to the applicable standards set out in this part. In addition, the Commission must prepare an environmental impact statement during review of the application, under the applicable provisions of 10 CFR part 51. The Commission must determine, after consultation with Federal Emergency Management Agency, as applicable, whether the information required of the applicant by § 53.1146(b)(1) shows that there is no significant impediment to the development of emergency plans that cannot be mitigated or eliminated by measures proposed by the applicant, whether any major features of emergency plans submitted by the applicant under § 53.1146(b)(2)(i) are acceptable under the applicable standards of § 53.855, and whether any emergency plans submitted by the applicant under § 53.1146(b)(2)(ii) provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

(b) *Administrative review of applications; hearings*. An early site permit application is subject to all procedural requirements in 10 CFR part 2, including the requirements for docketing in § 2.101(a)(1) through (4) of this chapter, and the requirements for issuance of a notice of hearing in § 2.104(a) and (d) of this chapter, provided that the designated sections may not be construed to require that the environmental report, or draft or final environmental impact statement includes an assessment of the benefits of construction and operation of the reactor or reactors, or an

analysis of alternative energy sources. The presiding officer in an early site permit hearing must not admit contentions proffered by any party concerning an assessment of the benefits of construction and operation of the reactor or reactors, or an analysis of alternative energy sources if those issues were not addressed by the applicant in the early site permit application. All hearings conducted on applications for early site permits filed under this part are governed by the procedures contained in subparts C, G, L, and N of 10 CFR part 2, as applicable.

§ 53.1155 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application for an early site permit to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS must report on those portions of the application which concern safety.

§ 53.1158 Issuance of early site permit.

(a) After conducting a hearing under § 53.1149(b) and receiving the report to be submitted by the ACRS under § 53.1155, the Commission may issue an early site permit, in the form the Commission deems appropriate, if the Commission finds that—

(1) An application for an early site permit demonstrates compliance with the applicable standards and requirements of the Act and the Commission's regulations;

(2) Notifications, if any, to other agencies or bodies have been duly made;

(3) There is reasonable assurance that the site is in conformity with the provisions of the Act and the Commission's regulations;

(4) The applicant is technically qualified to engage in any activities authorized;

(5) The proposed inspections, tests, analyses, and acceptance criteria, including any on emergency planning, are necessary and sufficient, within the scope of the early site permit, to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the

Commission's regulations;

(6) Issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public;

(7) Any significant adverse environmental impact resulting from activities requested under § 53.1146(c) can be redressed; and

(8) The findings required by subpart A of 10 CFR part 51 have been made.

(b) The early site permit must specify the site characteristics, design parameters, and terms and conditions of the early site permit the Commission deems appropriate. Before issuance of either a construction permit (CP) or combined license (COL) referencing an early site permit, the Commission must find that any relevant terms and conditions of the early site permit have been met. Any terms or conditions of the early site permit that could not be met by the time of issuance of the CP or COL, must be set forth as terms or conditions of the CP or COL.

(c) The early site permit must specify those § 53.1130(b) activities requested under § 53.1146(c) that the permit holder is authorized to perform.

§ 53.1161 Extent of activities permitted.

If the activities authorized by § 53.1158(c) are performed and the site is not referenced in an application for a construction permit or a combined license issued under this part while the permit remains valid, then the early site permit remains in effect solely for the purpose of site redress, and the holder of the permit must redress the site under the terms of the site redress plan required by § 53.1146(c). If, before redress is complete, a use not envisaged in the redress plan is found for the site or parts thereof, the holder of the permit must carry out the redress plan to the greatest extent possible consistent with the alternate use.

§ 53.1164 Duration of permit.

(a) Except as provided in paragraph (b) of this section, an early site permit issued under this subpart may be valid for not less than 10, nor more than 20 years from the date of issuance.

(b) An early site permit continues to be valid beyond the date of expiration in any proceeding on a construction permit (CP) application or a combined license (COL) application that references the early site permit and is docketed either before the date of expiration of the early site permit, or, if a timely application for renewal of the early site permit has been docketed, before the Commission has determined whether to renew the permit.

(c) An applicant for a CP or COL may, at its own risk, reference in its application a site for which an early site permit application has been docketed but not granted.

(d) Upon issuance of a CP or COL, a referenced early site permit is subsumed, to the extent referenced, into the CP or COL.

§ 53.1167 Limited work authorization after issuance of early site permit.

A holder of an early site permit may request an LWA under § 53.1130.

§ 53.1170 Transfer of early site permit.

An application to transfer an early site permit will be processed under § 53.1570.

§ 53.1173 Application for renewal.

(a) Not less than 12, nor more than 36 months before the expiration date stated in the early site permit, or any later renewal period, the permit holder may apply for a renewal of the permit. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application.

(b) Any person whose interests may be affected by renewal of the permit may request a hearing on the application for renewal. The request for a hearing must comply with § 2.309 of this chapter. If a hearing is granted, notice of the hearing will be

published under § 2.309 of this chapter.

(c) An early site permit, either original or renewed, for which a timely application for renewal has been filed, remains in effect until the Commission has determined whether to renew the permit. If the permit is not renewed, it continues to be valid in certain proceedings in accordance with the provisions of § 53.1164(b).

(d) The Commission must refer a copy of the application for renewal to the ACRS. The ACRS must report on those portions of the application which concern safety and must apply the criteria set forth in § 53.1176.

§ 53.1176 Criteria for renewal.

(a) The Commission must grant the renewal only if it determines that—

(1) The site complies with the Act, the Commission's regulations, and orders applicable and in effect at the time the site permit was originally issued; and

(2) Any new requirements the Commission may wish to impose—

(i) Are necessary for adequate protection to public health and safety or common defense and security;

(ii) Are necessary for compliance with the Commission's regulations, and orders applicable and in effect at the time the site permit was originally issued; or

(iii) Would provide a substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementation of those requirements are justified in view of this increased protection.

(b) A denial of renewal under the provisions of § 53.1176(a) does not bar the permit holder or another applicant from filing a new application for the site which proposes changes to the site or the way that it is used to correct the deficiencies cited in the denial of the renewal.

§ 53.1179 Duration of renewal.

Each renewal of an early site permit may be for not less than 10, nor more than 20 years, plus any remaining years on the early site permit then in effect before renewal.

§ 53.1182 Use of site for other purposes.

A site for which an early site permit has been issued under this part may be used for purposes other than those described in the permit, including the location of other types of energy facilities. The permit holder must inform the Director, Office of Nuclear Reactor Regulation (Director), of any significant uses for the site which have not been approved in the early site permit. The information about the activities must be given to the Director at least 30 days in advance of any actual construction or site modification for the activities. The information provided could be the basis for imposing new requirements on the permit, under the provisions of § 53.1188. If the permit holder informs the Director that the holder no longer intends to use the site for a commercial nuclear plant, the Director may terminate the permit.

§ 53.1188 Finality of early site permit determinations.

(a) *Commission finality*.

(1) While an early site permit is in effect under § 53.1164 or § 53.1179, the Commission may not change or impose new site characteristics, design parameters, or terms and conditions, including emergency planning requirements, on the early site permit unless the Commission—

(i) Determines that a modification is necessary to bring the permit or the site into compliance with the Commission's regulations and orders applicable and in effect at the time the permit was issued;

(ii) Determines the modification is necessary to assure adequate protection of the public health and safety or the common defense and security;

(iii) Determines that a modification is necessary based on an update under paragraph (b) of this section; or

(iv) Issues a variance requested under paragraph (d) of this section.

(2) In making the findings required for issuance of a construction permit (CP), combined license (COL), or operating license (OL), or the findings required by § 53.1452(g), or in any enforcement hearing other than one initiated by the Commission under paragraph (a)(1) of this section, if the application for the CP, COL, or OL references an early site permit, the Commission must treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the early site permit, except as provided for in paragraphs (b), (c), and (d) of this section.

(i) If the Commission grants a CP application that references an early site permit and an application for an OL or a COL references the CP, the Commission must treat as resolved those matters resolved in the proceeding for the issuance or renewal of the early site permit, except as provided for in paragraphs (b), (c), and (d) of this section.

(ii) If the early site permit approved an emergency plan (or major features thereof) that is in use by a licensee of a commercial nuclear plant, the Commission must treat as resolved changes to the early site permit emergency plan (or major features thereof) that are identical to changes made to the licensee's emergency plans under § 53.1565 occurring after issuance of the early site permit.

(iii) If the early site permit approved an emergency plan (or major features thereof) that is not in use by a licensee of a commercial nuclear plant, the Commission must treat as resolved changes that are equivalent to those that could be made under § 53.1565 without prior NRC approval had the emergency plan been in use by a licensee.

(b) *Updating of early site permit-emergency preparedness*. An applicant for a CP,

OL, or COL who has filed an application referencing an early site permit issued under this subpart must update the emergency preparedness information that was provided under § 53.1146(b) and discuss whether the updated information materially changes the bases for compliance with applicable NRC requirements.

(c) *Hearings and petitions*. (1) In any proceeding for the issuance of a CP, OL, or COL referencing an early site permit, contentions on the following matters may be litigated in the same manner as other issues material to the proceeding:

(i) The nuclear reactor proposed to be built does not fit within one or more of the site characteristics or design parameters included in the early site permit;

(ii) One or more of the terms and conditions of the early site permit have not been met;

(iii) A variance requested under paragraph (d) of this section is unwarranted or should be modified;

(iv) New or additional information is provided in the application that substantially alters the bases for a previous NRC conclusion or constitutes a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness; or

(v) Any significant environmental issue that was not resolved in the early site permit proceeding, or any issue involving the impacts of construction and operation of the facility that was resolved in the early site permit proceeding for which significant new information has been identified.

(2) Any person may file a petition requesting that the site characteristics, design parameters, or terms and conditions of the early site permit be modified, or that the permit be suspended or revoked. The petition will be considered under § 2.206 of this chapter. Before construction commences, the Commission must consider the petition

and determine whether any immediate action is required. If the petition is granted, an appropriate order will be issued. Construction under the CP or COL will not be affected by the granting of the petition unless the order is made immediately effective. Any change required by the Commission in response to the petition must demonstrate compliance with the requirements of paragraph (a)(1) of this section.

(d) *Variances*. An applicant for a CP, OL, or COL referencing an early site permit may include in its application a request for a variance from one or more site characteristics, design parameters, or terms and conditions of the early site permit, or from the Site Safety Analysis Report. In determining whether to grant the variance, the Commission must apply the same technically relevant criteria applicable to the application for the original or renewed early site permit. Once a CP or COL referencing an early site permit is issued, variances from the early site permit will not be granted for that CP or COL.

(e) *Early site permit amendment*. The holder of an early site permit may not make changes to the early site permit or the Site Safety Analysis Report without prior Commission approval. The request for a change to the early site permit must be in the form of an application for a license amendment and must demonstrate compliance with the requirements of §§ 53.1510 and 53.1520.

§ 53.1200 Standard design approvals.

Sections 53.1200 through 53.1221 set out procedures for the filing, NRC staff review, and referral to the ACRS of standard designs, or major portions thereof, for a commercial nuclear plant under this part.

§ 53.1203 Filing of applications.

Any person may submit a proposed standard design for a commercial nuclear plant to the NRC staff for its review. The submittal may consist of either the final design

for the entire facility or the final design for major portions thereof.

§ 53.1206 Contents of applications for standard design approvals; general information.

The application must contain all of the information required by § 53.1109(a) through (c) and (j).

§ 53.1209 Contents of applications for standard design approvals; technical information.

(a) *Major portions of a standard design.* If the applicant seeks review of major portions of a standard design, the application need only contain the information required by this section to the extent the requirements are applicable to the major portions of the standard design for which NRC staff approval is sought. If an applicant seeks approval of major portions of the design, the scope of the application for which approval is sought must include all functional design criteria necessary to demonstrate compliance with the safety criteria in §§ 53.210, 53.220 and 53.450(e), as applicable, for the major portions of the standard design for which NRC staff approval is sought. Such applicants must identify conditions related to interfaces with systems outside the scope of the major portions of the standard design for which NRC staff approval is sought, and functional or physical boundary conditions between the major portions of the standard design for which NRC staff approval is sought and the remainder of the standard design. These conditions must be demonstrated when the standard design approval is incorporated into a subsequent construction permit (CP), design certification, manufacturing license (ML), operating license (OL), or combined license (COL) application.

(b) *Final Safety Analysis Report.* The application must contain a final safety analysis report (FSAR) that describes the facility and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility,

or major portions thereof, for which the applicant seeks design approval, and must include the following information:

(1) *Site Parameters*. The site parameters postulated for the design under this part, including the design-basis external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters.

(2) *Design information.* Except as specified in this paragraph, an application for a standard design approval for a commercial nuclear plant must include the design information equivalent to that required for a standard design certification under § 53.1239(a)(2) through (27) for those portions of a commercial nuclear plant included in the standard design approval.

§ 53.1210 Contents of applications for standard design approvals; other application content

(a) *Availability Controls (if not included in the FSAR)*. In addition to the final safety analysis report (FSAR), the application must also include the following a description of the controls on plant operations, including availability controls, to provide reasonable confidence that the configurations and special treatments for NSRSS SSCs provide the capabilities and reliabilities sufficient to demonstrate compliance with the safety criteria of § 53.220.

(b) If there are structures, systems, and components (SSCs) of the plant which required research and development to confirm the adequacy of their design, provide a report in the application which documents the resolution of any safety questions associated with such SSCs.

(c) A description of how the performance of each design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating

experience, or a combination thereof, in accordance with § 53.440(a).

§ 53.1212 Standards for review of applications.

Applications filed under this part will be reviewed under the standards set out in 10 CFR parts 20, 53, and 73.

§ 53.1215 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application which concern safety.

§ 53.1218 Staff approval of design.

(a) Upon completion of its review of a submittal under §§ 53.1200 through 53.1221 and receipt of a report by the ACRS under § 53.1215, the NRC staff must publish a determination in the *Federal Register* as to whether or not the design is acceptable, subject to appropriate terms and conditions, and make an analysis of the design in the form of a report available at the NRC Web site, https://www.nrc.gov.

(b) A standard design approval issued under this section is valid for 15 years from the date of issuance and may not be renewed. A design approval continues to be valid beyond the date of expiration in any proceeding on an application for a construction permit (CP), operating license (OL), combined license (COL), or manufacturing license (ML) under this part that references the design approval and is docketed before the date of expiration of the design approval.

§ 53.1221 Finality of standard design approvals; information requests.

(a) An approved design must be used by and relied upon by the NRC staff and the ACRS in their reviews of any standard design certification or individual facility license application under this part that incorporates by reference a standard design approved under this part unless there exists significant new information that substantially affects the earlier determination or other good cause.

(b) The determination and report by the NRC staff do not constitute a commitment to issue a permit or license, or in any way affect the authority of the Commission, Atomic Safety and Licensing Board Panel, or presiding officers in any proceeding under part 2 of this chapter.

(c) Except for information requests seeking to verify compliance with the current licensing basis of the standard design approval, information requests to the holder of a standard design approval must be evaluated before issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each evaluation performed by the NRC staff must be in accordance with § 53.1580 and must be approved by the Executive Director for Operations or authorized designee before issuance of the request.

§ 53.1230 Standard design certifications.

Sections 53.1230 through 53.1263 set forth the requirements and procedures applicable to the Commission's issuance of rules granting standard design certifications for commercial nuclear plants under this part separate from the filing of an application for a construction permit or combined license for such a facility.

§ 53.1233 Filing of applications.

(a) An application for design certification may be filed notwithstanding the fact that an application for a construction permit, combined license, or manufacturing license for such a facility has not been filed.

(b) The application must comply with the applicable filing requirements of § 53.040 and §§ 2.811 through 2.819 of this chapter.

§ 53.1236 Contents of applications for standard design certifications; general information.

The application must contain all of the information required by § 53.1109(a)

through (c) and (j).

§ 53.1239 Contents of applications for standard design certifications; technical information.

The application must contain a level of design information sufficient to enable the Commission to judge the applicant's proposed means of assuring that construction conforms to the design and to reach a final conclusion on all safety questions associated with the design before the certification is granted. The information submitted for a design certification must include performance requirements and design information sufficiently detailed to permit the preparation of acceptance and inspection requirements by the NRC, and procurement specifications and construction and installation specifications by an applicant. The Commission will require, before design certification, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if the information is necessary for the Commission to make its safety determination.

(a) *Final Safety Analysis Report.* The application must contain a final safety analysis report (FSAR) that describes the facility and the limits on its operation, and presents a safety analysis of the structures, systems, and components (SSCs) and of the facility as a whole, and must include the following information:

(1) *Site Parameters*. The site parameters postulated for the design under this part, including the design-basis external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters.

(2*)*(i) *General Plant Description*. A general description of the commercial nuclear plant including reactor type, the intended use of the reactor, nuclear design (e.g., neutron spectrum, reactor control, multi-unit reactor control), overall layout of the plant including significant plant features and SSCs, maximum power level and the nature and

inventory of radioactive materials.

(ii) *Safety functions*. A description of the primary and additional safety functions under § 53.230 and a summary of how each safety function is satisfied.

(3) *Design Features and functional design criteria – licensing-basis events*. (i) A description of the design features required by § 53.400 and the functional design criteria required by §§ 53.410 and 53.420 that, when combined with corresponding human actions and programmatic controls, demonstrate that the plant will demonstrate compliance with the safety criteria defined in §§ 53.210 and 53.220 during LBEs.

(ii) A description of how design features demonstrate compliance with the requirements of § 53.440(a) through (i) and (k) through (m).

(4) *Design Features and Functional Design Criteria – Normal Operations*. A description of the design features and functional design criteria required by § 53.425 to demonstrate compliance with § 53.260 during normal operations.

(5) *Design Features and Functional Design Criteria – aircraft impact*. A description of the design features and functional design criteria required to demonstrate compliance with the requirements of § 53.440(j) for addressing the impact of a large, commercial aircraft.

(6) *Earthquake engineering*. The information necessary to demonstrate that the commercial nuclear plant complies with the earthquake engineering criteria in § 53.480.

(7) *Programmatic Controls and Interfaces*. (i) A description of the corresponding programmatic controls and interfaces necessary to achieve and maintain the reliability and capability of SSCs relied upon to demonstrate compliance with the functional design criteria required by §§ 53.410 and 53.420 and the safety criteria in §§ 53.210 and 53.220 and necessary to maintain consistency with analyses required by § 53.450.

(ii) For an application for a multi-unit commercial nuclear plant, the programmatic

controls and interfaces must also be described for different modular configurations, as required by § 53.440(i), including any restrictions that will be necessary during the construction and startup of any given unit to ensure the safe operation of the overall commercial nuclear plant to be licensed under this part.

(8) *Programmatic Controls for Normal Operations*. A description of the corresponding programmatic controls, including monitoring programs, necessary to demonstrate that that the criteria defined in § 53.260 are satisfied during normal operations.

(9) *Design Features and Functional Design Criteria for the Protection of Plant Workers*. A description of the design features and functional design criteria required by § 53.430 to demonstrate compliance with § 53.270.

(10) [Reserved].

(11) *Codes and Standards*. A description of generally accepted consensus codes and standards used to design the design features.

(12) *Materials*. A description of the materials used for safety-related (SR) and non-safety-related but safety-significant (NSRSS) SSCs and a description of the qualification of these materials for their service conditions over the plant lifetime, as required by § 53.440(c) and evaluated under § 53.440(d).

(13) [Reserved].

(14) *Safety and Security*. Confirmation that safety and security were considered together in the design process, as required by § 53.440(f).

(15) *Criticality*. Information demonstrating how the applicant will comply with requirements for criticality accidents in § 53.440(m).

(16) For an application for standard design certification of a multi-unit commercial nuclear plant, the possible operating configurations of the reactor units, including

common systems, interface requirements, and system interactions, as required by § 53.440(i).

(17)(i) The classification of SSCs according to their safety significance under § 53.460(a).

(ii) For SR and NSRSS SSCs, the conditions under which they must perform the safety functions required by § 53.230, including environmental conditions.

(18) *Risk Evaluation*. A description of the risk evaluation required by § 53.450(a) and its results.

(19) *Analyses*. A description of the analyses performed under § 53.450(b) through (g) that includes the following information:

(i) A description of the analysis of licensing-basis events (LBEs) and its results, as described in § 53.240. This analysis description must—

(A) Address the elements in § 53.450(e) and (f); and

(B) under § 53.460(c) —

(*1*) Describe any human actions that are necessary to prevent or mitigate LBEs;

(*2*) Describe how those human actions are capable of being reliably performed under the postulated environmental conditions present; and

(*3*) Describe how those human actions would be addressed by programs established under subpart F of this part.

(ii)(A) A description of how SSCs relied on to meet the safety criteria defined in § 53.210 are protected against or designed to withstand the effects of external hazards under § 53.415.

(B) The information necessary to demonstrate that the commercial nuclear plant complies with the earthquake engineering criteria in § 53.480.

(iii) A description of the defense-in-depth measures required by § 53.250.

(iv) A description of all plant operating states where there is the potential for the uncontrolled release of radioactive material to the environment, as required by § 53.450(b)(4).

(v) A description of the events that challenge plant control and safety systems whose failure could lead to an undesirable end state and/or radioactive material release, as required by § 53.450(b)(5).

(vi) A description of the analytical codes used in modeling plant behavior in analyses of LBEs and how these codes are qualified for the range of conditions for which they were used, as required by § 53.450(d).

(vii) If not described in addressing paragraph (a)(5) of this section, the results of other analyses required by § 53.450(g).

(20) *Special Treatments*. A description of special treatments established as required by § 53.460.

(21) [Reserved].

(22) *Quality Assurance.* A description of the quality assurance program (QAP) applied to the design of the SSCs of the commercial nuclear plant, as required by § 53.460(b). The description of the QAP for a commercial nuclear plant must include a discussion of how the applicable requirements of appendix B to part 50 of this chapter were satisfied.

(23) *Design Features and Controls to Address the Minimization of Contamination.* The information required by § 20.1406 of this chapter.

(24) *Interface Requirements*. (i) A description, analysis, and evaluation of the interfaces between the standard design and the balance of the commercial nuclear plant that may impact the ability of the plant to demonstrate compliance with the functional design criteria or the safety criteria of subparts B and C of this part.

(ii) Confirmation that interface requirements are verifiable through inspections, testing, or analysis. These requirements must be sufficiently detailed to allow for completion of the final safety analysis by license applicants that reference the certified design under this subpart. The method to be used for verification of interface requirements must be included as part of the proposed inspections, tests, analyses, and acceptance criteria required by § 53.1241(a)(3).

(iii) A representative conceptual design for those portions of the plant for which the application does not seek certification to aid the NRC in its review of the FSAR and to permit assessment of the adequacy of the interface requirements under paragraph (a)(24)(i) of this section.

(25) *Technical Qualifications*. A description of the technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter.

(26) *Technical Specifications*. Proposed technical specifications prepared under § 53.710(a) for those areas addressed by the design certification.

(27) *Role of personnel.* Information to address the following for the role of personnel in ensuring safe operations:

(i) A description of how the human factors engineering design requirements of § 53.440(n)(1) are addressed;

(ii) A description of how the human system interface design requirements of § 53.440(n)(2) are addressed;

(iii) A concept of operations that is of sufficient scope and detail to address the requirements of § 53.440(n)(3);

(iv) A functional requirements analysis and function allocation that is of sufficient scope and detail to address the requirements of § 53.440(n)(4).

(28) *Load following*. For commercial nuclear plants that will operate in a load following mode, information to address the requirements of § 53.440(o).

(b) [Reserved]

§ 53.1241 Contents of applications for standard design certifications; other application content.

(a) In addition to the final safety analysis report (FSAR), the application must also include the following:

(1) *Environmental report*. An environmental report as required by § 51.55 of this chapter.

(2) *Availability Controls* (if not included in the FSAR). A description of the controls on plant operations, including availability controls, to provide reasonable confidence that the configurations and special treatments for non-safety related but safety-significant (NSRSS) structures, systems, and components (SSCs) provide the capabilities and reliabilities required to demonstrate compliance with the safety criteria of § 53.220, or more restrictive alternative criteria adopted under § 53.470.

(3) *Inspections, tests, analyses, and acceptance criteria.* The proposed inspections, tests, analyses, and acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, a facility that incorporates the design certification has been constructed and will be operated in conformity with the design certification, the provisions of the Act, and the Commission's rules and regulations.

(b) If there are SSCs of the plant which required research and development to confirm the adequacy of their design, provide a report in the application which documents the resolution of any safety questions associated with such SSCs.

(c) A description of how the performance of each design feature has been

demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof, to meet the standard for review of § 53.090(d).

§ 53.1242 Review of applications.

(a*) Standards for review of applications.* Applications filed under this part will be reviewed for compliance with the standards set out in 10 CFR parts 20, 51, 53, and 73.

(b) *Administrative review of applications; hearings.* (1) A standard design certification is a rule that will be issued under the provisions of subpart H of 10 CFR part 2, as supplemented by the provisions of this section. The Commission must initiate the rulemaking after an application has been filed under § 53.1233 and must specify the procedures to be used for the rulemaking. The notice of proposed rulemaking published in the *Federal Register* must provide an opportunity for the submission of comments on the proposed design certification rule. If, at the time a proposed design certification rule is published in the *Federal Register* under this paragraph, the Commission decides that a legislative hearing should be held, the information required by § 2.1502(c) of this chapter must be included in the *Federal Register* document for the proposed design certification.

(2) Following the submission of comments on the proposed design certification rule, the Commission may, at its discretion, hold a legislative hearing under the procedures in subpart O of part 2 of this chapter. The Commission must publish a document in the *Federal Register* of its decision to hold a legislative hearing. The document must contain the information specified in § 2.1502(c) of this chapter and specify whether the Commission or a presiding officer will conduct the legislative hearing.

(3) Notwithstanding anything in § 2.390 of this chapter to the contrary, proprietary

information will be protected in the same manner and to the same extent as proprietary information submitted in connection with applications for licenses, provided that the design certification will be published in chapter I of this title.

(c) *Reference to an issued operating license or combined license*. In those cases where a design certification application is preceded by the issuance of an operating license or custom combined license for a commercial nuclear plant that is essentially the same as the standard design for which certification is being requested, the NRC review will follow the processes for referencing a standard design approval in § 53.1221, to the extent practicable.

§ 53.1245 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application which concern safety.

§ 53.1248 Issuance of standard design certification.

(a) After conducting a rulemaking proceeding under § 53.1242 on an application for a standard design certification and receiving the report to be submitted by the ACRS under § 53.1245, the Commission may issue a standard design certification in the form of a rule for the design that is the subject of the application, if the Commission determines that—

(1) The application demonstrates compliance with the applicable standards and requirements of the Act and the Commission's regulations;

(2) Notifications, if any, to other agencies or bodies have been duly made;

(3) There is reasonable assurance that the standard design conforms with the provisions of the Act and the Commission's regulations;

(4) The applicant is technically qualified;

(5) The proposed inspections, tests, analyses, and acceptance criteria are

necessary and sufficient, within the scope of the standard design, to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will be operated in accordance with the design certification, the provisions of the Act, and the Commission's regulations;

(6) Issuance of the standard design certification will not be inimical to the common defense and security or to the health and safety of the public;

(7) The findings required by subpart A of part 51 of this chapter have been made; and

(8) The applicant has implemented the quality assurance program described or referenced in the Safety Analysis Report.

(b) The design certification rule must specify the site parameters, design characteristics, and any additional requirements and restrictions of the design certification rule.

(c) After the Commission has adopted a final design certification rule, the applicant must not permit any individual to have access to or any facility or to possess restricted data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95, as applicable.

§ 53.1251 Reference to certification prior to granting.

An applicant for a construction permit, operating license, combined license, or manufacturing license under this part may, at its own risk, reference in its application a design for which a design certification application has been docketed but not granted.

§ 53.1263 Finality of standard design certifications.

(a)(1) The Commission may not modify, rescind, or impose new requirements on the certification information, whether on its own motion, or in response to a petition from

any person, unless the Commission determines in a rulemaking that the change—

(i) Is necessary either to bring the certification information or the referencing plants into compliance with the Commission's regulations applicable and in effect at the time the certification was issued;

(ii) Is necessary to provide adequate protection of the public health and safety or the common defense and security;

(iii) Reduces unnecessary regulatory burden and maintains protection to public health and safety and the common defense and security;

(iv) Provides the detailed design information to be verified under those inspections, tests, analyses, and acceptance criteria that are directed at certification information (i.e., design acceptance criteria);

(v) Is necessary to correct material errors in the certification information;

(vi) Substantially increases overall safety, reliability, or security of facility design, construction, or operation, and the direct and indirect costs of implementation of the rule change are justified in view of this increased safety, reliability, or security; or

(vii) Contributes to increased standardization of the certification information.

(2)(i) In a rulemaking under § 53.1263(a)(1), except for § 53.1263(a)(1)(ii), the Commission will give consideration to whether the benefits justify the costs for plants that are already licensed or for which an application for a permit or license is under consideration.

(ii) The rulemaking procedures for changes under § 53.1263(a)(1) must provide for notice and opportunity for public comment.

(3) Any modification the NRC imposes on a design certification rule under paragraph (a)(1) of this section will be applied to all plants referencing the certified design, except those to which the modification has been rendered technically irrelevant

by action taken under paragraphs (a)(4) or (b) of this section.

(4) The Commission may not impose new requirements by plant-specific order on any part of the design of a specific plant referencing the design certification rule if that part was approved in the design certification unless—

(i) A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time the certification was issued, or to assure adequate protection of the public health and safety or the common defense and security; and

(ii) Special circumstances as defined in § 53.080 are present. In addition to the factors listed in § 53.080, the Commission must consider whether the special circumstances which § 53.080 requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the plant-specific order.

(5) Except as provided in § 2.335 of this chapter, in making the findings required for issuance of a combined license (COL), construction permit (CP), operating license (OL), or manufacturing license (ML), or for any hearing under § 53.1452, the Commission must treat as resolved those matters resolved in connection with the issuance or renewal of a design certification rule.

(b) An applicant who references a design certification rule may request an exemption from one or more elements of the certification information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 53.080. In addition to the factors listed in § 53.080, the Commission must consider whether the special circumstances that § 53.080 requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. The granting of an exemption on request of an applicant is subject to litigation in the same manner as other issues in the OL or COL hearing.

(c) The Commission will require, before granting a CP, COL, OL, or ML that references a design certification rule, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if the information is necessary for the Commission to make its safety determination, including the determination that the application is consistent with the certification information. This information may be acquired by appropriate arrangements with the design certification applicant.

§ 53.1270 Manufacturing licenses.

Sections 53.1270 through 53.1295 set out the requirements and procedures applicable to Commission issuance of a license under this part authorizing manufacture of manufactured reactors to be installed at sites not identified in the manufacturing license application.

§ 53.1273 Filing of applications.

Any person, except one excluded by § 53.1118, may file an application for a manufacturing license under this part with the Director, Office of Nuclear Reactor Regulation.

§ 53.1276 Contents of applications for manufacturing licenses; general information.

Each application for a manufacturing license must include the information contained in § 53.1109(a) through (e), and (j).

§ 53.1279 Contents of applications for manufacturing licenses; technical information.

(a) *Final Safety Analysis Report-siting and design.* The application must include a final safety analysis report (FSAR) containing the information set forth below, with a level of design information sufficient to enable the Commission to judge the applicant's

proposed means of ensuring that the manufacturing conforms to the design and to reach a final conclusion on all safety questions associated with the design, permit the preparation of construction and installation specifications by an applicant who seeks to use the manufactured reactor, and permit the preparation of acceptance and inspection requirements by the NRC. The application must include the following information:

(1) *Site Parameters.* The site parameters postulated for the design under this part, including the design-basis external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters.

(2) *Design information.* Except as specified in this paragraph, the design information equivalent to that required for a standard design certification as defined in § 53.1239(a)(2) through (27) for those portions of a commercial nuclear plant included in the manufactured reactor.

(3) *Quality assurance program.* A description of the quality assurance program applied to the design and to be applied to the fabrication and testing of the structures, systems, and components (SSCs) of the manufactured reactor under § 53.620(a)(6), including a discussion of how the applicable requirements of appendix B to part 50 of this chapter have been and will be satisfied;

(4) *Conceptual designs*. Representative conceptual designs for one or more commercial nuclear plants using the manufactured reactor;

(5) *Operating configurations*. If multiple manufactured reactors may be installed at a commercial nuclear plant, a description of the possible operating configurations, including common systems, interface requirements, and system interactions. The final safety analysis must also account for differences among the possible configurations, including any restrictions that will be necessary during the construction and startup of a given manufactured reactor to ensure the safe operation of any reactor already

operating;

(6) *Interface requirements.* (i) The interface requirements between the manufactured reactor and the remaining portions of the commercial nuclear plant or connections to other facilities outside of the commercial nuclear plant.

(ii) Confirmation that interface requirements are verifiable through inspections, testing, or analysis. These requirements must be sufficiently detailed to allow for completion of the final safety analysis by license applicants that reference the manufactured reactor manufactured under this subpart. Applicants for a combined license (COL) under this part will need to verify the interface requirements at the installation site. The method to be used for verification of interface requirements must be included as part of the proposed inspections, tests, analyses, and acceptance criteria (ITAAC) required by § 53.1282(a).

(iii) Information to support development of radiation monitoring programs required under subpart F of this part by an applicant for a COL, including potential pathways for radionuclides produced within the manufactured reactor to enter interfacing systems.

(b) *Final Safety Analysis Report - Manufacturing information*. The FSAR must include the following information related to the manufacturing processes, organization, controls, and inspections:

(1) A description, including references to generally accepted consensus codes and standards, of the processes that will be used to procure, fabricate, and assemble components that make up the manufactured reactor. The description should clearly define which activities are proposed to be within the scope of the ML and those, such as the making of a component to be procured from a separate company for installation in the manufactured reactor, that are not considered to be within the scope of the ML;

(2) A description of the organizational and management structure singularly

responsible for direction of design and manufacture of the manufactured reactor. The information should include a description of the management plans, technical qualifications, and controls in place to demonstrate compliance with the requirements of § 53.620 for all facilities performing an activity within the scope of the ML;

(3) A description of the inspections and tests to be performed as part of the manufacturing process, including the inspection of procured components, inspection and testing of fabrication processes such as the molding, welding, or coating of components, and inspections and testing of the assembled manufactured reactor or portions of the manufactured reactor;

(4) A description of the fitness for duty program required by part 26 of this chapter and its implementation.

(c) *Deployment of the completed manufactured reactor*. The application must include the following information related to the deployment of a manufactured reactor:

(1) Procedures governing the preparation of the manufactured reactor or portions of the manufactured reactor for shipping to the site where it is to be operated; the conduct of shipping; and verifying the condition of the shipped items upon receipt at the site;

(2) A description of how the portions of the applicant's organization responsible for the design, manufacture, and installation of a manufactured reactor interact and how the applicant will facilitate interaction between them and any facility in which the manufactured reactor is to be installed;

(3) A description of the measures to be used for the control of interfaces, including the consideration of site parameters, between the holder of the ML and the holder of the COL for the commercial nuclear plant at which the manufactured reactor is to be installed.

(d) *Special considerations for factory fueling.* An application for a manufacturing license that authorizes fueling of the manufactured reactors at the factory must also include the following information related to the fueling operations and the required independent mechanisms to prevent inadvertent criticality and to otherwise ensure the safety of workers and the public during the manufacture, storage, and transport of each manufactured reactor module:

(1) A description of the safety program and integrated safety analysis required by subpart H of 10 CFR part 70. The description must include the procedures to be used for receipt, storage and loading of the fuel into the manufactured reactor. The description must either be in the form of a reference to the applicable part 70 application and license, if issued, or provided in the Safety Analysis Report supporting the manufacturing license if one application is used for both the manufacturing license and part 70 license.

(i) The application must specifically address the measures taken for fuel loading, in-factory inspections and non-nuclear testing, including at least two independent mechanisms each of which is sufficient to prevent inadvertent criticality, and an analysis of the safety and security of the fueled manufactured reactor within the factory, during possible periods of storage, and during transportation to the licensed site. The storage and transport of a fueled manufactured reactor must comply § 53.620(d) and 10 CFR parts 70, 71, and 73.

(ii) The application must specifically address the functional design criteria and design features included in the manufactured reactor, or physical or programmatic controls implemented during manufacturing, storage, or transport to prevent inadvertent criticality during various conditions, including when subject to potential hazards and human errors.

(2) A description of the procedures governing the transfer of authorities and

responsibilities for the fueled manufactured reactor from the holder of the ML to the holder of the COL for the installation site.

(3) A description of the controls under § 53.620 to address the receipt, storage, and loading of special nuclear material into a manufactured reactor, including:

(i) The fitness-for-duty program, under 10 CFR part 26.

(ii) A Radiation Protection Program under 10 CFR part 20.

(iii) An information security program under 10 CFR part 73.

(iv) A physical security program under 10 CFR part 73.

(v) A fire protection program under § 53.620(c)(2).

(vi) An emergency plan under § 53.620(c)(3).

(vii) A description of the plant staff training program under § 53.620(d).

§ 53.1282 Contents of applications for manufacturing licenses; other application content.

(a) *Inspections, tests, analyses, and acceptance criteria*. (1) The application must contain proposed inspections, tests, and analyses that the combined license holder must perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met:

(i) The reactor has been manufactured in conformity with the manufacturing license (ML), the provisions of the Act, and the Commission's rules and regulations; and

(ii) The manufactured reactor will be operated in conformity with the approved design and any license authorizing operation of the manufactured reactor.

(2) If the application references a standard design certification, the inspections, tests, analyses, and acceptance criteria (ITAAC) contained in the certified design must

apply to those portions of the facility design that are covered by the design certification.

(3) If the application references a standard design certification, the application may include a notification that a required inspection, test, or analysis in the design certification ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The *Federal Register* notification required by § 53.1285 must indicate that the application includes this notification.

(b) *Environmental report*. (1) The application must contain an environmental report as required by § 51.54 of this chapter.

(2) If the ML application references a standard design certification, the environmental report need not contain a discussion of severe accident mitigation design alternatives for the manufactured reactor as used in a commercial nuclear plant. Nonetheless, an application for an ML that references a standard design certification but includes the loading of fuel into the manufactured reactor at the factory must discuss severe accident mitigation design alternatives for the manufactured reactor while at the factory and must also discuss severe accident mitigation alternatives for the factory itself

(c) *Safeguards information*. An application for an ML authorizing loading of fuel into the manufactured reactor at the factory must contain a description of the program to protect safeguards information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

(d) *Performance demonstration.* A description of how the performance of each design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof, in accordance with § 53.090(d).

§ 53.1285 Review of applications.

(a) *Standards for review of applications.* Applications for manufacturing license under this part will be reviewed for compliance with the standards in 10 CFR parts 20, 26, 51, 53, and 73.

(b) *Administrative review of applications, hearings.* A proceeding on a manufacturing license (ML) is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing in § 2.101(a)(1) through (4) of this chapter, and the requirements for issuance of a notice of proposed action in § 2.105 of this chapter, *provided, howeve*r, that the designated sections may not be construed to require that the environmental report or draft or final environmental impact statement include an assessment of the benefits of constructing and/or operating the manufactured reactor or an evaluation of alternative energy sources. All hearings on MLs are governed by the hearing procedures contained in 10 CFR part 2, subparts C, E, G, L, and N.

§ 53.1286 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application which concern safety.

§ 53.1287 Issuance of manufacturing license.

(a) After completing any hearing under § 53.1285(b), and receiving the report submitted by the ACRS, the Commission may issue a manufacturing license (ML) if the Commission finds that—

(1) Applicable standards and requirements of the Act and the Commission's regulations have been met;

(2) There is reasonable assurance that the manufactured reactor will be manufactured, and can be transported, incorporated into a commercial nuclear plant, and operated in conformity with the ML, the provision of the Act, and the Commission's

regulations;

(3) The proposed manufactured reactor can be incorporated into a commercial nuclear plant and operated at sites having characteristics that fall within the site parameters postulated for the design of the manufactured reactors without undue risk to the health and safety of the public;

(4) The applicant is technically qualified to design and manufacture the proposed manufactured reactor;

(5) The proposed inspections, tests, analyses, and acceptance criteria are necessary and sufficient, within the scope of the ML, to provide reasonable assurance that the manufactured reactor has been manufactured and will be operated in conformity with the license, the provisions of the Act, and the Commission's regulations;

(6) The issuance of a license to the applicant will not be inimical to the common defense and security or to the health and safety of the public; and

(7) The findings required by subpart A of 10 CFR part 51 have been made.

(b) Each ML issued under this subpart must specify—

(1) Terms and conditions as the Commission deems necessary and appropriate;

(2) Technical specifications for operation of the manufactured reactor, as the Commission deems necessary and appropriate;

(3) Site parameters and design characteristics for the manufactured reactor;

(4) The interface requirements to be met by the site-specific elements of the facility, such as the energy conversions systems and ultimate heat sink, not within the scope of the manufactured reactor; and

(5) The entity with design authority for the manufactured reactor covered by the license.

§ 53.1288 Finality of manufacturing licenses.

(a)(1) Notwithstanding any provision in § 53.1590, during the term of a manufacturing license (ML) issued under this part the Commission may not modify, rescind, or impose new requirements on the design of the manufactured reactor, or the requirements for the manufacture of the manufactured reactor, unless the Commission determines that a modification is necessary to bring the design of the reactor or its manufacture into compliance with the Commission's requirements applicable and in effect at the time the ML was issued, or to provide reasonable assurance of adequate protection to public health and safety or common defense and security.

(2) Any modification to the design of a manufactured reactor that is imposed by the Commission under paragraph (a)(1) of this section will be applied to all manufactured reactors manufactured under the license, including those that have already been transported and sited, except those manufactured reactors to which the modification has been rendered technically irrelevant by action taken under § 53.1530 or paragraph (b) of this section.

(3) In making the findings required under this part for issuance of a combined license (COL), in any hearing under § 53.1452, or in any enforcement hearing other than one initiated by the Commission under paragraph (a)(1) of this section, for which a manufactured reactor manufactured under this subpart is referenced or used, the Commission must treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the ML, including the adequacy of design of the manufactured reactor, the costs and benefits of severe accident mitigation design alternatives, and the bases for not incorporating severe accident mitigation design alternatives into the design of the manufactured reactor to be manufactured.

(b) An applicant who references or uses a manufactured reactor manufactured under an ML under this part may include in the application a request for a departure from

the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The Commission may grant a request only if it determines that the departure will comply with the requirements of § 53.080, and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure. The granting of a departure on request of an applicant is subject to litigation in the same manner as other issues in the COL hearing.

§ 53.1291 Duration of manufacturing licenses.

A manufacturing license (ML) issued under this part is valid for not less than 5, nor more than 15 years from the date of issuance. Upon expiration of the ML, the manufacture of any uncompleted manufactured reactors must cease unless a timely application for renewal has been docketed with the NRC.

§ 53.1293 Transfer of manufacturing licenses.

A manufacturing license may be transferred under § 53.1570.

§ 53.1295 Renewal of manufacturing licenses.

(a)(1) Not less than 12 months, nor more than 5 years before the expiration of the manufacturing license (ML), or any later renewal period, the holder of the ML issued under this part may apply for a renewal of the license. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application.

(2) The filing of an application for a renewed license must be in accordance with subpart A of 10 CFR part 2 and § 53.1100.

(3) An ML issued under this part, either original or renewed, for which a timely application for renewal has been filed, remains in effect until the Commission has made a final determination on the renewal application. Upon a final determination by the Commission to deny a renewal application for an ML, the manufacture of any

uncompleted reactors must cease.

(4) Any person whose interest may be affected by renewal of the license may request a hearing on the application for renewal. The request for a hearing must comply with § 2.309 of this chapter. If a hearing is granted, notice of the hearing will be published in accordance with § 2.104 of this chapter.

(5) The Commission must refer a copy of the application for renewal to the ACRS. The ACRS must report on those portions of the application which concern safety.

(b) The Commission may grant the renewal if the Commission determines—

(1) The ML complies with the Act and the Commission's regulations and orders applicable and in effect at the time the ML was originally issued; and

(2) Any new requirements the Commission may wish to impose are—

(i) Necessary for adequate protection to public health and safety or common defense and security;

(ii) Necessary for compliance with the Commission's regulations and orders applicable and in effect at the time the ML was originally issued; or

(iii) A substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementation of those requirements are justified in view of this increased protection.

(c) A renewed ML may be issued for a term of not less than 5, nor more than 15 years, plus any remaining years on the ML then in effect before renewal. The renewed license must be subject to the requirements of §§ 53.1288 and 53.1293.

§ 53.1300 Construction permits.

Sections 53.1300 through 53.1348 set out the requirements and procedures applicable to Commission issuance of construction permits (CPs) for commercial nuclear

plants. A CP for the construction of a commercial nuclear plant under this part will be issued before the issuance of an operating license (OL) if the application is otherwise acceptable and will be converted upon completion of the facility and Commission action, into an OL as provided in §§ 53.1387.

§ 53.1306 Contents of applications for construction permits; general information.

An application for a construction permit (CP) must include the information required by § 53.1109 and the following information:

(a) Information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, under the regulations in this chapter, the activities for which the permit is sought. As applicable, the following should be provided:

(1) The applicant must submit information that demonstrates that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs, including estimates of the total construction costs and related fuel cycle costs of the facility and must indicate the source(s) of funds to cover these costs.

(2) Each application for a CP submitted by a newly-formed entity organized for the primary purpose of constructing and operating a facility must also include information showing:

(i) The legal and financial relationships the entity has or proposes to have with its stockholders or owners;

(ii) The stockholders' or owners' financial ability to meet any contractual obligation to the entity that they have incurred or proposed to incur.

(3) The Commission may request an established entity or newly-formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may

include information regarding an applicant's ability to continue the conduct of the activities authorized by the CP and to decommission the facility.

(b) If the applicant proposes to construct or alter a facility, the application must state the earliest and latest dates for completion of the construction or alteration.

§ 53.1309 Contents of applications for construction permits; technical information.

The application must contain a Preliminary Safety Analysis Report (PSAR) that describes the facility and the limits on its operation and presents a preliminary safety analysis of the structures, systems, and components (SSCs) of the facility as a whole. The PSAR must include the following information, at a level of detail sufficient to enable the Commission to reach a conclusion on safety matters that must be resolved by the Commission before issuance of a construction permit (CP):

(a)(1) *Site information.* An application for a CP for a commercial nuclear reactor must include the site information equivalent to that required for an early site permit in § 53.1146(a)(1)(iv) through (x).

(2) *Design information*. Except as specified in this paragraph, an application for a CP for a commercial nuclear plant must include the design information equivalent to that required for a standard design certification as defined in § 53.1239(a)(2) through (27).

(i) *Quality assurance program.* A description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility under § 53.610(a)(6), including a discussion of how the requirements of appendix B to part 50 of this chapter will be satisfied.

(ii) *Preliminary design information.* The information provided in the application may include some aspects of the design that are not fully developed, and the information is therefore preliminary. The completed design, including any changes during construction, must be described in the final safety analysis report (FSAR) required in

§ 53.1369 that supports an application for an operating license (OL).

(iii) *Planned research or testing*. Descriptions of how design features and related functional design criteria will fulfill the safety criteria in subpart B and how that has been or will be demonstrated through either analysis, appropriate test programs, experience, or a combination thereof. Where any design feature has not been fully developed or demonstrated to fulfill the functional design criteria at the time of an application for a CP, the applicant must provide a plan for future analysis, research and development, test programs, gathering of experience, or a combination thereof to provide reasonable confidence that the required demonstration will be available for an application for an OL

(iv) *Programmatic controls*. Descriptions of the programmatic controls may include those to be provided in the FSAR or other licensing basis documents because they are necessary to achieve and maintain the reliability and capability of SSCs relied upon to demonstrate compliance with the established safety criteria and functional design criteria required in subpart B, and to maintain consistency with analyses required by § 53.450.

(3) *Technical qualifications*. A description of the technical qualifications of the applicant to engage in the proposed activities under the regulations in this chapter.

(4) *Emergency preparedness*. A discussion of the applicant's preliminary plans for coping with emergencies. Appendix E to part 50 of this chapter sets forth items which shall be included in these plans.

(5) *Physical security*. A report that provides a preliminary description of how the site characteristics support the development of adequate security plans and measures consistent with the requirements in § 53.540.

(6) *Fitness-for-duty program*. A description of the fitness-for-duty program required by 10 CFR part 26 and its implementation.

(b)[Reserved].

§ 53.1312 Contents of applications for construction permits; other application content.

(a) In addition to the preliminary safety analysis report (PSAR), the application must include the following:

(1) An environmental report either under § 51.50(a) of this chapter if a limited work authorization (LWA) under § 53.1130 is not requested in conjunction with the construction permit (CP) application, or under §§ 51.49 and 51.50(a) of this chapter if an LWA is requested in conjunction with the CP application; or

(2) If the applicant wishes to request that an LWA under § 53.1130 be issued before issuance of the CP, the information otherwise required by § 53.1130, in accordance with either § 2.101(a)(1) through (a)(5), or § 2.101(a)(9) of this chapter.

(b) If the CP application references an early site permit, standard design approval, or standard design certification issued under this part, then the following requirements apply:

(1) The PSAR need not contain information or analyses submitted to the Commission in connection with the referenced NRC approval, permit, or certification, provided, however, that the PSAR incorporates the material by reference and confirms that the site and design of the facility falls within parameter values postulated in the referenced NRC approval, permit, or certification.

(2) The PSAR must provide a means to demonstrate that all terms and conditions that have been included in the referenced NRC approval, permit, or certification will be satisfied by the date of issuance of the operating license (OL), as appropriate. If the PSAR does not demonstrate that each site characteristic falls within the corresponding postulated site parameter and each design characteristic of the facility

falls within the corresponding postulated design parameter, the application must justify a departure, variance, or exemption from the referenced NRC approval, license, or certification in regard to that particular site or design characteristic in compliance with the requirements of this part.

(3) If a referenced early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the PSAR must include any new or additional information that updates and corrects the information that was provided under § 53.1146(b)(2) and discuss whether the new or additional information materially changes the bases for compliance with the applicable requirements.

§ 53.1315 Review of applications.

(a) *Standards for review of applications.* Applications filed under this part will be reviewed according to the standards set out in 10 CFR parts 20, 51, 53, 73, and 140.

(b) *Administrative review of applications; hearings*. A proceeding on a construction permit (CP) application is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). All hearings on CP applications are governed by the procedures contained in 10 CFR part 2.

§ 53.1318 Finality of referenced NRC approvals, permits, and certifications.

If the application for a construction permit under this part references an early site permit, standard design approval, or standard design certification, the scope and nature of matters resolved for the application are governed by the relevant provisions addressing finality, including §§ 53.1188, 53.1221, and 53.1263.

§ 53.1324 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application that concern safety and must apply the

standards referenced in § 53.1315, in accordance with the finality provisions in § 53.1318.

§ 53.1327 Authorization to conduct limited work authorization activities.

(a) If the application does not reference an early site permit which authorizes the holder to perform the activities under § 53.1130, the applicant may not perform those activities without obtaining the separate authorization required by § 53.1130. Authorization may be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by § 53.1130(b)(1)(ii) and (iv), and the Director, Office of Nuclear Reactor Regulation makes the determination required by § 53.1130(b)(1)(iii).

(b) If, after an applicant has performed the activities permitted by paragraph (a) of this section, the application for the construction permit is withdrawn or denied, then the applicant must implement an approved site redress plan.

§ 53.1330 Exemptions, departures, and variances.

(a) Applicants for a construction permit (CP) under this part, or any amendment to a CP, may include in the application a request for an exemption from one or more of the Commission's regulations. The Commission may grant a request if it determines that the exemption complies with § 53.080.

(b) An applicant for a CP who has filed an application referencing an NRC approval, permit, or certification issued under this part may include in the application a request for exemptions, departures, or variances related to the subject referenced NRC approval, permit, or certification. In determining whether to grant the departure, variance, or exemption, the Commission must apply the same technically relevant criteria as were applicable to the application for the original or renewed approval, license, or certification.

§ 53.1333 Issuance of construction permits.

(a) After conducting a hearing in accordance with § 53.1315 and receiving the report submitted by the ACRS, the Commission may issue a construction permit (CP) only if the Commission finds that—

(1) The applicant has described the proposed design of the facility and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report;

(3) Safety features or components, if any, that require research and development have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components; and

(4) On the basis of the foregoing, there is reasonable assurance of the following—

(i) Such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility; and

(ii) Taking into consideration the site criteria contained subpart D, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

(b) A CP must contain the terms and conditions for the permit, as the Commission deems necessary and appropriate. The Commission may, in its discretion, incorporate in any CP provisions requiring the applicant to furnish periodic reports of the progress and results of research and development programs designed to resolve safety questions.

§ 53.1336 Finality of construction permits.

Notwithstanding any provision in § 53.1590, a construction permit (CP) constitutes an authorization to proceed with construction but does not constitute Commission approval of the safety of any design feature or specification unless the applicant specifically requests such approval and such approval is incorporated in the permit. The applicant, at its option, may request such approvals in the CP or by amendment to the CP. If approved by the NRC and included in the permit, the NRC will consider modifications to the approved design features or specifications in accordance with § 53.1590.

§ 53.1342 Duration of construction permit.

(a) A construction permit (CP) will state the earliest and latest dates for completion of construction or alteration of the facility, not to exceed 40 years from date of issuance.

(b) If the proposed construction or alteration of the facility is not completed by the latest completion date, the CP shall expire, and all rights are forfeited. However, upon good cause shown, the Commission will extend the completion date for a reasonable period of time. The Commission will recognize, among other things, developmental problems attributed to the experimental nature of the facility or fire, flood, explosion, strike, sabotage, domestic violence, enemy action, an act of the elements, and other acts beyond the control of the permit holder, as a basis for extending the completion date.

§ 53.1345 Transfer of construction permits.

A construction permit (CP) may be transferred under § 53.1570.

§ 53.1348 Termination of construction permits.

When a permit holder has determined to permanently cease construction, the

holder must, within 30 days, submit a written certification to the NRC.

§ 53.1360 Operating licenses.

Sections 53.1360 through 53.1405 set out the requirements and procedures applicable to Commission issuance of an operating license for a nuclear power facility.

§ 53.1366 Contents of applications for operating licenses; general information.

An application for an operating license (OL) must include the information required by § 53.1109 and the following information:

(a) Except for an electric utility applicant, information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, in accordance with the regulations in this chapter, the activities for which the license is sought. As applicable, the following should be provided:

(1) The applicant must submit information that demonstrates the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license. The applicant must submit estimates for total annual operating costs for each of the first 5 years of operation of the facility. The applicant must also indicate the source(s) of funds to cover these costs.

(2) Each application for an OL submitted by a newly-formed entity organized for the primary purpose of operating the facility must also include information showing—

(i) The legal and financial relationships the entity has or proposes to have with its stockholders or owners;

(ii) The stockholders' or owners' financial ability to meet any contractual obligation to the entity which they have incurred or proposed to incur.

(3) The Commission may request an established entity or newly-formed entity to submit additional or more detailed information respecting its financial arrangements and

status of funds if the Commission considers this information appropriate. This may include information regarding a licensee's ability to continue the conduct of the activities authorized by the license and to decommission the facility.

(b) The application must include information in the form of a report, as described in subpart G, indicating how reasonable assurance will be provided that funds will be available to decommission the facility, including a copy of the financial instrument obtained to satisfy the requirements of § 53.1040.

§ 53.1369 Contents of applications for operating licenses; technical information.

(a) *Final Safety Analysis Report*. The application must contain a final safety analysis report (FSAR) that describes the facility and the limits on its operation and presents a safety analysis of the structures, systems, and components (SSCs) of the facility as a whole. The FSAR must include the following information, at a level of detail sufficient to enable the Commission to reach a final conclusion on all safety matters that must be resolved by the Commission before issuance of an operating license (OL). The FSAR must include the following information:

(1) *Site information*. An application for an OL for a commercial nuclear reactor must include the site information equivalent to that required for an early site permit in § 53.1146(a)(1)(iv) through (x), including all current information, such as the results of environmental and meteorological monitoring programs, which has been developed since issuance of the construction permit (CP), relating to site evaluation factors identified in this part.

(2) *Design information*. Except as specified in this paragraph, an FSAR for an OL for a commercial nuclear plant must include the final design information equivalent to that required for a standard design certification as defined in § 53.1239(a)(2) through (27).

(i) The completed design, including any changes during construction, must be described.

(ii) Where any design feature had not been fully developed or demonstrated at the time of application for the CP, the applicant must provide the analysis, research and development, test programs, gathering of experience, or a combination thereof to provide the required demonstration to fulfill the functional design criteria.

(3) *Technical qualifications*. A description of the technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter.

(4) *Safeguards information.* A description of the program to protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

(5) *Role of personnel.* (i) A description of the completed assessments related to the role of personnel in ensuring safe operations considering the analyses required by § 53.730. These assessments must include the following:

(*1*) Human factors engineering design requirements of § 53.440(n)(1);

(*2*) Human system interface design requirements of § 53.440(n)(2);

(*3*) Concept of operations of § 53.730(c);

(*4*) Functional requirements analysis and function allocation of § 53.730(d);

(ii) A description of the program to be used for evaluating and applying operating experience as required by § 53.730(e);

(iii) A staffing plan and supporting analyses as required by § 53.730(f).

(6) *Training, examination, and proficiency programs.* (i) A description of the training, examination, and proficiency programs required by § 53.730(g);

(ii) A description of the training programs required by § 53.830.

(7) *Emergency plan*. Emergency plans complying with the requirements of § 53.855.

(i) The emergency plan must include all emergency plan certifications, as applicable, that have been obtained from the State, local, and participating Tribal governmental agencies with emergency planning responsibilities that are wholly or partially within the emergency planning zone plume exposure pathway. These certifications must state that—

(*1*) The proposed emergency plans are practicable;

(*2*) These agencies are committed to participating in any further development of the plans, including any required field demonstrations; and

(*3*) These agencies are committed to executing their responsibilities under the plans in the event of an emergency.

(ii) If certifications cannot be obtained after sustained, good faith efforts by the applicant, then the application must contain information, including a utility plan, sufficient to show that the proposed plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site.

(iii) If complete and integrated emergency plans were submitted, reviewed, and approved as part of the CP application, new certifications that demonstrate compliance with the requirements of paragraph (i)(1) of this section are not required.

(8) *Organization.* A description of the applicant's organizational structure, allocations of responsibilities and authorities, and personnel qualifications requirements for operation.

(9) *Maintenance program*. A description of a maintenance program under § 53.715.

(10) *Quality assurance*. A description of the quality assurance program under

§ 53.865.

(11) *Radiation protection program*. A radiation protection program description under § 53.850.

(12) *Security program*. A physical security plan that describes how the applicant will comply with § 53.860 (and 10 CFR part 11, if applicable, including the identification and description of jobs as required by § 11.11(a) of this chapter, at the proposed facility). The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with the requirements of 10 CFR parts 11 and 73, if applicable.

(13) *Safeguards contingency plan*. A safeguards contingency plan in accordance with the criteria set forth in appendix C to 10 CFR part 73. The safeguards contingency plan must include plans for dealing with threats, thefts, and radiological sabotage, as defined in 10 CFR part 73, relating to the special nuclear material and nuclear facilities licensed under this chapter and in the applicant's possession and control. Each application for this type of license must include the information contained in the applicant's safeguards contingency plan. (Implementing procedures required for this plan need not be submitted for approval.)[1]

(14) *Security training and qualification*. A training and qualification plan that describes how the applicant will demonstrate compliance with the criteria set forth in § 73.100 of this chapter or appendix B to 10 CFR part 73.

(15) *Cyber security plan*. A cyber security plan in accordance with the criteria set forth in § 73.54 or § 73.110 of this chapter.

(16) *Security, safeguards and cyber security plan implementation*. A description of the implementation of the physical security plan, safeguards contingency plan, training and qualification plan, and cyber security plan. Each applicant who prepares a physical security plan, a safeguards contingency plan, a training and qualification plan, or a cyber

security plan must protect the plans and other related Safeguards Information against unauthorized disclosure in accordance with the requirements of §§ 73.21 and 73.22 of this chapter.

(17) *Fire protection program*. A description of the fire protection program under § 53.875.

(18) *Inservice inspection/inservice testing program*. A description of the inservice inspection/inservice testing program under § 53.880.

(19) *Fitness-for-duty program*. A description of the fitness-for-duty program required by 10 CFR part 26 and its implementation.

(20) *Other programs*. A description and evaluation of the results of the applicant's programs, including research and development, if any, to demonstrate that any safety questions identified at the CP stage have been resolved.

(21) *Safety design feature performance*. A description of how the performance of each safety design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof, in accordance with § 53.090(d).

(b) If the OL application references an early site permit, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the early site permit provided that the FSAR must either include or incorporate by reference the early site permit Site Safety Analysis Report and contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit.

(2) If the FSAR does not demonstrate that design of the facility falls within the site characteristics and design parameters, the application must include a request for a variance that complies with the requirements of §§ 53.1188(d) and 53.1384.

(3) The FSAR must demonstrate that all terms and conditions that have been included in the early site permit will be satisfied by the date of issuance of the OL. Any terms or conditions of the early site permit that could not be met by the time of issuance of the OL must be set forth as terms or conditions of the OL.

(4) If the early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the FSAR must include any new or additional information that updates and corrects the information that was provided under § 53.1146(b)(2) and discuss whether the new or additional information materially changes the bases for compliance with the applicable requirements. The application must identify changes to the emergency plans or major features of emergency plans that have been incorporated into the proposed facility emergency plans and that constitute or would constitute a change in an emergency plan that results in reducing the licensee's capability to perform an emergency planning function in the event of a radiological emergency.

(5) If complete and integrated emergency plans are approved as part of the early site permit, new certifications meeting the requirements of paragraph (a)(8)(i) of this section are not required.

(c) If the OL application references a standard design approval, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the design approval, provided, however, that the FSAR must either include or incorporate by reference the standard design approval FSAR and

must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the characteristics of the site fall within the site parameters specified in the design approval. In addition, the plant-specific risk evaluation must use the risk evaluation for the design approval and must be updated to account for site specific design information and any design changes or departures.

(2) The FSAR must demonstrate that all terms and conditions that have been included in the design approval will be satisfied by the date of issuance of the OL.

(d) If the OL application references a standard design certification, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the standard design certification, provided, however, that the FSAR must either include or incorporate by reference the standard design certification FSAR and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the standard design certification. In addition, the plant-specific risk evaluation must use the risk evaluation for the standard design certification and must be updated to account for site-specific design information and any design changes or departures.

(2) The FSAR must demonstrate that the interface requirements established for the design under § 53.1239(a)(24) have been met.

(3) The FSAR must demonstrate that all requirements and restrictions set forth in the referenced standard design certification rule must be satisfied by the date of issuance of the OL. Any requirements and restrictions set forth in the referenced standard design certification rule that could not be satisfied by the time of issuance of the OL, must be set forth as terms or conditions of the OL.

[1] A physical security plan that contains all the information required in both § 73.55 or § 73.100 of this chapter and appendix C to 10 CFR part 73 satisfies the requirement for a contingency plan.

§ 53.1372 Contents of applications for operating licenses; other application content.

In addition to the final safety analysis report (FSAR), the application must also include the following:

(a) *Environmental report*. An environmental report in accordance with § 51.53(b) of this chapter.

(b) *Availability controls (if not included in the FSAR*). A description of the controls on plant operations, including availability controls, to provide reasonable confidence of safe operation and that the configurations and special treatments for non-safety-related but safety significant structures, systems, and components provide the capabilities and reliabilities required to satisfy the safety criteria of § 53.220 if not addressed by Technical Specifications under § 53.710(a).

§ 53.1375 Review of applications.

(a) *Standards for review of applications.* Applications filed under this part will be reviewed according to the standards set out in 10 CFR parts 20, 26, 51, 53, 73, and 140.

(b) *Administrative review of applications; hearings*. A proceeding on an OL is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). All hearings on OLs are governed by the procedures contained in 10 CFR part 2.

§ 53.1381 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application that concern safety.

§ 53.1384 Exemptions, departures, and variances.

(a) Applicants for an operating license (OL) under this part, or any amendment to an OL, may include in the application a request for an exemption from one or more of the Commission's regulations. The Commission may grant an exemption request if it determines that the exemption complies with § 53.080.

(b) An applicant for an OL who has filed an application referencing an NRC approval, permit, license, or certification issued under this part may include in the application a request for departures, variances, or exemptions related to the subject referenced NRC approval, permit, license, or certification. In determining whether to grant the departure, variance, or exemption, the Commission must apply the same technically relevant criteria as were applicable to the application for the original or renewed approval, license, or certification.

§ 53.1387 Issuance of operating licenses.

Upon completion of the construction or alteration of a facility, in compliance with the terms and conditions of the construction permit and subject to any necessary testing of the facility for health or safety purposes, the Commission will, in the absence of good cause shown to the contrary, issue an operating license (OL) or an appropriate amendment of the license, as the case may be.

(a)(1) After receiving the report submitted by the ACRS, the Commission may issue an OL if the Commission finds that—

(i) Construction of the facility has been substantially completed in conformity with the CP and the application as amended, the provisions of the Act, and the rules and regulations of the Commission;

(ii) Any required notifications to other agencies or bodies have been duly made;

(iii) The facility will operate in conformity with the application as amended, the provisions of the Act, and the rules and regulations of the Commission;

(iv) There is reasonable assurance that—

(A) the activities authorized by the OL can be conducted without endangering the health and safety of the public; and

(B) such activities will be conducted in compliance with the regulations in this chapter.

(v) The applicant is technically and financially qualified to engage in the activities authorized, however, no finding of financial qualification is necessary for an electric utility applicant for an OL;

(vi) Issuance of the license will not be inimical to the common defense and security or to the health and safety of the public;

(vii) The applicable provisions of 10 CFR part 140 have been satisfied; and

(viii) The findings required by subpart A of 10 CFR part 51 have been made.

(2) [Reserved]

(b) [Reserved]

(c) The OL will include appropriate provisions with respect to any uncompleted items of construction and such limitations or conditions as are required to assure that operation during the period of the completion of such items will not endanger public health and safety.

(d) The Commission will issue an OL in such form and containing such conditions and limitations, including technical specifications, as it deems necessary and appropriate.

§ 53.1390 Finality of operating licenses.

(a) After issuance of an operating license (OL), the Commission may not modify, add, or delete any term or condition of the OL that are not derived from a referenced standard design certification, except in accordance with the provisions of § 53.1590.

(b) If the OL references a certified design, then changes to or departures from information within the scope of the referenced standard design certification rule are subject to the applicable change processes in that rule.

§ 53.1396 Duration of operating license.

The Commission will issue an operating license under this part for the term requested by the applicant, not to exceed 40 years from the date of issuance, or for the estimated useful life of the facility if the Commission determines that the estimated useful life is less than the term requested.

§ 53.1399 Transfer of an operating license.

An operating license may be transferred under § 53.1570.

§ 53.1402 Application for renewal.

The filing of an application for a renewed license must be in accordance with § 53.1595.

§ 53.1405 Continuation of an operating license.

Each operating license (OL) for a facility that has permanently ceased operations continues in effect beyond the expiration date to authorize ownership and possession of the facility until the Commission notifies the licensee in writing that the license is terminated. During this period of continued effectiveness, the licensee must—

(a) Take actions necessary to decommission and decontaminate the facility and continue to maintain the facility, including, where applicable, the storage, control, and maintenance of the spent fuel in a safe condition; and

(b) Conduct activities in accordance with all other restrictions applicable to the facility in accordance with the NRC's regulations and the provisions of the OL for the facility.

§ 53.1410 Combined licenses.

Sections 53.1410 through 53.1461 set out the requirements and procedures applicable to Commission issuance of combined licenses for commercial nuclear plants under this part.

§ 53.1413 Contents of applications for combined licenses; general information.

An application for a combined license must include the information required by § 53.1109 and the following information:

(a) Except for an electric utility applicant in regard to financial assurance required after a Commission finding under § 53.1452, the application must include information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, in accordance with the regulations in this chapter, the activities for which the permit or license is sought. As applicable, the following should be provided:

(1) The applicant must submit information that demonstrates that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs. The applicant must submit estimates of the total construction costs of the facility and related fuel cycle costs and must indicate the source(s) of funds to cover these costs.

(2) The applicant must submit information that demonstrates the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license. The applicant must submit estimates for total annual operating costs for each of the first 5 years of operation of the facility. The applicant must also indicate the source(s) of funds to cover these costs.

(3) Each application for a COL submitted by a newly-formed entity organized for the primary purpose of constructing and operating a facility must also include information showing—

(i) The legal and financial relationships the entity has or proposes to have with its

stockholders or owners; and

(ii) The stockholders' or owners' financial ability to meet any contractual obligation to the entity which they have incurred or proposed to incur.

(4) The Commission may request an established entity or newly-formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding a licensee's ability to continue the conduct of the activities authorized by the license and to decommission the facility.

(b) The application must include information in the form of a report, as described in subpart G of this part, indicating how reasonable assurance will be provided that funds will be available to decommission the facility.

§ 53.1416 Contents of applications for combined licenses; technical information.

(a) *Final Safety Analysis Report*. The application must contain a final safety analysis report (FSAR) that describes the facility and the limits on its operation and presents a safety analysis of the structures, systems, and components (SSCs) of the facility as a whole. The Commission will require, before issuance of a combined license (COL), that engineering documents, such as analyses, drawings, procurement specifications, or construction and installation specifications, be completed and available for audit if the more detailed information is necessary for the Commission to verify the information in the application and make its safety determination. The FSAR must include the following information, at a level of detail sufficient to enable the Commission to reach a final conclusion on all safety matters that must be resolved by the Commission before issuance of a COL:

(1) *Site information*. An application for a COL for a commercial nuclear reactor must include the site information required for an early site permit in § 53.1146(a)(1)(iv)

through (x).

(2) *Design information*. An application for a COL for a commercial nuclear plant must include the design information equivalent to that required for a standard design certification as defined in § 53.1239(a)(2) through (27).

(3) *Technical qualifications*. A description of the technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter.

(4) *Safeguards information*. A description of the program to protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable. (5) *Role of personnel*. (i) A description of the completed assessments related to the role of personnel in ensuring safe operations considering the analyses required by § 53.730. These assessments must include the following:

(A) Human factors engineering design requirements of § 53.440(n)(1);

(B) Human system interface design requirements of § 53.440(n)(2);

(C) Concept of operations of § 53.730(c); and

(D) Functional requirements analysis and function allocation of § 53.730(d);

(ii) A description of the program to be used for evaluating and applying operating experience as required by § 53.730(e);

(iii) A staffing plan and supporting analyses as required by § 53.730(f).

(6) *Training, examination, and proficiency programs.* (i) A description of the training, examination, and proficiency programs required by § 53.730(g); and

(ii) A description of the training programs required by § 53.830.

(7) *Emergency plan*. Emergency plans complying with the requirements of § 53.855.

(i) The emergency plans must include, as applicable, all emergency plan certifications that have been obtained from the State, local and participating Tribal governmental agencies with emergency planning responsibilities. These certifications must state that—

(A) The proposed emergency plans are practicable;

(B) These agencies are committed to participating in any further development of the plans, including any required field demonstrations; and

(C) These agencies are committed to executing their responsibilities under the plans in the event of an emergency.

(ii) If certifications cannot be obtained after sustained, good faith efforts by the applicant, then the application must contain information, including a utility plan, sufficient to show that the proposed plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site.

(8) *Organization.* A description of the applicant's organizational structure, allocations of responsibilities and authorities, and personnel qualifications requirements for operation.

(9) *Maintenance program*. A description of a maintenance program under § 53.715.

(10) *Quality assurance*. A description of the quality assurance program under § 53.865.

(11) *Radiation protection program*. A radiation protection program description under § 53.850.

(12) *Security program*. A physical security plan that describes how the applicant will comply with § 53.860 (and 10 CFR part 11, if applicable, including the identification and description of jobs as required by § 11.11(a) of this chapter, at the proposed facility).

The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with the requirements of 10 CFR parts 11 and 73, if applicable.

(13) *Safeguards contingency plan*. A safeguards contingency plan in accordance with the criteria set forth in appendix C to 10 CFR part 73. The safeguards contingency plan must include plans for dealing with threats, thefts, and radiological sabotage, as defined in 10 CFR part 73, relating to the special nuclear material and nuclear facilities licensed under this chapter and in the applicant's possession and control. Each application for this type of license must include the information contained in the applicant's safeguards contingency plan.[1] (Implementing procedures required for this plan need not be submitted for approval.)

(14) *Security training and qualification*. A training and qualification plan that describes how the applicant will demonstrate compliance with the criteria set forth in § 73.100 of this chapter or appendix B to 10 CFR part 73.

(15) *Cyber security plan*. A cyber security plan in accordance with the criteria set forth in § 73.54 or § 73.110 of this chapter.

(16) *Security, safeguards and cyber security plan implementation*. A description of the implementation of the physical security plan, safeguards contingency plan, training and qualification plan, and cyber security plan. Each applicant who prepares a physical security plan, a safeguards contingency plan, a training and qualification plan, or a cyber security plan must protect the plans and other related Safeguards Information against unauthorized disclosure in accordance with the requirements of §§ 73.21 and 73.22 of this chapter.

(17) *Fire protection program*. A description of the fire protection program under § 53.875.

(18) *Inservice inspection/inservice testing program*. A description of the inservice

inspection/inservice testing program under § 53.880.

(19) *Fitness-for-duty program*. A description of the fitness-for-duty program under part 26 of this chapter and its implementation.

(b) If there are SSCs of the plant for which research and development is necessary to confirm the adequacy of their design, a report which documents the resolution of any safety questions associated with such SSCs.

(c) A description of how the performance of each safety design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof, in accordance with § 53.090(d).

(d) If the COL application references an early site permit, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the early site permit provided that the FSAR must either include or incorporate by reference the early site permit Site Safety Analysis Report and contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit.

(2) If the FSAR does not demonstrate that design of the facility falls within the site characteristics and design parameters, the application must include a request for a variance that complies with the requirements of §§ 53.1188(d) and 53.1437.

(3) The FSAR must demonstrate that all terms and conditions that have been included in the early site permit will be satisfied by the date of issuance of the COL. Any terms or conditions of the early site permit that could not be met by the time of issuance of the COL must be set forth as terms or conditions of the COL.

(4) If the early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the FSAR must include any new or additional information that updates and corrects the information that was provided under § 53.1146(b)(2) and discuss whether the new or additional information materially changes the bases for compliance with the applicable requirements. The application must identify changes to the emergency plans or major features of emergency plans that have been incorporated into the proposed facility emergency plans and that constitute or would constitute a change in an emergency plan that results in reducing the licensee's capability to perform an emergency planning function in the event of a radiological emergency.

(5) If complete and integrated emergency plans are approved as part of the early site permit, new certifications meeting the requirements of paragraph (a)(9)(i) of this section are not required.

(e) If the COL application references a standard design approval, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the design approval, provided, however, that the FSAR must either include or incorporate by reference the standard design approval FSAR and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the characteristics of the site fall within the site parameters specified in the design approval. In addition, the plant-specific risk evaluation must use the risk evaluation for the design approval and must be updated to account for site specific design information and any design changes or departures.

(2) The FSAR must demonstrate that all terms and conditions that have been included in the design approval will be satisfied by the date of issuance of the COL.

(f) If the COL application references a standard design certification, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the standard design certification, provided, however, that the FSAR must either include or incorporate by reference the standard design certification FSAR and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the standard design certification. In addition, the plant-specific risk evaluation must use the risk evaluation for the standard design certification and must be updated to account for site-specific design information and any design changes or departures.

(2) The FSAR must demonstrate that the interface requirements established for the design under § 53.1239(a)(24) have been met.

(3) The FSAR must demonstrate that all requirements and restrictions set forth in the referenced standard design certification rule must be satisfied by the date of issuance of the COL. Any requirements and restrictions set forth in the referenced standard design certification rule that could not be satisfied by the time of issuance of the COL, must be set forth as terms or conditions of the COL.

(g) If the COL application references the use of one or more manufactured reactors licensed under § 53.1270, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the manufacturing license (ML), provided, however, that the FSAR must either include or incorporate by reference the ML FSAR and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters

specified in the ML. In addition, the plant-specific risk evaluation must use the risk evaluation for the manufactured reactor and must be updated to account for site-specific design information and any design changes or departures.

(2) The FSAR must demonstrate that the interface requirements established for the design have been met.

(3) The FSAR must demonstrate that all terms and conditions that have been included in the ML will be satisfied by the date of issuance of the COL. Any terms or conditions of the ML that could not be met by the time of issuance of the COL, must be set forth as terms or conditions of the COL.

[1] A physical security plan that contains all the information required in both § 73.55 or § 73.100 of this chapter and appendix C to 10 CFR part 73 demonstrates compliance with the requirement for a contingency plan.

§ 53.1419 Contents of applications for combined licenses; other application content.

(a) In addition to the final safety analysis report (FSAR), the application must also include the following:

(1) *Environmental report.*

(i) An environmental report either in accordance with § 51.50(c) of this chapter if a limited work authorization (LWA) under § 53.1130 is not requested in conjunction with the combined license (COL) application, or in accordance with §§ 51.49 and 51.50(c) of this chapter if an LWA is requested in conjunction with the COL application; or

(ii) If the applicant wishes to request that an LWA under § 53.1130 be issued before issuance of the COL, the information otherwise required by § 53.1130, in accordance with either § 2.101(a)(1) through (a)(4), or § 2.101(a)(9) of this chapter;

(2) *Availability controls (if not included in the FSAR).* A description of the controls on plant operations, including availability controls, to provide reasonable confidence of

safe operation and that the configurations and special treatments for non-safety-related but safety-significant structures, systems, and components provide the capabilities and reliabilities required to satisfy the safety criteria of § 53.220 if not addressed by Technical Specifications under § 53.710(a); and

(3) *Inspections, tests, analyses, and acceptance criteria.* The proposed inspections, tests, and analyses, including those applicable to emergency planning, that the licensee must perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will be operated in conformity with the COL, the provisions of the Act, and the Commission's rules and regulations.

(i) If the application references an early site permit with inspections, tests, analyses, and acceptance criteria (ITAAC), the early site permit ITAAC must apply to those aspects of the COL which are approved in the early site permit.

(ii) If the application references a standard design certification, the ITAAC contained in the certified design must apply to those portions of the facility design which are approved in the standard design certification.

(iii) If the application references a manufacturing license (ML), the ITAAC contained in the ML must apply to those portions of the facility design which are approved in the ML.

(iv) If the application references an early site permit with ITAAC, a standard design certification, an ML, or combination thereof, the application may include a notification that a required inspection, test, or analysis in the ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The *Federal Register* notification required by § 53.1422 of this chapter must indicate that

the application includes this notification.

(b) [Reserved]

§ 53.1422 Review of applications.

(a) *Standards for review of applications.* Applications filed under this part will be reviewed according to the standards set out in 10 CFR parts 20, 51, 53, 73, and 140.

(b) *Administrative review of applications; hearings*. A proceeding on a combined license (COL) is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). If an applicant requests a Commission finding on certain inspections, tests, analyses, and acceptance criteria (ITAAC) with the issuance of the COL, then those ITAAC will be identified in the notice of hearing. All hearings on COLs are governed by the procedures contained in 10 CFR part 2.

§ 53.1425 Finality of referenced NRC approvals.

If the application for a combined license (COL) under this part references an early site permit, standard design certification rule, standard design approval, or manufacturing license, issued under this part, the scope and nature of matters resolved for the application and any COL issued are governed by the relevant provisions addressing finality, including §§ 53.1188, 53.1221, 53.1263, and 53.1288.

§ 53.1431 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application that concern safety and must apply the standards referenced in § 53.1422, in accordance with the finality provisions in § 53.1425.

§ 53.1434 Authorization to conduct limited work authorization activities.

(a) If the application for a combined license (COL) under this part does not reference an early site permit which authorizes the holder to perform the activities under § 53.1130(b), the applicant may not perform those activities without obtaining the separate authorization required by § 53.1130(a). Authorization may be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by § 53.1130(b)(1)(ii) and (b)(1)(iv), and the Director, Office of Nuclear Reactor Regulation makes the determination required by § 53.1130(b)(1)(iii).

(b) If, after an applicant has performed the activities permitted by a limited work authorization issued under § 53.1130, the application for the COL is withdrawn or denied, then the applicant must implement the approved site redress plan.

§ 53.1437 Exemptions, departures, and variances.

(a) An applicant for a combined license (COL), or any amendment to a COL, may include in the application a request for an exemption from one or more of the Commission's regulations.

(1) If the request is for an exemption from any part of a referenced standard design certification rule, the Commission may grant the request if it determines that the exemption complies with any exemption provisions of the referenced standard design certification rule, or with § 53.1263 if there are no applicable exemption provisions in the referenced standard design certification rule.

(2) For all other requests for exemptions, the Commission may grant a request if it determines that the exemption complies with § 53.080.

(b) An applicant for a COL who has filed an application referencing an early site permit issued under § 53.1158 may include in the application a request for a variance from one or more site characteristics, design parameters, or terms and conditions of the permit, or from the Site Safety Analysis Report. In determining whether to grant the

variance, the Commission must apply the same technically relevant criteria as were applicable to the application for the original or renewed site permit. Once a COL referencing an early site permit is issued, variances from the early site permit will not be granted for that CP or COL.

(c) An applicant for a COL who has filed an application referencing a manufactured reactor may include in the application a request for a departure from one or more design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor under the manufacturing license issued under § 53.1287. The Commission may grant such a request only if it determines that the departure will comply with the requirements of § 53.080, and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure.

(d) Issuance of a variance under paragraph (b) of this section or a departure under paragraph (c) of this section is subject to litigation during the COL proceeding in the same manner as other issues material to that proceeding.

§ 53.1440 Issuance of combined licenses.

(a)(1) After conducting a hearing under § 53.1422(b) and receiving the report submitted by the ACRS, the Commission may issue a combined license (COL) if the Commission finds that—

(i) The applicable standards and requirements of the Act and the Commission's regulations have been met;

(ii) Any required notifications to other agencies or bodies have been duly made;

(iii) There is reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of the Act, and the Commission's regulations;

(iv) The applicant is technically and financially qualified to engage in the activities authorized; however, no finding of financial qualification is necessary for an electric utility applicant for a COL;

(v) Issuance of the license will not be inimical to the common defense and security or to the health and safety of the public; and

(vi) The findings required by subpart A of 10 CFR part 51 have been made.

(2) The Commission may also find, at the time it issues the COL, that certain acceptance criteria in one or more of the inspections, tests, analyses, and acceptance criteria in a referenced early site permit, standard design certification, or manufacturing license have been met. This finding will finally resolve that those acceptance criteria have been met, those acceptance criteria will be deemed to be excluded from the COL, and findings under § 53.1452(g) with respect to those acceptance criteria are unnecessary.

(b) The Commission must identify within the COL the inspections, tests, and analyses, including those applicable to emergency planning, that the licensee must perform, and the acceptance criteria that, if met, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's rules and regulations.

(c) A COL must contain the terms and conditions, including technical specifications, as the Commission deems necessary and appropriate.

§ 53.1443 Finality of combined licenses.

(a) After issuance of a combined license (COL), the Commission may not modify, add, or delete any term or condition of the COL, the design of the facility, the inspections, tests, analyses, and acceptance criteria contained in the license that are not

derived from a referenced standard design certification or manufacturing license (ML), except under the provisions of § 53.1452 or § 53.1590.

(b) If the COL does not reference a standard design certification or a manufactured reactor under a manufacturing license (ML) issued under § 53.1287, then a licensee may make changes subject to the applicable change processes in subpart I of this part.

(c) If the COL references a certified design, then—

(1) Changes to or departures from information within the scope of the referenced standard design certification rule are subject to the applicable change processes in that rule; and

(2) Changes that are not within the scope of the referenced standard design certification rule are subject to the applicable change processes in subpart I of this part unless they also involve changes to or noncompliance with information within the scope of the referenced standard design certification rule. In these cases, the applicable provisions of this section and the standard design certification rule apply.

(d) If the COL references a manufactured reactor under an ML issued under § 53.1287, then—

(1) Changes to or departures from information within the scope of the manufactured reactor's design are subject to the change processes in § 53.1288; and

(2) Changes that are not within the scope of the manufactured reactor's design are subject to the applicable change processes in subpart I.

(e) The Commission may issue and make immediately effective any amendment to a COL upon a determination by the Commission that the amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person. The amendment may be issued and made

immediately effective in advance of the holding and completion of any required hearing. The amendment will be processed under the procedures specified in § 53.1515.

(f) Any modification to, addition to, or deletion from the terms and conditions of a COL, including any modification to, addition to, or deletion from the inspections, tests, and analyses, or related acceptance criteria contained in the license is a proposed amendment to the license. There must be an opportunity for a hearing on the amendment.

§ 53.1449 Inspection during construction.

(a) *Licensee schedule for inspections, tests, or analyses*. The licensee must submit to the NRC, no later than 1 year after issuance of the combined license (COL) or at the start of construction as defined at § 53.020, whichever is later, its schedule for completing the inspections, tests, or analyses in the inspections, tests, analyses and acceptance criteria (ITAAC). The licensee must submit updates to the ITAAC schedules every 6 months thereafter and, within 1 year of its scheduled date for initial loading of fuel, the licensee must submit updates to the ITAAC schedule every 30 days until the final notification is provided to the NRC under paragraph (c)(1) of this section.

(b) *Licensee and applicant conduct of activities subject to ITAAC*. With respect to activities subject to an ITAAC, an applicant for a COL may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any one of the prescribed acceptance criteria are met.

(c) *Licensee notifications*. (1) *ITAAC closure notification*. The licensee must notify the NRC that prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria are met. The notification must contain sufficient information to demonstrate that the prescribed inspections, test, and analyses have

been performed and that the prescribed acceptance criteria are met.

(2) *ITAAC post-closure notifications*. Following the licensee's ITAAC closure notifications under paragraph (c)(1) of this section until the Commission makes the finding under § 53.1452(g), the licensee must notify the NRC, in a timely manner, of new information that materially alters the basis for determining that either inspections, tests, or analyses were performed as required, or that acceptance criteria are met. The notification must contain sufficient information to demonstrate that, notwithstanding the new information, the prescribed inspections, tests, and analyses have been performed as required, and the prescribed acceptance criteria are met.

(3) *Uncompleted ITAAC notification*. If the licensee has not provided, by the date 225 days before the scheduled date for initial loading of fuel, the notification required by paragraph (c)(1) of this section for all ITAAC, then the licensee must notify the NRC that the prescribed inspections, tests, or analyses for all uncompleted ITAAC will be performed and that the prescribed acceptance criteria will be met prior to operation. The notification must be provided no later than the date 225 days before the scheduled date for initial loading of fuel, and must provide sufficient information to demonstrate that the prescribed inspections, tests, or analyses will be performed and the prescribed acceptance criteria for the uncompleted ITAAC will be met, including, but not limited to, a description of the specific procedures and analytical methods to be used for performing the prescribed inspections, tests, and analyses and determining that the prescribed acceptance criteria are met.

(4) *All ITAAC complete notification*. The licensee must notify the NRC that all ITAAC are complete.

(d) *Licensee determination of noncompliance with ITAAC*. (1) In the event that an activity is subject to an ITAAC derived from a referenced standard design certification

and the licensee has not demonstrated that the prescribed acceptance criteria are met, the licensee may take corrective actions to successfully complete that ITAAC or request an exemption from the standard design certification ITAAC, as applicable. A request for an exemption must also be accompanied by a request for a license amendment under § 53.1443(f).

(2) In the event that an activity is subject to an ITAAC not derived from a referenced standard design certification and the licensee has not demonstrated that the prescribed acceptance criteria are met, the licensee may take corrective actions to successfully complete that ITAAC or request a license amendment under § 53.1443(f).

(e) *NRC inspection, publication of notices, and availability of licensee notifications*. The NRC must ensure that the prescribed inspections, tests, and analyses in the ITAAC are performed.

(1) At appropriate intervals until the last date for submission of requests for hearing under § 53.1452(a), the NRC must publish notices in the *Federal Register* of the NRC staff's determination of the successful completion of inspections, tests, and analyses.

(2) The NRC must make publicly available the licensee notifications under paragraph (c) of this section. The NRC must, no later than the date of publication of the notice of intended operation required by § 53.1452(a), make publicly available those licensee notifications under paragraph (c) of this section that have been submitted to the NRC at least 7 days before that notice.

§ 53.1452 Operation under a combined license.

(a) The licensee must notify the NRC of its scheduled date for initial loading of fuel no later than 270 days before the scheduled date and must notify the NRC of updates to its schedule every 30 days thereafter. For licensees installing fueled

manufactured reactors under a combined license (COL), the scheduled date for the initial loading of fuel is the scheduled date for completion of installation of the fueled manufactured reactor. Not less than 180 days before the date scheduled for initial loading of fuel into a plant by a licensee that has been issued a COL under this part, the Commission must publish notice of intended operation in the *Federal Register*. The notice must provide that any person whose interest may be affected by operation of the plant may, within 60 days, request that the Commission hold a hearing on whether the facility as constructed complies, or on completion will comply, with the acceptance criteria in the COL, except that a hearing must not be granted for those inspections, tests, analyses, and acceptance criteria (ITAAC) that the Commission found were met under § 53.1440(a)(2).

(b) A request for hearing under paragraph (a) of this section must show, *prima facie* that—

(1) One or more of the acceptance criteria of the ITAAC in the COL have not been, or will not be, met; and

(2) The specific operational consequences of nonconformance would be contrary to providing reasonable assurance of adequate protection of the public health and safety.

(c) The Commission, acting as the presiding officer, must determine whether to grant or deny the request for hearing under the applicable requirements of § 2.309 of this chapter. If the Commission grants the request, the Commission, acting as the presiding officer, must determine whether during a period of interim operation there will be reasonable assurance of adequate protection to the public health and safety. The Commission's determination must consider the petitioner's *prima facie* showing and any answers thereto. If the Commission determines there is such reasonable assurance, it

must allow operation during an interim period under the COL.

(d) The Commission, in its discretion, must determine appropriate hearing procedures, whether informal or formal adjudicatory, for any hearing under paragraph (a) of this section, and must state its reasons therefore.

(e) The Commission must, to the maximum possible extent, render a decision on issues raised by the hearing request within 180 days of the publication of the notice provided by paragraph (a) of this section or by the anticipated date for initial loading of fuel into the reactor, whichever is later.

(f) A petition to modify the terms and conditions of the COL will be processed as a request for action under § 2.206 of this chapter. The petitioner must file the petition with the Secretary of the Commission. Before the licensed activity allegedly affected by the petition (fuel loading, low power testing, etc.) commences, the Commission must determine whether any immediate action is required. If the petition is granted, then an appropriate order will be issued. Fuel loading and operation under the COL will not be affected by the granting of the petition unless the order is made immediately effective.

(g) The licensee must not operate the facility until the Commission makes a finding that the acceptance criteria in the COL are met, except for those acceptance criteria that the Commission found were met under § 53.1440(a)(2). If the COL is for a modular design, each reactor unit may require a separate finding as construction proceeds.

(h) After the Commission has made the finding in paragraph (g) of this section, the ITAAC do not, by virtue of their inclusion in the COL, constitute regulatory requirements either for licensees or for renewal of the license; except for the specific ITAAC for which the Commission has granted a hearing under paragraph (a) of this section, all ITAAC expire upon final Commission action in the proceeding. However,

subsequent changes to the facility or procedures described in the FSAR (as updated) must comply with the requirements in § 53.1443(e) or (f), as applicable.

§ 53.1455 Duration of combined license.

(a) A combined license is issued for a specified period not to exceed 40 years from the date on which the Commission makes a finding that acceptance criteria are met under § 53.1452(g) or allowing operation during an interim period under the COL under § 53.1452(c).

(b) If the proposed construction or alteration of the facility is not completed by the latest completion date, the COL shall expire, and all rights are forfeited. However, upon good cause shown, the Commission will extend the completion date for a reasonable period of time. The Commission will recognize, among other things, developmental problems attributed to the experimental nature of the facility or fire, flood, explosion, strike, sabotage, domestic violence, enemy action, an act of the elements, and other acts beyond the control of the permit holder, as a basis for extending the completion date.

§ 53.1456 Transfer of a combined license.

A combined license may be transferred under § 53.1570.

§ 53.1458 Application for renewal.

The filing of an application for a renewed license must be in accordance with § 53.1595.

§ 53.1461 Continuation of combined license.

Each combined license (COL) for a facility that has permanently ceased operations continues in effect beyond the expiration date to authorize ownership and possession of the facility until the Commission notifies the licensee in writing that the license is terminated. During this period of continued effectiveness, the licensee must—

(a) Take actions necessary to decommission and decontaminate the facility and continue to maintain the facility, including, where applicable, the storage, control and maintenance of the spent fuel, in a safe condition; and

(b) Conduct activities in accordance with all other restrictions applicable to the facility in accordance with the NRC's regulations and the provisions of the COL for the facility.

§ 53.1470 Standardization of commercial nuclear plant designs: licenses to construct and operate nuclear power reactors of identical design at multiple sites.

(a) Except as otherwise specified in this section, the provisions of this section apply to construction permit (CP), operating license (OL), and combined license (COL) applications for commercial nuclear plants of identical design (the "common design") under this part.

(b) Each application for a CP, OL, or COL submitted pursuant to this section must be submitted as specified in subpart H of this part and § 2.101 of this chapter. Each application must state that the applicant wishes to construct a facility identical to a facility proposed for one or more sites other than the applicant's and the applicant wishes to have the application considered under this section. Each application must list each of the other applications to be treated together under this section.

(c) Each application must include the information required by the applicable sections of this subpart, *provided however*, that the application must identify the common design, and, if applicable, reference a standard design certification or standard design approval under this part, or the use of a reactor manufactured under this part. The final safety analysis report (FSAR) for each application must either incorporate by reference or include the final safety analysis of the common design, including, if applicable, the FSAR for the referenced standard design certification, standard design

approval, or the manufactured reactor.

(d) Each application submitted pursuant to this section must contain an environmental report under § 53.1312(a)(1), § 53.1372(a), or § 53.1419(a)(1), as applicable, that complies with the applicable provisions of 10 CFR part 51, *provided, however*, that the application may incorporate by reference a single environmental report on the environmental impacts of the common design that are applicable to each site.

(e) Upon a determination that each application is acceptable for docketing under § 2.101 of this chapter, each application will be docketed and a notice of docketing for each application will be published in the *Federal Register*, under § 2.104 of this chapter, *provided, however*, that the notice must state that the application will be processed under the provisions of this section and subpart D of 10 CFR part 2. At the discretion of the Commission, a single notice of docketing for multiple applications may be published in the *Federal Register.*

(f) The NRC must prepare an environmental assessment or draft and final environmental impact statements for each of the applications under 10 CFR part 51. Scoping under §§ 51.28 and 51.29 of this chapter for each of the license applications may be conducted simultaneously and joint scoping may be conducted with respect to the environmental issues relevant to the common design. If the applications reference a standard design certification, then the environmental assessment or environmental impact statement for each of the applications must incorporate by reference the standard design certification environmental assessment. If the applications do not reference a standard design certification, then the NRC must prepare environmental assessments or draft and final supplemental environmental impact statements which address severe accident mitigation design alternatives for the common design, which must be incorporated by reference into the environmental assessment or environmental impact

statement prepared for each application. Scoping under §§ 51.28 and 51.29 of this chapter for the supplemental environmental impact statement may be conducted simultaneously and may be part of the scoping for each of the applications.

(g) The ACRS must report on each of the applications as required by the applicable sections of this subpart. Each report must be limited to those safety matters for each application that are not relevant to the common design. In addition, the ACRS must separately report on the safety of the common design, *provided, however*, that the report need not address the safety of a referenced standard design certification or reactor manufactured under this part.

(h) The Commission must designate a presiding officer to conduct the proceeding with respect to the health and safety, common defense and security, and environmental matters relating to the common design and affecting at least two applications. The hearing will be governed by the applicable provisions of subparts A, C, G, L, N, and O of 10 CFR part 2 relating to applications for CPs, OLs, and COLs. The presiding officer must issue a partial initial decision on the common design.

(i) If the design for the power reactor(s) proposed in a particular application is not identical to the others, that application may not be processed under this section and subpart D of 10 CFR part 2.

(j) As used in this section, the design of a nuclear power reactor included in a single referenced Safety Analysis Report means the design of those structures, systems, and components important to radiological health and safety and the common defense and security.

Subpart I — Maintaining and Revising Licensing Basis Information

§ 53.1500 Licensing basis information.

This subpart provides the requirements for each holder of a license for a commercial nuclear plant licensed under this part to maintain licensing basis information as defined in § 53.020; evaluate changes to site characteristics, plant design features, and programmatic controls to determine needed approvals and revisions; and submit appropriate updates to the NRC.

§ 53.1502 Specific terms and conditions of licenses.

(a) Each license issued under this part is subject to the provisions of the Act and to all rules, regulations, and orders of the Commission. The terms and conditions of the license will be subject to amendment, revision, or modification, by reason of amendments of the Act or by reason of rules, regulations, and orders issued in accordance with the terms of the Act.

(b) Each license issued under this part must be subject to all conditions imposed as a matter of law by sections 401(a)(2) and 401(d) of the Federal Water Pollution Control Act, as amended (33 U.S.C.A. 1341(a)(2) and (d)).

(c) A holder of an operating license or combined license under this part may take reasonable action that departs from a license condition or a technical specification included in a license issued under this part in a national security emergency established by a law enacted by the Congress or by an order or directive issued by the President pursuant to statutes or the Constitution of the United States. The authority under this paragraph must be exercised in accordance with law, including section 57e. of the Act, and is in addition to the authority granted under § 53.740(h), which remains in effect unless otherwise directed by the Commission during a national security emergency. The authority under this paragraph may be exercised—

(1) When this action is immediately needed to implement national security objectives as designated by the national command authority through the Commission, and

(2) No action consistent with license conditions and technical specifications that can satisfy national security objectives is immediately apparent.

(d)(1) If the NRC finds that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency (including findings based on requirements of 10 CFR part 50, appendix E, section IV.D.3) and if the deficiencies (including deficiencies based on requirements of 10 CFR part 50, appendix E, section IV.D.3) are not corrected within 4 months of that finding, the Commission will determine whether the facility must be shut down or cease operations until such deficiencies are remedied or whether other enforcement action is appropriate. In determining whether a shutdown, cessation of operations, or other enforcement action is appropriate, the Commission will take into account, among other factors, whether the licensee can demonstrate to the Commission's satisfaction that the deficiencies in the plan are not significant for the plant in question, or that adequate interim compensating actions have been or will be taken promptly, or that that there are other compelling reasons for continued operation.

(2) If the planning standards for radiological emergency preparedness apply to offsite emergency response plans, then the NRC will base its finding on a review of the Federal Emergency Management Agency findings and determinations as to whether State, participating Tribal and local emergency plans are adequate and capable of being implemented, and on the NRC assessment as to whether the licensee's emergency plans are adequate and capable of being implemented. Nothing in this paragraph must be construed as limiting the authority of the Commission to take action under any other

regulation or authority of the Commission or at any time other than that specified in this paragraph.

§ 53.1505 Changes to licensing basis information requiring prior NRC approval.

(a) Sections 53.1510 through 53.1520 provide the process for a licensee to request and the NRC to issue amendments to licenses, including any conditions contained therein, technical specifications or other attachments to a license, and any orders issued by the NRC modifying a license. Sections 53.1525 and 53.1530 govern proposed changes to a commercial nuclear plant referencing a certified design or manufacturing license.

(b) A licensee may propose changing licensing basis information established by NRC regulations by requesting an exemption in accordance with § 53.080.

§ 53.1510 Application for amendment of license.

Whenever a holder of a license under this part desires to amend the license, an application for an amendment must be filed with the Commission, as specified in § 53.040, that fully describes the changes desired and, following as far as applicable, the form prescribed for original applications. Applications for amendments involving changes to plant structures, systems, and components, programmatic controls, or the role of plant personnel must include an assessment of the changes in relation to the safety requirements in subpart B of this part and the analyses requirements of § 53.450, as applicable, an analysis of whether the amendment involves no significant hazards consideration using the standards in § 53.1520, and a consideration of environmental factors.

§ 53.1515 Public notices; State consultation.

The Commission will use the following procedures for an application requesting an amendment to an operating license or combined license issued under this part.

(a) *Public notices.*

(1)(i) The Commission may publish in the *Federal Register* under § 2.105 an individual notice of proposed action for an amendment for which it makes a proposed determination that no significant hazards consideration is involved, or, at least once every 30 days, publish a periodic *Federal Register* notice of proposed actions, which identifies each amendment issued and each amendment proposed to be issued since the last such periodic notice, or it may publish both such notices.

(ii) For each amendment proposed to be issued, the notice will—

(A) Contain the staff's proposed determination under the standards in § 53.1520;

(B) Provide a brief description of the amendment and of the facility involved; (C) Solicit public comments on the proposed determination; and

(D) Provide for a 30-day comment period.

(iii) The comment period will begin on the day after the date of the publication of the first notice, and, normally, the amendment will not be granted until after this comment period expires.

(2) The Commission may inform the public about the final disposition of an amendment request for which it has made a proposed determination of no significant hazards consideration either by issuing an individual notice of issuance under § 2.106 of this chapter or by publishing such a notice in its periodic system of *Federal Register* notices. In either event, it will not make and will not publish a final determination of no significant hazards consideration unless it receives a request for a hearing on that amendment request.

(3) Where the Commission makes a final determination that no significant hazards consideration is involved and that the amendment should be issued, the

amendment will be effective on issuance, even if adverse public comments have been received and even if an interested person meeting the provisions for intervention called for in § 2.309 of this chapter has filed a request for a hearing. The Commission need hold any required hearing only after it issues an amendment, unless it determines that a significant hazards consideration is involved, in which case the Commission will provide an opportunity for a prior hearing.

(4) Where the Commission finds that an emergency situation exists, in that failure to act in a timely way would result in derating or shutdown of a nuclear reactor, or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, it may issue a license amendment involving no significant hazards consideration without prior notice and opportunity for a hearing or for public comment. In such a situation, the Commission will not publish a notice of proposed determination on no significant hazards consideration but will publish a notice of issuance under § 2.106 of this chapter providing for opportunity for a hearing and for public comment after issuance. The Commission expects its licensees to apply for license amendments in timely fashion. It will decline to dispense with notice and comment on the determination of no significant hazards consideration if it determines that the licensee has abused the emergency provision by failing to make timely application for the amendment and thus itself creating the emergency. Whenever an emergency situation exists, a licensee requesting an amendment must explain why this emergency situation occurred and why it could not avoid this situation, and the Commission will assess the licensee's reasons for failing to file an application sufficiently in advance of that event.

(5) Where the Commission finds that exigent circumstances exist, in that a licensee and the Commission must act quickly and that time does not permit the

Commission to publish a *Federal Register* notice allowing 30 days for prior public comment, and it also determines that the amendment involves no significant hazards considerations, it—

(i)(A) Will either issue a *Federal Register* notice providing notice of an opportunity for hearing and allowing at least 2 weeks from the date of the notice for prior public comment; or

(B) Will use local media to provide reasonable notice to the public in the area surrounding a licensee's facility of the licensee's amendment and of its proposed determination as described in paragraph (a)(1) of this section, consulting with the licensee on the proposed media release and on the geographical area of its coverage;

(ii) Will provide for a reasonable opportunity for the public to comment, using its best efforts to make available to the public whatever means of communication it can for the public to respond quickly, and, in the case of telephone comments, have these comments recorded or transcribed, as necessary and appropriate;

(iii) When it has issued a local media release, may inform the licensee of the public's comments, as necessary and appropriate;

(iv) Will publish a notice of issuance under § 2.106 of this chapter;

(v) Will provide a hearing after issuance, if one has been requested by a person who satisfies the provisions for intervention specified in § 2.309 of this chapter; and

(vi) Will require the licensee to explain the exigency and why the licensee cannot avoid it and use its normal public notice and comment procedures in paragraph (a)(1) of this section if it determines that the licensee has failed to use its best efforts to make a timely application for the amendment in order to create the exigency and to take advantage of this procedure.

(6) Where the Commission finds that significant hazards considerations are involved, it will issue a *Federal Register* notice providing an opportunity for a prior hearing even in an emergency situation, unless it finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

(b) *State consultation*.

(1) At the time a licensee requests an amendment, it must notify the State in which its facility is located of its request by providing that State with a copy of its application and its reasoned analysis about no significant hazards considerations and indicate on the application that it has done so.

(2) The Commission will advise the State of its proposed determination about no significant hazards consideration normally by sending it a copy of the *Federal Register* notice.

(3) The Commission will make the names of the Project Manager or other NRC personnel it designated to consult with the State available to the State official designated to consult about its proposed determination. The Commission will consider any comments of that State official. If it does not hear from the State in a timely manner, it will consider that the State has no interest in its determination; nonetheless, to ensure that the State is aware of the application, before it issues the amendment, it will make a good faith effort to communicate directly with that official. (Inability to consult with a responsible State official following good faith attempts will not prevent the Commission from making effective a license amendment involving no significant hazards consideration.)

(4) The Commission will make a good faith attempt to consult with the State before it issues a license amendment involving no significant hazards consideration. If,

however, it does not have time to use its normal consultation procedures because of an emergency situation, it will attempt to communicate directly with the appropriate State official. (Inability to consult with a responsible State official following good faith attempts will not prevent the Commission from making effective a license amendment involving no significant hazards consideration, if the Commission deems it necessary in an emergency situation.)

(5) After the Commission issues the requested amendment, it will send a copy of its determination to the State.

(c) *Caveats about State consultation.*

(1) The State consultation procedures in paragraph (b) of this section do not give the State a right—

(i) To veto the Commission's proposed or final determination;

(ii) To a hearing on the determination before the amendment becomes effective; or

(iii) To insist upon a postponement of the determination or upon issuance of the amendment.

(2) These procedures do not alter present provisions of law that reserve to the Commission exclusive responsibility for setting and enforcing radiological health and safety requirements for commercial nuclear plants.

§ 53.1520 Issuance of amendment.

(a) In determining whether an amendment to a license will be issued to the applicant, the Commission will be guided by the considerations which govern the issuance of initial licenses to the extent applicable and appropriate. If the application is for amendment of an operating license (OL) or combined license (COL) and involves the material alteration of a commercial nuclear plant, a construction permit (CP) will be

issued before the issuance of the amendment to the license, provided however, that if the application involves a COL before the date that the Commission makes the finding under § 53.1452(g), no application for or issuance of a CP is required. If the amendment involves a significant hazards consideration, the Commission will give notice of its proposed action—

(1) Under § 2.105 of this chapter before acting thereon; and

(2) As soon as practicable after the application has been docketed.

(b) The Commission will be particularly sensitive to a license amendment request that involves irreversible consequences (such as one that permits a significant increase in the amount of effluents or radiation emitted by a commercial nuclear plant).

(c) The Commission may make a final determination, under the procedures in § 53.1515, that a proposed amendment to an OL or a COL for a commercial nuclear plant under this part involves no significant hazards consideration, if operation of the plant in accordance with the proposed amendment would not—

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of an accident from any accident previously evaluated; or

(3) Involve a significant reduction in a margin of safety.

§ 53.1525 Revising certification information within a design certification rule.

(a) A holder of an operating license or combined license who references a design certification rule issued under this part must request an exemption if proposing to change one or more elements of the certification information. The Commission may grant such a request only if it determines that the exemption will comply with the

requirements of § 53.080 and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure.

(b) The request for an exemption must be included with any associated license amendment request, which must be requested and processed in accordance with §§ 53.1510, 53.1515, and 53.1520.

(c) Licensees must evaluate changes to the design as described in the final safety analysis report not involving changes to the certification information using the criteria in § 53.1550.

§ 53.1530 Revising design information within a manufacturing license.

(a) The holder of a manufacturing license (ML) may not make changes to the design of the manufactured reactor authorized to be manufactured without obtaining an amendment pursuant to § 53.1510 and, as applicable, § 53.1520.

(b) The holder of a combined license (COL) under this part who references or uses a manufactured reactor under this part must request approval for any proposed departure from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The Commission may grant such a request only if it determines that the departure will comply with the requirements of § 53.080, and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure. The granting of a departure on request of an applicant is subject to litigation in the same manner as other issues in the combined license hearing. The application for such departures must be submitted and processed in accordance with §§ 53.080, 53.1510, 53.1515, and 53.1520. In those cases where an ML references a design certification rule, the amendment application from the holder of the COL must also request an exemption from the design certification rule under § 53.1525 if one or more elements of the certification information

are adversely affected by the proposed change. The holder of the COL must evaluate changes to the commercial nuclear plant as described in the final safety analysis report but outside of the scope of the referenced ML using the criteria in § 53.1550.

§ 53.1535 Amendments during construction.

(a) The holder of a construction permit (CP) or limited work authorization (LWA) under this part may request an amendment to the CP or LWA in order to gain Commission approval of the safety of selected design features or specifications, including proposed departures from a design certification rule or manufacturing license. Amendments to CPs or LWAs under this part must be requested and processed under §§ 53.1510 and 53.1520.

(b) The holder of a combined license under this part for which the NRC has not yet made a finding in accordance with § 53.1452(g) must request amendments required by § 53.1525 or § 53.1550 no later than 45 days from the date the licensee begins the construction of the structures, systems, and components to implement the change or departure requiring NRC approval. The licensee proceeds with such changes at its own risk recognizing that there is a possibility that the amendment will not be granted.

§ 53.1540 Updating licensing basis information and determining the need for NRC approval.

(a) Sections 53.1545 through 53.1565 provide the process for a holder of an operating license (OL), combined license (COL), or ML to modify licensing basis information and to evaluate potential changes to its facilities, procedures, programs, and organizations to determine if NRC approval is required. These sections apply through termination of the operating license or combined license or expiration of the manufacturing license.

(b) Definitions for the purposes of §§ 53.1545 through 53.1560—

Change means a modification or addition to, or removal from, the commercial nuclear plant or procedures that affects a safety function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions, including functions that are necessary under § 53.440, will be accomplished.

Departure from a method of evaluation described in the FSAR (as updated) used in establishing the functional design criteria for safety-related structures, systems, or components or in the safety analyses means—

(1) Changing any of the elements of the method described in the FSAR (as updated) unless the results of the analysis are conservative or essentially the same; or

(2) Changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

Facility as described in the FSAR (as updated) means—

(1) The structures, systems and components (SSCs) that are described in the FSAR (as updated),

(2) The design and performance requirements for such SSCs described in the FSAR (as updated), and

(3) The evaluations or methods of evaluation included in the UFSAR (as updated) for such SSCs which demonstrate that their intended function(s) will be accomplished.

Final Safety Analysis Report (as updated) means the FSAR submitted under § 53.1369 or § 53.1416, as amended and supplemented, and as updated under § 53.1545, as applicable.

Procedures as described in the Final Safety Analysis Report (as updated) means those procedures that contain information described in the UFSAR such as how SSCs are operated and controlled (including assumed operator actions and response times).

§ 53.1545 Updating Final Safety Analysis Reports.

(a) Each holder of an operating license (OL) or combined license (COL) under this part for which the Commission has made the finding under § 53.1452(g) must update the final safety analysis report (FSAR) originally submitted as part of the application for the license every 24 months or more frequently to assure that the information included in the report contains the latest information developed. The submittal must include the effects on the content of the FSAR of—

(1) Changes made to the facility or procedures as described in the FSAR;

(2) Safety analyses and evaluations performed by the licensee either in support of approved license amendments or in support of conclusions that changes did not require a license amendment under § 53.1550;

(3) Updates to the risk evaluations under § 53.450;

(4) The cumulative effects of the changes to the facility or procedures on the margins to the safety criteria in §§ 53.210, 53.220, and 53.450(e) since the last FSAR update; and

(5) Analyses of new safety issues performed by or on behalf of the licensee at Commission request.

(b)(1) The licensee must submit revisions containing updated information to the Commission, under § 53.040, identifying the location of revised or new information.

(2) The submittal must include—

(i) A certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittal, necessary to reflect information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made; and

(ii) An identification of changes made under the provisions of § 53.1550 but not previously submitted to the Commission.

(c) Each applicant for or holder of a COL under this part for which the Commission has not made the finding under § 53.1452(g) must submit an update to the FSAR annually by providing the information required in (a)(1) through (a)(5) of this section and meeting the requirements of paragraph (b) of this section. COL applicants who have requested the NRC to suspend its review of the COL application and COL holders who have informed the NRC that they do not plan to pursue construction need not submit an annual update of the FSAR. If a COL applicant requests that the NRC resume its review, or a COL holder notifies the NRC that the COL holder plans to commence or resume construction, then the COL applicant or holder must submit to NRC an update to its FSAR within 90 days of the request or notification, as applicable, and annually thereafter.

(d) Each holder of an ML under this part must submit an update of the FSAR reflecting any modification to the design that is directed or approved by the Commission under § 53.1288 or § 53.1530, and any new analyses of the design requested by the Commission under § 53.1580.

(e) The updated FSAR must be retained by the licensee.

§ 53.1550 Evaluating changes to facility as described in Final Safety Analysis Reports.

(a) A The holder of an operating license or combined license may make changes in the facility as described in the final safety analysis report FSAR (as updated) and make changes in the procedures as described in the FSAR (as updated) without obtaining a license amendment pursuant to § 53.1510 only if—

(1) An amendment to the technical specifications incorporated in the license is not required and

(2) The change meets all of the following criteria:

(i) The change would not result in a more than minimal increase in the frequency of occurrence of design-basis accident (DBA) previously evaluated in the FSAR (as updated).

(ii) The change would not result in a more than minimal increase in the frequency of occurrence of a malfunction of a safety-related (SR) or non-safety-related but safety-significant (NSRSS) structure, system, or component (SSC) previously evaluated in the FSAR (as updated).

(iii) The change would not result in a more than minimal increase in the consequences of a DBA previously evaluated in the FSAR (as updated).

(iv) The change would not involve a more than minor increase in the consequences of a malfunction of an SR or NSRSS SSC previously evaluated in the FSAR (as updated).

(v) The change would not result in the identification of a new DBA under § 53.450(f) than any previously evaluated in the FSAR (as updated).

(vi) The change would not create a possibility for a malfunction of an SR or NSRSS SSC with a different result than any previously evaluated in the FSAR (as updated).

(vii) The change would not result in a design-basis limit for a fission product barrier as described in the FSAR (as updated) being exceeded or altered.

(viii) The change would not result in a departure from a method of evaluation described in the UFSAR used in assessing LBEs under § 53.450 unless the results of the analysis under § 53.450 are conservative or essentially the same, the revised

method of evaluation has been previously approved by the NRC for the intended application, or the revised method of evaluation can be used under an NRC-endorsed consensus code or standard.

(ix) The change would not prevent meeting the design requirements in § 53.440(j) to limit the release of radionuclides from reactor systems, waste stores, or other significant inventories of radioactive materials assuming the impact of a large, commercial aircraft.

(3) In implementing this paragraph, the FSAR (as updated) is considered to include FSAR changes since submittal of the last update of the FSAR under § 53.1545.

(4) The provisions in this section do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(b)(1) A licensee who references a design certification rule may make departures from the standard design, without prior Commission approval, unless the proposed departure involves a change to the design as described in the rule certifying the design, in which case the requirements of § 53.1525 are applicable.

(2) The licensee must maintain records of all departures from the certified design of the facility and these records must be maintained and available for audit until the termination of the license. The licensee must identify the location and nature of departures from licensing basis information within supporting documents for a certified design within the updates to the Safety Analysis Report required by § 53.1545.

(3) Licensees for which the NRC has docketed the certifications required under § 53.1070 need not retain records of departures from the design of the facility associated with SSCs that have been permanently removed from service using an NRC-approved change process.

(c)(1) The licensee must maintain records of changes in the facility and procedures made under paragraph (a) of this section. These records must include a written evaluation which provides the bases for the determination that the change does not require a license amendment under paragraph (a)(2) of this section.

(2) The licensee must submit, as specified in § 53.040, a report containing a brief description of any departures and changes, including a summary of the evaluation of each. A report must be submitted at intervals not to exceed 24 months. For COLs, the report must be submitted at intervals not to exceed 6 months during the period from the date of application for a COL to the date the Commission makes its findings under § 53.1452(g).

(3) The records of changes in the facility must be maintained until the termination of an OL or COL issued under this part, or the termination of a renewed license issued under § 53.1595—whichever is later. Records of changes in procedures must be maintained for a period of 5 years.

§ 53.1560 Updating program documents included in licensing basis information.

(a) Each holder under this part of an operating license (OL) or combined license (COL) for which the Commission has made the finding under § 53.1452(g) must biennially or more frequently update the program documents submitted as part of the application for the license to assure that the information included in the documents contains the latest information developed. The submittals must include the effects on the content of the program documents of—

(1) Changes made in the facility, procedures, licensee's organization, or site environs;

(2) Safety analyses and evaluations performed by the applicant or licensee either in support of approved license amendments or in support of conclusions that changes did not require a license amendment in accordance with § 53.1550;

(3) Analyses of new safety issues performed by or on behalf of the licensee at Commission request; and

(4) Changes to the programs as a result of operating experience, corrective actions, or other reasons deemed appropriate to ensure the programs serve their underlying purpose to satisfy applicable NRC regulations.

(b)(1) The licensee must submit revisions containing updated information to the Commission, as specified in § 53.040, identifying the location of revised or new information.

(2) The submittal must include—

(i) A certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittals, necessary to reflect information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made; and

(ii) An identification of changes made under the provisions of § 53.1550 but not previously submitted to the Commission.

(c) The updated program documents must be retained by the licensee until the Commission terminates their license.

§ 53.1565 Evaluating changes to programs included in licensing basis information.

(a) A licensee may make changes to the facility, procedures, or organizations or address changes to site environs as described in the program documents included in licensing basis information without obtaining prior NRC approval only if—

(1) An amendment to the technical specifications incorporated in the license is not required;

(2) An exemption from an NRC regulation is not required; and

(3) The change conforms to program-specific requirements included in regulations in this part, technical specifications, or the NRC-approved program document included and reviewed as part of a license application under subpart H or an amendment under this subpart.

(b) In implementing this section, the program documents (as updated) include changes since submittal of the last updates of the program documents pursuant to § 53.1560.

(c) [Reserved].

(d) To make changes to the facility, procedures, or organizations or to address changes to site environs as described in the program documents included in licensing basis information for individual programs, the following requirements must be satisfied:

(1) *Quality assurance program—operation*. (i) Each holder under this part of an operating license or combined license (COL), after the Commission makes the finding under § 53.1452(g), may make a change to a previously accepted quality assurance program (QAP) description included or referenced in the Safety Analysis Report without prior NRC approval, provided the change does not reduce the commitments in the program description as accepted by the NRC. Changes to the QAP description that do not reduce the commitments must be submitted to the NRC in accordance with the requirements of § 53.1545. In addition to QAP changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered to be reductions in commitment:

(A) The use of a QA standard approved by the NRC which is more recent than the QA standard in the licensee's QAP at the time of the change;

(B) The use of a QA alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility;

(C) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

(D) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text;

(E) The elimination of QAP information that duplicates language in QA regulatory guides and QA standards to which the licensee is committed; and

(F) Organizational revisions that ensure that persons and organizations performing QA functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(ii) Changes to the QAP description that do reduce the commitments must be submitted to the NRC and receive NRC approval prior to implementation, as follows:

(A) Changes made to the QAP description as presented in the Safety Analysis Report or in a topical report must be submitted as specified in § 53.040.

(B) The submittal of a change to the Safety Analysis Report QAP description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of subpart K of this part and the Safety Analysis Report QAP description

commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(C) A copy of the forwarding letter identifying the change must be maintained as a facility record for 3 years.

(D) Changes to the QAP description included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

(2) *Quality assurance program—siting, construction, and manufacturing*. Each holder of a limited work authorization, early site permit, construction permit, manufacturing license, or COL, before the Commission makes the finding under § 53.1452(g) of this chapter, under this part may make a change to a previously accepted QAP description included or referenced in the Safety Analysis Report without prior NRC approval, provided the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the QAP description that do not reduce the commitments must be submitted to NRC within 90 days. Changes to the QAP description that reduce the commitments must be submitted to NRC and receive NRC approval before implementation, as follows:

(i) Changes to the Safety Analysis Report must be submitted for review as specified in § 53.040. Changes made to NRC-accepted QA topical report descriptions must be submitted as specified in § 53.040.

(ii) The submittal of a change to the Safety Analysis Report QAP description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the

criteria of subpart K of this part and the Safety Analysis Report QAP description commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(iii) A copy of the forwarding letter identifying the changes must be maintained as a facility record for 3 years.

(iv) Changes to the QAP description included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

(3) *Emergency preparedness program*.

(i) Definitions for the purpose of paragraph (d)(3) of this section:

(*1*) Change means an action that results in modification or addition to, or removal from, the licensee's emergency plan. All such changes are subject to the provisions of this section except where the applicable regulations establish specific criteria for accomplishing a particular change.

(*2*) Emergency plan means the document(s), prepared and maintained by the licensee, that identify and describe the licensee's methods for maintaining emergency preparedness and responding to emergencies. An emergency plan includes the plan as originally approved by the NRC and all subsequent changes made by the licensee with, and without, prior NRC review and approval under paragraph (d)(3) of this section.

(*3*) Emergency planning function means a capability or resource necessary to prepare for and respond to a radiological emergency, as set forth in the elements of section Iv. of appendix E to this part and, for nuclear power reactor licensees, the planning standards of § 50.47(b).

(*4*) Reduction in effectiveness means a change in an emergency plan that results in reducing the licensee's capability to perform an emergency planning function in the event of a radiological emergency.

(ii)(A) The licensee must provide for the development, revision, implementation, and maintenance of its emergency preparedness program. The licensee must ensure that all program elements are reviewed by persons who have no direct responsibility for the implementation of the emergency preparedness program either—

(*1*) At intervals not to exceed 12 months or,

(*2*) As necessary, based on an assessment by the licensee against performance indicators, and as soon as reasonably practicable after a change occurs in personnel, procedures, equipment, or facilities that potentially could adversely affect emergency preparedness, but no longer than 12 months after the change. In any case, all elements of the emergency preparedness program must be reviewed at least once every 24 months.

(B) The review must include an evaluation for adequacy of interfaces with State participating Tribal and local governments and of licensee drills, exercises, capabilities, and procedures. The results of the review, along with recommendations for improvements, must be documented, reported to the licensee's corporate and plant management, and retained for a period of 5 years. The part of the review involving the evaluation for adequacy of interface with State, participating Tribal and local governments must be available to the appropriate State, participating Tribal and local governments.

(iii) The licensee may make changes to its emergency plan without NRC approval only if the licensee performs and retains an analysis demonstrating that the changes do not reduce the effectiveness of the plan and the plan, as changed, continues

to satisfy the requirements in § 53.855. A change reduces the effectiveness of the plan if it results in reducing the licensee's capability to perform an emergency planning function required by § 53.855 in the event of a radiological emergency.

(iv) The licensee must retain a record of each change to the emergency plan made without prior NRC approval for a period of 3 years from the date of the change and must submit, as specified in § 53.040, a report of each such change, including a summary of its analysis, within 30 days after the change is put in effect.

(v) The changes to a licensee's emergency plan that reduce the effectiveness of the plan may not be implemented without prior approval by the NRC. A licensee desiring to make such a change must submit an application for an amendment to its license. In addition to the filing requirements of §§ 53.1510, 53.1515, and 53.1520, the request must include all emergency plan pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the licensee's emergency plan, as revised, will continue to satisfy the requirements of § 53.855.

(vi) The nuclear power reactor licensee must retain the emergency plan and each change for which NRC approval was obtained, pursuant to paragraph (d)(3)(iv) of this section, as a record until the Commission terminates the license for the nuclear power reactor.

(4) *Security programs.*

(i) The licensee must prepare and maintain safeguards contingency plan procedures in accordance with appendix C of part 73 of this chapter for affecting the actions and decisions contained in the Responsibility Matrix of the safeguards contingency plan. The licensee may not make a change that would decrease the safeguard effectiveness of a physical security plan, or guard training and qualification

plan, or cyber security plan submitted under subpart H or part 73 of this chapter, or of the first four categories of information (Background, Generic Planning Base, Licensee Planning Base, Responsibility Matrix) contained in a licensee safeguards contingency plan submitted under subpart H or part 73 of this chapter, as applicable, without prior approval of the Commission. A licensee desiring to make such a change must submit an application for amendment to the licensee's license under §§ 53.1510, 53.1515, and 53.1520.

(ii) The licensee may make changes to the plans referenced in paragraph (4)(i) of this section without prior Commission approval if the changes do not decrease the safeguards effectiveness of the plan. The licensee must maintain records of changes to the plans made without prior Commission approval for a period of 3 years from the date of the change, and must submit, as specified in § 53.040, a report containing a description of each change within 2 months after the change is made. Prior to the safeguards contingency plan being put into effect, the licensee must have—

(A) All safeguards capabilities specified in the safeguards contingency plan available and functional;

(B) Detailed procedures developed according to appendix C to part 73 of this chapter available at the licensee's site; and

(C) All appropriate personnel trained to respond to safeguards incidents as outlined in the plan and specified in the detailed procedures.

(iii) The licensee must provide for the development, revision, implementation, and maintenance of its safeguards contingency plan. The licensee must ensure that all program elements are reviewed by individuals independent of both security program management and personnel who have direct responsibility for implementation of the security program either—

(A) At intervals not to exceed 12 months; or

(B) As necessary, based on an assessment by the licensee against performance indicators, and as soon as reasonably practicable after a change occurs in personnel, procedures, equipment, or facilities that potentially could adversely affect security, but no longer than 12 months after the change. In any case, all elements of the safeguards contingency plan must be reviewed at least once every 24 months.

(iv) The review must include a review and audit of safeguards contingency procedures and practices, an audit of the security system testing and maintenance program, and a test of the safeguards systems along with commitments established for response by local law enforcement authorities. The results of the review and audit, along with recommendations for improvements, must be documented, reported to the licensee's corporate and plant management, and kept available at the plant for inspection for a period of 3 years.

§ 53.1570 Transfer of licenses.

(a) No commercial nuclear plant license issued under this part, or any right thereunder, shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission gives its consent in writing.

(b)(1) An application for transfer of a license must include As much of the information described in §§ 53.1109, 53.1306, 53.1366, and 53.1413 with respect to the identity and technical and financial qualifications of the proposed transferee as would be required by those sections if the application were for an initial license. The Commission may require additional information such as data respecting proposed safeguards against hazards from radioactive materials and the applicant's qualifications to protect against such hazards.

(2) The application must also include a statement of the purposes for which the transfer of the license is requested, the nature of the transaction necessitating or making desirable the transfer of the license, and an agreement to limit access to Restricted Data or Classified National Security Information pursuant to § 53.1115. The Commission may require any person who submits an application for license pursuant to the provisions of this section to file a written consent from the existing licensee or a certified copy of an order or judgment of a court of competent jurisdiction attesting to the person's right (subject to the licensing requirements of the Act and these regulations) to possession of the facility or site involved.

(c) After appropriate notice to interested persons, including the existing licensee, and observance of such procedures as may be required by the Act or regulations or orders of the Commission, the Commission will approve an application for the transfer of a license, if the Commission determines—

(1) That the proposed transferee is qualified to be the holder of the license; and

(2) That transfer of the license is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.

§ 53.1580 Information requests.

Each licensee under this part must at any time before termination of the license, upon request of the Commission, submit, as specified in § 53.040 written statements, signed under oath or affirmation, to enable the Commission to determine whether or not the license should be modified, suspended, or revoked. Except for information sought to verify licensee compliance with the current licensing basis for that facility, the NRC must prepare the reason or reasons for each information request prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety

significance of the issue to be addressed in the requested information. Each such justification provided for an evaluation performed by the NRC staff must be approved by the Executive Director for Operations or his or her designee prior to issuance of the request.

§ 53.1585 Revocation, suspension, modification of licenses and approvals for cause.

A license for a facility or standard design approval issued under this part may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or in the supplemental or other statement of fact required of the applicant; or because of conditions revealed by the application or statement of fact of any report, record, inspection, or other means which would warrant the Commission to refuse to grant a license or approval on an original application (other than those relating to the duration of the license, those relating to § 53.090(b), and those relating to § 53.090(c)(2)); or for failure to manufacture a reactor, or construct or operate a facility in accordance with the terms of the license, provided, however, that failure to make timely completion of the proposed construction or alteration of a facility under a construction permit or combined license under this part shall be governed by the provisions of § 53.1342(b) and § 53.1455(b), respectively; or for violation of, or failure to observe, any of the terms and provisions of the act, regulations, license, approval, or order of the Commission.

§ 53.1590 Backfitting.

(a)(1) Backfitting means the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's

regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after the date of issuance of the license or design approval for a commercial nuclear plant or the manufacturing license issued under this part.

(2) Except as provided in paragraph (a)(4) of this section, the Commission shall require a systematic and documented analysis pursuant to paragraph (b) of this section for backfits which it seeks to impose.

(3) Except as provided in paragraph (a)(4) of this section, the Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (b) of this section, that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.

(4) The provisions of paragraphs (a)(2) and (a)(3) of this section are inapplicable and, therefore, backfit analysis is not required and the standards in paragraph (a)(3) of this section do not apply where the Commission or staff, as appropriate, finds and declares, with appropriate documented evaluation for its finding, either—

(i) That a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee; or

(ii) That regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security; or

(iii) That the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate.

(5) The Commission must always require the backfitting of a facility if it determines that such regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security.

(6) The documented evaluation required by paragraph (a)(4) of this section must include a statement of the objectives of and reasons for the modification and the basis for invoking the exception. If immediately effective regulatory action is required, then the documented evaluation may follow rather than precede the regulatory action.

(7) If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written licensee commitments, or there are two or more ways to reach a level of protection which is adequate, then ordinarily the applicant or licensee is free to choose the way which best suits its purposes. However, should it be necessary or appropriate for the Commission to prescribe a specific way to comply with its requirements or to achieve adequate protection, then cost may be a factor in selecting the way, provided that the objective of compliance or adequate protection is met.

(b) In reaching the determination required by paragraph (a)(3) of this section, the Commission will consider how the backfit should be scheduled in light of other ongoing regulatory activities at the facility and, in addition, will consider information available concerning any of the following factors as may be appropriate and any other information relevant and material to the proposed backfit:

(1) The statement of the specific objectives that the proposed backfit is designed to achieve;

(2) The general description of the activity that would be required by the licensee or applicant in order to complete the backfit;

(3) The potential change in the risk to the public from the accidental off-site release of radioactive material;

(4) The potential impact on radiological exposure of facility employees;

(5) The installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay;

(6) The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements;

(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;

(8) The potential impact of differences in facility type, design or age on the relevancy and practicality of the proposed backfit;

(9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

(c) No licensing action will be withheld during the pendency of backfit analyses required by the Commission's rules.

(d) The Executive Director for Operations shall be responsible for implementation of this section, and all analyses required by this section shall be approved by the Executive Director for Operations or his or her designee.

§ 53.1595 Renewal.

[Reserved].

Subpart J — Reporting and Other Administrative Requirements

§ 53.1600 General information.

Each applicant and licensee under this part must provide access to sites and facilities licensed or proposed to be licensed in § 53.1610, must maintain records and make reports to the NRC in accordance with requirements in §§ 53.1620 through 53.1650, must satisfy financial qualification and reporting requirements in §§ 53.1660 through 53.1700, and must obtain and maintain required financial protections in case of an accident in §§ 53.1720.

§ 53.1610 Inspections.

(a) Each applicant for or holder of a manufacturing license (ML), operating license (OL), combined license (COL), construction permit (CP), or early site permit must permit inspection, by duly authorized representatives of the Commission, of its records, premises, activities, and of licensed materials in possession or use, related to the license as may be necessary to effectuate the purposes of the Act and the Energy Reorganization Act of 1974.

(b)(1) Each holder of an ML, OL, COL, or CP must, upon request by the Director, Office of Nuclear Reactor Regulation, provide rent-free office space for the exclusive use of the Commission inspection personnel. Heat, air conditioning, light, electrical outlets, and janitorial services must be furnished by each licensee and each holder of a CP. The office must be convenient to and have full access to the facility and must provide the inspectors both visual and acoustic privacy.

(2) For a site or facility with an assigned resident inspector, the space provided must be adequate to accommodate a full-time inspector, a part-time secretary, and transient NRC personnel and must be generally commensurate with other office facilities at the site. For sites or facilities assigned multiple resident inspectors, additional space may be requested. The office space that is provided must be subject to the approval of

the Director, Office of Nuclear Reactor Regulation. All furniture, supplies, and communication equipment will be furnished by the Commission.

(3) The licensee or permit holder must afford any NRC resident inspector assigned to that site, or other NRC inspectors identified by the Regional Administrator as likely to inspect the facility, immediate unfettered access, equivalent to access provided regular plant employees, following proper identification and compliance with applicable access control measures for security, radiological protection, and personal safety.

(4) The licensee or permit holder must ensure that the arrival and presence of an NRC inspector, who has been properly authorized facility access as described in paragraph (b)(3) of this section, is not announced or otherwise communicated by its employees or contractors to other persons at the facility unless specifically requested by the NRC inspector.

§ 53.1620 Maintenance of records, making of reports.

(a) Each holder of a manufacturing license (ML), operating license (OL), combined license (COL), construction permit (CP), or early site permit must maintain all records and make all reports, in connection with the activity, as may be required by the conditions of the license or permit or by the regulations and orders of the Commission in effectuating the purposes of the Act and the Energy Reorganization Act of 1974. Reports must be submitted in accordance with § 53.040.

(b) [Reserved]

(c) Records that are required by the regulations in this part, by license condition, or by technical specifications must be retained for the period specified by the appropriate regulation, license condition, or technical specification. If a retention period is not otherwise specified, these records must be retained until the Commission terminates the facility license or, in the case of an early site permit, until the permit expires.

(d)(1) Records which must be retained under this part may be the original or a reproduced copy or a microform if the reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations. The record may also be stored in electronic media with the capability of producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with, and loss of records.

(2) If there is a conflict between the Commission's regulations in this part, license condition, or technical specification, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this part for such records shall apply unless the Commission, under § 53.080 of this part, has granted a specific exemption from the record retention requirements in the regulations in this part.

(e) Each licensee must notify the Commission as specified in § 53.040 of this part, of successfully completing power ascension testing or startup testing as applicable within 30 calendar days of completing the testing.

§ 53.1630 Immediate notification requirements for operating commercial nuclear plants.

(a) *General requirements.*[1]: (1) Each holder of an operating license under this part or a combined license under this part after the Commission makes the finding under § 53.1452(g), must notify the NRC Operations Center via the Emergency Notification System of—

(i) The declaration of any of the Emergency Classes specified in the licensee's approved Emergency Plan; or

(ii) Those non-emergency events specified in paragraph (b) of this section that occurred within 3 years of the date of discovery.

(2) If the Emergency Notification System is inoperative, the licensee must make the required notifications via commercial telephone service, other dedicated telephone system, or any other method which will ensure that a report is made as soon as practical to the NRC Headquarters Operations Center at the numbers specified in appendix A to part 73 of this chapter.

(3) The licensee must notify the NRC immediately after notification of the appropriate State or local agencies and not later than 1 hour after the time the licensee declares one of the Emergency Classes.

(4) The licensee must activate the data links with the NRC as specified in their emergency plans after declaring an Emergency Class for events of actual or potential substantial degradation of plant safety or security, probable risk to site personnel life, or site equipment damage caused by hostile action. The data links may also be activated by the licensee during emergency drills or exercises if the licensee's computer system has the capability to transmit the exercise data.

(5) When making a report under paragraph (a)(1) of this section, the licensee must identify—

(i) The Emergency Class declared; or

(ii) Paragraph (b)(1), "One-hour reports," paragraph (b)(2), "Four-hour reports," or paragraph (b)(3), "Eight-hour reports," as the paragraph of this section requiring notification of the non-emergency event.

(b) *Non-emergency events* – (1) *One-hour reports*. If not reported as a declaration of an Emergency Class under paragraph (a) of this section, the licensee must notify the NRC as soon as practical and in all cases within one hour of the occurrence of any deviation from the plant's Technical Specifications authorized under § 53.740(h) of this part.

(2) *Four-hour reports*. If not reported under paragraphs (a) or (b)(1) of this section, the licensee must notify the NRC as soon as practical, and in all cases, within 4 hours of the occurrence of any of the following:

(i) The initiation of any commercial nuclear plant shutdown required by the plant's Technical Specifications.

(ii) Any event or condition that results in actuation of the reactor protection system when the reactor is critical except when the actuation results from and is part of a pre-planned sequence during testing or reactor operation.

(iii) Any event or condition that results in an unplanned actuation of a safety-related (SR) standby cooling system or the unplanned sole reliance on an SR standby cooling system for those systems that are in constant operation.

(iv) Any event or condition that results in an unplanned movement of, change of state in, or chemical interaction involving a significant amount of radioactive material within the commercial nuclear plant.

(v) Any event or situation, related to the health and safety of the public or onsite personnel, or protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made. Such an event may include an onsite fatality or inadvertent release of radioactively contaminated materials.

(3) *Eight-hour reports*. If not reported under paragraphs (a), (b)(1) or (b)(2) of this section, the licensee must notify the NRC as soon as practical and in all cases within 8 hours of the occurrence of any of the following:

(i) Any event or condition that results in—

(A) The condition of the commercial nuclear plant, including its principal safety barriers, being seriously degraded; or

(B) The commercial nuclear plant being in an unanalyzed condition that significantly degrades plant safety.

(ii) Any event or condition that results in valid actuation of an SR system, except when the actuation results from and is part of a pre-planned sequence during testing or reactor operation.

(iii) Any event or condition that at the time of discovery could have prevented the fulfilment of the safety functions identified under § 53.230. Events covered may include one or more procedural errors, equipment failures, and/or discovery of design, analysis, fabrication, construction, and/or procedural inadequacies. However, individual component failures need not be reported pursuant to this paragraph if other equipment was operable and available to perform the required safety function.

(iv) Any event requiring the transport of a radioactively contaminated person to an offsite medical facility for treatment.

(v) Any event that results in a major loss of emergency assessment capability, offsite response capability, or offsite communications capability (e.g., significant portion of control room indication, Emergency Notification System, or offsite notification system).

(c) *Follow-up Notification*: With respect to the notifications made under paragraphs (a) and (b) of this section, in addition to making the required initial notification, each licensee, must during the course of the event—

(1) Immediately Report: (i) any further degradation in the level of safety of the plant or other worsening plant conditions, including those that require the declaration of any of the Emergency Classes, if such a declaration has not been previously made, or

(ii) any change from one Emergency Class to another, or

(iii) a termination of the Emergency Class.

(2) Immediately Report: (i) the results of ensuing evaluations or assessments of plant conditions,

(ii) the effectiveness of response or protective measures taken, and

(iii) important information related to plant behavior that is not understood.

(3) Maintain an open, continuous communication channel with the NRC Operation Center upon request by the NRC.

[1] Other requirements for immediate notification of the NRC by licensed operating commercial nuclear plants are contained elsewhere in this chapter, in particular §§ 20.1906, 20.2202, 72.216, 73.71, and 73.77 of this chapter.

§ 53.1640 Licensee event report system.

(a) *Reportable events*.

(1) Each holder of an operating license under this part or a combined license under this part after the Commission makes the finding under § 53.1452(g), must submit a Licensee Event Report (LER) for any event of the type described in this paragraph within 60 days after discovery of the event. In the case of an invalid actuation reported under § 53.1640(a)(2), other than automatic reactor shutdown when the reactor is critical, the licensee may, at its option, provide a telephone notification to the NRC Operations Center within 60 days after discovery of the event instead of submitting a written LER. Unless otherwise specified in this section, the licensee must report an event if it occurred within 3 years of the date of discovery regardless of the plant mode or power level, and regardless of the significance of the structure, system, or component that initiated the event.

(2) The licensee must report—

(i)(A) The completion of any commercial nuclear plant shutdown required by the plant's Technical Specifications.

(B) Any operation or condition which was prohibited by the plant's Technical Specifications except when—

(1) The Technical Specification is administrative in nature;

(2) The event consisted solely of a case of a late surveillance test where the oversight was corrected, the test was performed, and the equipment was found to be capable of performing its specified safety functions; or

(3) The Technical Specification was revised prior to discovery of the event such that the operation or condition was no longer prohibited at the time of the event.

(C) Any deviation from the plant's Technical Specifications authorized under § 53.740(h).

(ii) Any event or condition that resulted in—

(A) The condition of the commercial nuclear plant, including its principal safety barriers, being seriously degraded; or

(B) The commercial nuclear plant being in an unanalyzed condition that significantly degrades plant safety.

(iii) Any natural phenomena or other external condition that posed an actual threat to the safety of the commercial nuclear plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the commercial nuclear plant.

(iv) Any event or condition that resulted in manual or automatic actuation of any system classified as safety-related (SR) for an identified safety function under § 53.460

or the unplanned sole reliance on an SR system for those systems that are in constant operation, except when—

(A) The actuation resulted from and was part of a pre-planned sequence during testing; or

(B) The actuation was invalid and—

(*1*) Occurred while the system was properly removed from service; or

(*2*) Occurred after the safety function had been already completed.

(v) Any event or condition that could have prevented the fulfillment of the safety functions identified under § 53.230.

(vi) Events covered in paragraph (a)(2)(v) of this section may include one or more procedural errors, equipment failures, and/or discovery of design, fabrication, construction, and/or procedural inadequacies. However, individual component failures need not be reported pursuant to paragraph (a)(2)(v) of this section if any other equipment was operable and available to perform the required safety function.

(vii)(A) Any event or condition that as a result of a single cause could have prevented the fulfillment of any of the safety functions identified under § 53.230.

(B) Events covered in paragraph (a)(2)(vii)(A) of this section may include cases of procedural error, equipment failure, and/or discovery of a design, analysis, fabrication, construction, and/or procedural inadequacy. However, licensees are not required to report an event pursuant to paragraph (a)(2)(vii)(A) of this section if the event results from—

(*1*) A shared dependency among trains or channels that is a natural or expected consequence of the approved plant design; or

(*2*) Normal and expected wear or degradation.

(viii)(A) Any airborne radioactive release that, when averaged over a time period of 1-hour, resulted in airborne radionuclide concentrations in an unrestricted area that exceeds 20 times the applicable concentration limits specified in appendix B to 10 CFR part 20, table 2, column 1.

(B) Any liquid effluent release that, when averaged over a time period of 1-hour, exceeds 20 times the applicable concentrations specified in appendix B to 10 CFR part 20, table 2, column 2, at the point of entry into the receiving waters (i.e., unrestricted area) for all radionuclides except tritium and dissolved noble gases.

(ix) Any event that posed an actual threat to the safety of the commercial nuclear plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the plant, including fires, toxic gas releases, or radioactive releases.

(b) *Contents*. The LER must contain—

(1) A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.

(2)(i) A clear, specific narrative description of what occurred so that knowledgeable readers conversant with the design of commercial nuclear plants, but not familiar with the details of a particular plant, can understand the complete event.

(ii) The narrative description must include the following specific information as appropriate for the particular event:

(A) Plant operating conditions before the event.

(B) Status of systems, structures, or components that were inoperable at the start of the event and that contributed to the event.

(C) Dates and approximate time of the occurrences.

(D) The cause of each component or system failure or personnel error, if known.

(E) The failure mode, mechanism, and effect of each failed component, if known.

(F) [Reserved]

(G) For failures of components with multiple functions, include a list of systems or secondary functions that were also affected.

(H) For failure that rendered a component or system classified as SR or NSRSS inoperable, an estimate of the elapsed time from the discovery of the failure until the component or system was returned to service.

(I) The method of discovery of each component or system failure or procedural error.

(J) For each human performance related root cause, the licensee must discuss the cause(s) and circumstances.

(K) Automatically and manually initiated safety system responses.

(L) The manufacturer and model number (or other identification) of each component that failed during the event.

(3) An assessment of the safety consequences and implications of the event. This assessment must include—

(i) The availability of systems or components that could have performed the same function as the components and systems that failed during the event, and

(ii) For events that occurred when the reactor was shut down, the availability of systems or components that are needed to shut down the reactor and maintain safe shutdown conditions, remove residual heat, control the release of radioactive material, or mitigate the consequences of an accident.

(4) A description of any corrective actions planned as a result of the event, including those to reduce the probability of similar events occurring in the future.

(5) Reference to any previous similar events at the same plant that are known to the licensee.

(6) The name and contact information of a person within the licensee's organization who is knowledgeable about the event and can provide additional information concerning the event and the plant's characteristics.

(c) *Supplemental Information*: The Commission may require the licensee to submit specific additional information beyond that required by paragraph (b) of this section if the Commission finds that supplemental material is necessary for complete understanding of an unusually complex or significant event. These requests for supplemental information will be made in writing and the licensee must submit, as specified in § 53.040, the requested information as a supplement to the initial LER.

(d) *Submission of Reports*: LERs must be prepared on Form NRC 366 and submitted to the NRC, as specified in § 53.040.

(e) *Report Legibility*: The reports and copies that licensees are required to submit to the Commission under the provisions of this section must be of sufficient quality to permit legible reproduction and micrographic processing.

(f) [Reserved]

(g) [Reserved].

§ 53.1645 Reports of radiation exposure to members of the public.

(a) Each holder of an OL, and each holder of a COL after the Commission has made the finding under § 53.1452(g), must submit a report to the Commission annually that specifies the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents and the dose in unrestricted areas due to direct radiation exposure from contained radiation sources during the previous 12 months. In addition, the report shall include an estimate of the dose received by the maximally

exposed member of the public in an unrestricted area from effluents and direct radiation from contained sources during the previous 12 months and include any other information as may be required by the Commission to estimate maximum potential annual radiation doses to the public. The report must be submitted as specified in § 53.040, and the time between submission of the reports must be no longer than 12 months. If the TEDE to members of the public in unrestricted areas during the reporting period is greater than the established design objectives under § 53.425(c) or 10 mrem/year TEDE, the report must specify the causes for exceeding the design objective and describe any corrective actions. On the basis of these reports and any additional information the Commission may obtain from the licensee or others, the Commission may require the licensee to take action as the Commission deems appropriate.

(b) If during any calendar quarter the radiation exposure to a member of the public in the unrestricted areas, calculated on the same basis as the respective design objective exposure, exceeds one-half of the annual design objective exposure, the licensee must investigate the causes, define and initiate a program of corrective actions, and submit a report of the causes and actions as specified in § 53.040. The report shall be submitted within 30 days from the end of the quarter when one-half of the annual design objective exposure was exceeded.

§ 53.1650 Facility information and verification.

(a) In response to a written request by the Commission, each applicant for a CP or license and each recipient of a CP or a license must submit facility information, as described in § 75.10 of this chapter, on International Atomic Energy Agency (IAEA) Design Information Questionnaire forms and site information on DOC/NRC Form AP-A and associated forms;

(b) As required by the Additional Protocol, must submit location information described in § 75.11 of this chapter on DOC/NRC Form AP-1 and associated forms; and (c) Must permit verification thereof by the IAEA and take other action as necessary to implement the US/IAEA Safeguards Agreement, as described in part 75 of this chapter.

§ 53.1660 Financial requirements.

Sections 53.1670 through 53.1700 set out the requirements and procedures related to financial qualifications and related reporting requirements.

§ 53.1670 Financial qualifications.

Except for an electric utility applicant for a license to operate a commercial nuclear plant, an applicant for a CP, OL, or COL under this part must possess or have reasonable assurance of obtaining the funds necessary for the activities for which the permit or license is sought.

§ 53.1680 Annual financial reports.

Each licensee and each holder of a CP must submit its annual financial report, including the certified financial statements, to the Commission, as specified in § 53.040, upon issuance of the report. However, licensees and holders of a CP who submit a Form 10-Q with the Securities and Exchange Commission or a Form 1 with FERC need not submit the annual financial report or the certified financial statement under this section.

§ 53.1690 Licensee's change of status; financial qualifications.

(a) An electric utility licensee holding an OL or COL (including a renewed license) for a commercial nuclear plant, no later than seventy-five (75) days prior to ceasing to be an electric utility in any manner not involving a license transfer under § 53.1399 or § 53.1456 must provide the NRC with the financial qualifications information that would be required for obtaining an initial OL or COL under this part. The financial qualifications

information must address the first full 5 years of operation after the date the licensee ceases to be an electric utility.

(b)(1) Any holder of a license for a commercial nuclear plant issued under this part must notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code by or against—

(i) The licensee;

(ii) An entity (as 11 U.S.C. 101(14) defines that term) controlling the licensee or listing the license or licensee as property of the estate; or

(iii) An affiliate (as 11 U.S.C. 101(2) defines that term) of the licensee.

(2) This notification must indicate—

(i) The bankruptcy court in which the petition for bankruptcy was filed; and

(ii) The date of the filing of the petition.

§ 53.1700 Creditor regulations.

(a) Pursuant to section 184 of the Act, the Commission consents, without individual application, to the creation of any mortgage, pledge, or other lien upon any facility not owned by the United States which is the subject of a license or upon any leasehold or other interest in such facility; provided—

(1) That the rights of any creditor so secured may be exercised only in compliance with and subject to the same requirements and restrictions as would apply to the licensee pursuant to the provisions of the license, the Act, and regulations issued by the Commission under the Act; and

(2) That no creditor so secured may take possession of the facility pursuant to the provisions of this section prior to either the issuance of a license from the Commission authorizing such possession or the transfer of the license.

(b) Any creditor so secured may apply for transfer of the license covering such facility by filing an application for transfer of the license under § 53.1570. The Commission will act upon such application under Subpart I of this part.

(c) Nothing contained in this regulation shall be deemed to affect the means of acquiring, or the priority of, any tax lien or other lien provided by law.

(d) As used in this section—

License includes any license under this part, which may be issued by the Commission with regard to a facility;

Creditor includes, without implied limitation, the trustee under any mortgage, pledge or lien on a facility made to secure any creditor, any trustee or receiver of the facility appointed by a court of competent jurisdiction in any action brought for the benefit of any creditor secured by such mortgage, pledge or lien, any purchaser of such facility at the sale thereof upon foreclosure of such mortgage, pledge, or lien or upon exercise of any power of sale contained therein, or any assignee of any such purchaser.

Facility includes, but is not limited to, a site which is the subject of an early site permit under this part, and a reactor manufactured under an manufacturing license under this part.

§ 53.1720 Insurance required to stabilize and decontaminate plant following an accident.

Each commercial nuclear plant licensee under this part must take reasonable steps to obtain insurance available at reasonable costs and on reasonable terms from private sources or to demonstrate that it possesses an equivalent amount of protection covering the licensee's obligation, in the event of an accident at the licensee's nuclear reactor, to stabilize and decontaminate the plant and the plant site at which such an accident may occur, provided that—

(a) The insurance required by this section must have a minimum coverage limit for each commercial nuclear plant site of $1.06 billion, an amount based on plant-specific estimates of costs to stabilize and decontaminate a plant, or whatever amount of insurance is generally available from private sources, whichever is less. The required insurance must clearly state that, as and to the extent provided in paragraph (d) of this section, any proceeds must be payable first for stabilization of the plant and next for decontamination of the plant and the plant site. If a licensee's coverage falls below the required minimum, the licensee must within 60 days take all reasonable steps to restore its coverage to the required minimum. The required insurance may, at the option of the licensee, be included within policies that also provide coverage for other risks, including, but not limited to, the risk of direct physical damage.

(b)(1) With respect to policies issued or annually renewed, the proceeds of such required insurance must be dedicated, as and to the extent provided in this paragraph, to reimbursement or payment on behalf of the insured of reasonable expenses incurred or estimated to be incurred by the licensee in taking action to fulfill the licensee's obligation, in the event of an accident at the licensee's plant, to ensure that the plant is in, or is returned to, and maintained in, a safe and stable condition and that radioactive contamination is removed or controlled such that personnel exposures are consistent with the occupational exposure limits in 10 CFR part 20. These actions must be consistent with any other obligation the licensee may have under this chapter and must be subject to paragraph (d) of this section. As used in this section, an "accident" means an event that involves the release of radioactive material from its intended place of confinement within the commercial nuclear plant such that there is a present danger of release off site in amounts that would pose a threat to the public health and safety.

(2) The stabilization and decontamination requirements set forth in paragraph (d) of this section must apply uniformly to all insurance policies required under this section.

(c) The licensee shall report to the NRC on April 1 of each year the current levels of this insurance or financial security it maintains and the sources of this insurance or financial security.

(d)(1) In the event of an accident at the licensee's plant, whenever the estimated costs of stabilizing the licensed plant and of decontaminating the plant and the plant site exceed one tenth of the minimum insurance under paragraph (a) of this section, the proceeds of the insurance required by this section must be dedicated to and used, first, to ensure that the licensed plant is in, or is returned to, and can be maintained in, a safe and stable condition so as to prevent any significant risk to the public health and safety and, second, to decontaminate the plant and the plant site in accordance with the licensee's cleanup plan as approved by order of the Director, Office of Nuclear Reactor Regulation. This priority on insurance proceeds must remain in effect for 60 days or, upon order of the Director, for such longer periods, in increments not to exceed 60 days except as provided for activities under the cleanup plan required in paragraphs (d)(3) and (d)(4) of this section, as the Director may find necessary to protect the public health and safety. Actions needed to bring the plant to and maintain the plant in a safe and stable condition may include one or more of the following, as appropriate:

(i) Shutdown of the reactor(s) and other processes at the plant;

(ii) Establishment and maintenance of long-term cooling with stable decay heat removal;

(iii) Maintenance of sub-criticality;

(iv) Control of radioactive releases; and

(v) Securing of structures, systems, or components to minimize radiation exposure to onsite personnel or to the offsite public or to facilitate later decontamination or both.

(2) The licensee must inform the Director, Office of Nuclear Reactor Regulation in writing when the plant is and can be maintained in a safe and stable condition so as to prevent any significant risk to the public health and safety. Within 30 days after the licensee informs the Director that the plant is in this condition, or at such earlier time as the licensee may elect or the Director may for good cause direct, the licensee must prepare and submit a cleanup plan for the Director's approval. The cleanup plan must identify and contain an estimate of the cost of each cleanup operation that will be required to decontaminate the reactor sufficiently to permit the licensee either to resume operation of the reactor or to apply to the Commission under subpart G of this part for authority to decommission the reactor and to surrender the license voluntarily. Cleanup operations may include one or more of the following, as appropriate:

(i) Processing any contaminated materials generated by the accident and by decontamination operations to remove radioactive materials;

(ii) Decontamination of surfaces inside the plant buildings to levels consistent with the Commission's occupational exposure limits in 10 CFR part 20, and decontamination or disposal of equipment;

(iii) Decontamination or removal and disposal of internal parts, damaged fuel from the reactor coolant or fuel systems, or related process or waste systems; and

(iv) Cleanup of the reactor coolant or fuel systems or related process or waste systems.

(3) Following review of the licensee's cleanup plan, the Director will order the licensee to complete all operations that the Director finds are necessary to

decontaminate the reactor sufficiently to permit the licensee either to resume operation of the reactor or to apply to the Commission under subpart G of this part for authority to decommission the reactor and to surrender the license voluntarily. The Director must approve or disapprove, in whole or in part for stated reasons, the licensee's estimate of cleanup costs for such operations. Such order may not be effective for more than one year, at which time it may be renewed. Each subsequent renewal order, if imposed, may be effective for not more than 6 months.

(4) Of the balance of the proceeds of the required insurance not already expended to place the plant in a safe and stable condition under paragraph (b)(1) of this section, an amount sufficient to cover the expenses of completion of those decontamination operations that are the subject of the Director's order must be dedicated to such use, provided that, upon certification to the Director of the amounts expended previously and from time to time for stabilization and decontamination and upon further certification to the Director as to the sufficiency of the dedicated amount remaining, policies of insurance may provide for payment to the licensee or other loss payees of amounts not so dedicated, and the licensee may proceed to use in parallel (and not in preference thereto) any insurance proceeds not so dedicated for other purposes.

Subparts K through W [Reserved]

Subpart X — Enforcement

§ 53.9000 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued under those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued under the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

§ 53.9010 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 53 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in 10 CFR part 53 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 53.000, 53.015, 53.020, 53.040, 53.080, 53.090, 53.100, 53.110, 53.120, 53.600, 53.725, 53.726, 53.735, 53.760, 53.820, 53.1000, 53.1050, 53.1100, 53.1103, 53.1106, 53.1109, 53.1112, 53.1115, 53.1118, 53.1121, 53.1124, 53.1140, 53.1143, 53.1144, 53.1146, 53.1149, 53.1155, 53.1158, 53.1164, 53.1170, 53.1173, 53.1176, 53.1179, 53.1188, 53.1200, 53.1203,

53.1206, 53.1209, 53.1210, 53.1212, 53.1215, 53.1218, 53.1221, 53.1230, 53.1236, 53.1239, 53.1241, 53.1242, 53.1245, 53.1248, 53.1251, 53.1263, 53.1270, 53.1273, 53.1276, 53.1279, 53.1282, 53.1285, 53.1286, 53.1287, 53.1288, 53.1291, 53.1293, 53.1295, 53.1300, 53.1306, 53.1309, 53.1312, 53.1315, 53.1318, 53.1324, 53.1330, 53.1333, 53.1336, 53.1348, 53.1360, 53.1366, 53.1369, 53.1372, 53.1375, 53.1381, 53.1384, 53.1387, 53.1390, 53.1396, 53.1405, 53.1410, 53.1416, 53.1419, 53.1422, 53.1425, 53.1431, 53.1437, 53.1440, 53.1443, 53.1452, 53.1455, 53.1456, 53.1458, 53.1461, 53.1470, 53.1500, 53.1510, 53.1515, 53.1520, 53.1525, 53.1530, 53.1535, 53.1540, 53.1560, 53.1585, 53.1590, 53.1595, 53.1600, 53.1660, 53.1670, 53.1700, 53.9000, and 53.9010.

PART 55 – OPERATORS' LICENSES

129. The authority citation for part 55 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 107, 161, 181, 182, 183, 186, 187, 223, 234 (42 U.S.C. 2137, 2201, 2231, 2232, 2233, 2236, 2237, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); 44 U.S.C. 3504 note.

§ 55.1 [Amended]

130. In § 55.1, in paragraph (a) add " part 53," after "part 52,".

131. In § 55.2 revise paragraphs (b) and (c) and add new paragraph (d) to read as follows:

§ 55.2 Scope

* * * * *

(b) Any individual designated by a facility licensee licensed under parts 50, 52, or 54 of this chapter to be responsible for directing the licensed activities of a licensed operator.

(c) Any facility licensee licensed under parts 50, 52, or 54 of this chapter.

(d) Any individual who manipulates the controls of any interaction-dependent mitigation facility licensed under part 53 of this chapter, any individual designated by a facility licensee licensed under part 53 of this chapter to be responsible for directing the licensed activities of a licensed operator, and any facility license under part 53 of this chapter except that:

(1) The requirements of § 53.735 apply in lieu of the requirements of subpart B of this part, and

(2) The requirements of § 53.730(g) and § 53.780 apply in lieu of the requirements of subpart E, § 55.53(h), and § 55.59 of this part, and

(3) The requirements of subpart X in part 53 of this chapter apply in lieu of the requirements of subpart H of this part.

132. In § 55.5, revise paragraphs (b)(1) and (2) to read as follows:

§ 55.5 Communications

* * * * *

(b)(1) Except for test and research reactor facilities, the Director, Office of Nuclear Reactor Regulation, has delegated to the Regional Administrators of Regions I, II, III, and IV authority and responsibility under the regulations in this part for the issuance and renewal of licenses for operators and senior operators of nuclear power reactors licensed under parts 50, 52, or 54 of this chapter and for the issuance and renewal of licenses for operators and senior operators of interaction-dependent mitigation facilities licensed under part 53 of this chapter and located in these regions.

(2) Any application for a license or license renewal filed under the regulations in this part involving a nuclear power reactor licensed under parts 50, 52 or 54 of this chapter or interaction-dependent mitigation facilities licensed under part 53 of this chapter and any related inquiry, communication, information, or report must be submitted to the Regional Administrator by an appropriate method listed in paragraph (a) of this section. The Regional Administrator or the Administrator's designee will transmit to the Director, Office of Nuclear Reactor Regulation, any matter that is not within the scope of the Regional Administrator's delegated authority.

* * * * *

PART 70 – DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

133. The authority citation for 10 CFR part 70 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57(d), 108, 122, 161, 182, 183, 184, 186, 187, 193, 223, 234, 274, 1701 (42 U.S.C. 2071, 2073, 2077(d), 2138, 2152, 2201, 2232, 2233, 2234, 2236, 2237, 2243, 2273, 2282, 2021, 2297f); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

§ 70.20a [Amended]

134. In § 70.20a(b), add "52, 53," after "50,".

§ 70.22 [Amended]

135. In § 70.22, wherever it may appear, remove "part 50" and add in its place "parts 50, 52, or 53."

136. In § 70.24, revise paragraph (d) to read as follows:

§ 70.24 Criticality accident requirements.

* * * * *

(d)(1) The requirements in paragraphs (a) through (c) of this section do not apply to a holder of a construction permit or operating license for a nuclear power reactor

issued under part 50 or part 53 of this chapter or a combined license issued under part 52 or part 53 of this chapter, if the holder complies with the requirements of paragraph (b) of 10 CFR 50.68 or paragraph (m)(2) of 10 CFR 53.440.

(2) An exemption from § 70.24 held by a licensee who thereafter elects to comply with requirements of paragraph (b) of 10 CFR 50.68 or paragraph (m)(2) of 10 CFR 53.440 does not exempt that licensee from complying with any of the requirements in § 50.68 or § 53.440(m) but shall be ineffective so long as the licensee elects to comply with § 50.68(b) or § 53.440(m)(2), as applicable.

§ 70.32 [Amended]

137. In § 70.32:

a. In paragraph (c)(1) remove “part 50” and add in its place “parts 50, 52, or 53”; and

b. in paragraph (d), remove “or § 70.34” and add in its place “§ 70.34 or § 53.1510”.

138. In § 70.50, revise paragraph (d) to read as follows:

§ 70.50 Reporting requirements.

* * * * *

(d) The provisions of § 70.50 do not apply to licensees subject to § 50.72 or § 53.1630 of this chapter. They do apply to those licensees under parts 50, 52, and 53 of this chapter possessing material licensed under this part that are not subject to the notification requirements in § 50.72 or § 53.1630of this chapter.

PART 72 – LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

139. The authority citation for 10 CFR part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

§ 72.3 [Amended]

140. In § 72.3, in the definition for Independent spent fuel storage installation or ISFSI remove “part 50” and add in its place “parts 50, 52, or 53”.

141. In § 72.30, revise paragraph (e)(5) to read as follows:

§ 72.30 Financial assurance and recordkeeping for decommissioning.

* * * * *

(e) * * *

(5) In the case of licensees who are issued a power reactor license under parts 50, 52, or 53 of this chapter or ISFSI licensees who are an electric utility, as defined in parts 50 or 53 of this chapter, with a specific license issued under this part, the methods of § 50.75(b), (e), and (h) or §§ 53.1010, 53.1040, 53.1045(b), and 53.1060 as applicable. In the event that funds remaining to be placed into the licensee's ISFSI decommissioning external sinking fund are no longer approved for recovery in rates by a competent rate making authority, the licensee must make changes to provide financial assurance using one or more of the methods stated in paragraphs (1) through (4) of this section.

* * * * *

§ 72.32 [Amended]

142. In § 72.32(c)(2), add “or § 53.020” after “10 CFR part 100.”

§ 72.40 [Amended]

143. In § 72.40(c), remove “part 50” and add in its place “parts 50 or 53.”

§ 72.75 [Amended]

144. In § 72.75(i)(1)(ii), wherever it may appear, remove “part 50” and add in its place “parts 50, 52, or 53”.

§ 72.184 [Amended]

145. In § 72.184(a), remove “part 50” and add in its place “parts 50, 52, or 53.”

§ 72.210 [Amended]

146. In § 72.210, remove “part 50 or 10 CFR part 52” and add in its place “parts 50, 52, or 53.”

§ 72.212 [Amended]

147. In § 72.212(b)(8), add “or § 53.1550” after “§ 50.59(c).”

148. In § 72.218, revise paragraphs (a) and (b) to read as follows:

§ 72.218 Termination of licenses.

(a) The notification regarding the program for the management of spent fuel at the reactor required by § 50.54(bb) or § 53.1060 of this chapter must include a plan for removal of the spent fuel stored under this general license from the reactor site. The plan must show how the spent fuel will be managed before starting to decommission systems and components needed for moving, unloading, and shipping this spent fuel.

(b) An application for termination of a reactor operating license issued under 10 CFR part 50 and submitted under § 50.82 of this chapter, or a combined license issued under 10 CFR part 52 and submitted under § 52.110 of this chapter, or a reactor operating or combined license under 10 CFR part 53 and submitted under § 53.1070 must contain a description of how the spent fuel stored under this general license will be removed from the reactor site.

* * * * *

PART 73 – PHYSICAL PROTECTION OF PLANTS AND MATERIALS

149. The authority citation for 10 CFR part 73 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 147, 149, 161, 170D, 170E, 170H, 170I, 223, 229, 234, 1701 (42 U.S.C. 2073, 2167, 2169, 2201, 2210d, 2210e, 2210h, 2210i, 2273, 2278a, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

Section 73.37(b)(2) also issued under sec. 301, Pub. L. 96-295, 94 Stat. 789 (42 U.S.C. 5841 note).

§ 73.1 [Amended]

150. In § § 73.1(b)(1)(i), add “, or 53” after “50, 52”.

§ 73.2 [Amended]

151. In § 73.2(a), add “, or 53” after “50, 52”.

§ 73.8 [Amended]

152. In § 73.8(b), add “73.77, 73.100, 73.110, 73.120,” in numerical order.

§ 73.50 [Amended]

153. In § 73.50 introductory text, remove “parts 50 or 52” and add in its place “parts 50, 52, or 53”.

154. In § 73.55, revise paragraphs (a)(4) and (6), (i)(4)(iii), (l)(1) and (7)(ii), (p)(1)(i), (r)(2) and (4)(iii) to read as follows:

§ 73.55 Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage.

(a) * * *

(4) Applicants for an operating license under the provisions of part 50 or part 53 of this chapter or holders of a combined license under the provisions of part 52 or part 53 of this chapter must implement the requirements of this section before fuel is allowed onsite (protected area).

* * *

(6) Applicants for an operating license under the provisions of part 50 or part 53 of this chapter, or holders of a combined license under the provisions of part 52 or part 53 of this chapter that do not reference a standard design certification or reference a standard design certification issued after May 26, 2009, must meet the requirement of § 73.55(i)(4)(iii).

* * * * *

* * * * *

(i) * * *

(4) * * *

(iii) Applicants for an operating license under the provisions of part 50 of this chapter, or holders of a combined license under the provisions of part 52 of this chapter, or licensees under part 53 of this chapter that elect to demonstrate compliance with § 73.55, consistent with § 53.860(a)(2), must construct, locate, protect, and equip both the central and secondary alarm stations to the standards for the central alarm station contained in this section. Both alarm stations must be equal and redundant, such that all functions needed to satisfy the requirements of this section can be performed in both alarm stations.

* * * * *

(l) * * *

(1) Commercial nuclear power reactors licensed under 10 CFR parts 50, 52, or 53 and authorized to use special nuclear material in the form of MOX fuel assemblies containing up to 20 weight percent PuO_2 must, in addition to demonstrating compliance with the requirements of this section, protect un-irradiated MOX fuel assemblies against theft or diversion as described in this paragraph.

* * * * *

(7) * * *

(ii) Additional measures for the physical protection of un-irradiated MOX fuel assemblies containing greater than 20 weight percent PuO_2 must be determined by the Commission on a case-by-case basis and documented during initial review of the license application or through license amendment under § 50.90 or § 53.1510.

* * * * *

(p) * * *

(1) * * *

(i) Under §§ 50.54(x) and 50.54(y), or § 53.740(h) of this chapter, the licensee may suspend any security measures under this section in an emergency when this action is immediately needed to protect the public health and safety and no action consistent with license conditions and technical specifications that can provide adequate or equivalent protection is immediately apparent. This suspension of security measures must be approved as a minimum by a licensed senior operator or generally licensed operator, or, for a facility for which the certifications required under §§ 50.82(a)(1), 52.110(a), or 53.1070(a) have been submitted, by a licensed senior operator, generally licensed operator, or certified fuel handler before taking this action.

* * * * *

(r) * * *

(2) The licensee must submit proposed alternative measure(s) to the Commission for review and approval under §§ 50.4 and 50.90, or § 53.040 and § 53.1510 of this chapter before implementation.

* * * * *

(4) * * *

(iii) Based on comparison of the costs of the alternative measures to the costs of demonstrating compliance with the Commission's requirements using the essential elements of § 50.109 or § 53.1590 of this chapter, the costs of fully demonstrating compliance with the Commission's requirements are not justified by the protection that would be provided.

155. In § 73.56, revise paragraph (a)(3) to read as follows:

§ 73.56 Personnel access authorization requirements for nuclear power plants.

(a) * * *

(3) Each applicant for an operating license under the provisions of part 50 of this chapter, each holder of a combined license under the provisions of part 52 of this chapter, and applicants for an operating license or holders of a combined license under part 53 of this chapter that do not meet the criterion of § 53.860(a)(2) of this chapter, must implement the requirements of this section before fuel is allowed on site (protected area).

* * * * *

156. In § 73.57, revise paragraph (a)(3) to read as follows:

§ 73.57 Requirements for criminal history records checks of individuals granted unescorted access to a nuclear power facility, a non-power reactor, or access to Safeguards Information.

(a) * * *

(3) Before receiving its operating license under 10 CFR parts 50 or 53 of this chapter, each applicant for a license to operate a nuclear power reactor or a non-power reactor may submit fingerprints for those individuals who will require unescorted access to the nuclear power facility or non-power reactor facility. Before the Commission makes its finding under §§ 52.103(g) or 53.1452(g) of this chapter, each holder of a combined

license may submit fingerprints for those individuals who will require unescorted access to the nuclear power facility.

* * * * *

§ 73.58 [Amended]

157. In § 73.58, remove “part 50 or 52” and add in its place “parts 50, 52, or 53”.

§ 73.67 [Amended]

158. In § 73.67, in paragraphs (d) introductory text and (f) introductory text, remove “part 50,” and add in its place “parts 50, 52, or 53, provided that the special nuclear material is located within a protected area and protected under § 73.55 or § 73.100,”.

159. In § 73.77, revise paragraphs (a), (b), (c)(6), and (7) to read as follows:

§ 73.77 Cyber security event notifications.

* * * * *

(a) Each licensee subject to the provisions of § 73.54 or § 73.110 must notify the NRC Headquarters Operations Center via the Emergency Notification System (ENS), under paragraph (c) of this section:

(1) Within one hour after discovery of a cyber attack that adversely impacted:

(i) Safety-related or important-to-safety functions, security functions, or emergency preparedness functions (including offsite communications); or that compromised support systems and equipment resulting in adverse impacts to safety, security, or emergency preparedness functions within the scope of § 73.54; or,

(ii) Functions performed by digital assets that would prevent a postulated fission product release resulting in offsite doses exceeding the values in § 53.210 of this chapter, or functions performed by digital assets used by the licensee for implementing the physical security requirements in § 53.860(a) of this chapter.

(2) Within 4 hours:

(i) After discovery of a cyber attack that could have caused an adverse impact to:

(A) Safety-related or important-to-safety functions, security functions, or emergency preparedness functions (including offsite communications); or that could have compromised support systems and equipment, which if compromised, could have adversely impacted safety, security, or emergency preparedness functions within the scope of § 73.54; or,

(B) Functions performed by digital assets that would prevent a postulated fission product release resulting in offsite doses exceeding the values in § 53.210 of this chapter, or functions performed by digital assets used by the licensee for implementing the physical security requirements in § 53.860(a) of this chapter.

(ii) After discovery of a suspected or actual cyber attack initiated by personnel with physical or electronic access to digital computer and communication systems and networks within the scope of § 73.54 or § 73.110.

(iii) After notification of a local, State, or other Federal agency (e.g., law enforcement, FBI, etc.) of an event related to the licensee's implementation of their cyber security program for digital computer and communication systems and networks within the scope of § 73.54 or § 73.110 that does not otherwise require a notification under paragraph (a) of this section.

(3) Within 8 hours after receipt or collection of information regarding observed behavior, activities, or statements that may indicate intelligence gathering or pre-operational planning related to a cyber attack against digital computer and communication systems and networks within the scope of § 73.54 or § 73.110.

(b) *Twenty-four hour recordable events.*

(1) The licensee shall use the site corrective action program to record vulnerabilities, weaknesses, failures and deficiencies in their § 73.54 or § 73.110 cyber security program within 24 hours of their discovery.

* * * * *

(c) * * *

(6) *Declaration of emergencies*. Notifications made to the NRC for the declaration of an emergency class shall be performed in accordance with § 50.72 or § 53.1630 of this chapter, as applicable.

(7) *Elimination of duplication*. Separate notifications and reports are not required for events that are also reportable under §§ 50.72 and 50.73 or §§ 53.1630 and 53.1640 of this chapter. However, these notifications should also indicate the applicable § 73.77 reporting criteria.

* * * * *

Security Requirements at Commercial Nuclear Plants

160. Add undesignated center heading, “Security Requirements at Commercial Nuclear Plants” after § 73.81.

161. Add § 73.100 to read as follows:

§ 73.100 Technology-inclusive requirements for physical protection of licensed activities at commercial nuclear plants against radiological sabotage

(a) *Introduction*.

(1) Each holder of a license to operate a commercial nuclear plant under part 53 of this chapter that elects to implement the requirements of this section must do so through its physical security plan, training and qualification plan, safeguards contingency plan, and cyber security plan, referred to collectively hereafter as ‘‘security plans,” before initial fuel load into the reactor.

(2) The security plans must identify, describe, and account for site-specific conditions that affect the licensee's capability to satisfy the requirements of this section.

(b) *General performance objective and requirements*.

(1) The licensee must establish, implement, and maintain a physical protection program and a security organization, which will have as their objective to provide reasonable assurance that activities involving special nuclear material are not inimical to the common defense and security and do not constitute an unreasonable risk to the public health and safety.

(2) To satisfy the general performance objective of paragraph (b)(1) of this section, the physical protection program must protect against the design-basis threat of radiological sabotage as stated in § 73.1. Specifically, the licensee must—

(i) Ensure that the physical protection program capabilities to protect against the design-basis threat of radiological sabotage are maintained at all times; and

(ii) Provide defense in depth in achieving performance requirements through the integration of engineered systems, administrative controls, and management measures.

(3) The physical protection program must be designed and implemented to achieve and maintain the reliability and availability of structures, systems, and components required for demonstrating compliance with the following performance requirements at all times:

(i) Intrusion detection. The licensee must be capable of detecting attempted and actual unauthorized access to interior and exterior areas containing structures, systems, and components needed to implement safety and security functions.

(ii) Intrusion assessment. The licensee must be capable of timely assessment to determining the cause of a detected intrusion.

(iii) Security communication. The licensee must be capable of continuous

security communications. Communication systems must account for design-basis threats that can interrupt or interfere with continuity or integrity of communications.

(iv) Security response. The physical protection program must be designed to provide timely security response to interdict and neutralize adversary attacks up to and including the design-basis threat of radiological sabotage. The physical protection program must be designed to provide layers of security response, with each layer assuring that a single failure does not result in the loss of capability to neutralize the design-basis threat adversary. Structures, systems, and components relied on for delay functions must be designed to allow for timely security responses to adversary attacks with adequate defense in depth.

(A) The security response may rely on the use of onsite responders, law enforcement or other offsite armed responders, or a combination thereof, to fulfill the interdiction and neutralization functions required by paragraph (b)(3)(iv) of this section. A licensee relying entirely or partially on law enforcement or other offsite armed responders must—

(*1*) maintain the capability to detect, assess, interdict, and neutralize threats as required by paragraphs (b)(3)(i), (b)(3)(ii), and (b)(3)(iv) of this section;

(*2*) provide adequate delay to enable law enforcement or other offsite armed responders to fulfill the interdiction and neutralization functions for threats up to and including the design-basis threat of radiological sabotage;

(*3*) provide necessary information about the facility and make available periodic training to law enforcement or other offsite armed responders who will fulfill the interdiction and neutralization functions for threats up to and including the design-basis threat of radiological sabotage;

(*4*) fully describe in the safeguards contingency plan the role that law

enforcement or other offsite armed responders will play in the licensee's protective strategy. The description must provide sufficient detail to enable the NRC to determine that the licensee's physical protection program provides reasonable assurance of adequate protection against threats up to and including the design-basis threat of radiological sabotage; and

(*5*) identify criteria and measures to compensate for the degradation or absence of law enforcement or other offsite armed responders and propose suitable compensatory measures that meet the requirements of paragraph (h)(3) of this section to address this degradation.

(B) For licensees relying entirely or partially on law enforcement responders to fulfill the interdiction and neutralization functions required by paragraph (b)(3)(iv) of this section, the training and qualification requirements related to armed response personnel in paragraphs (c) and (e) of this section do not apply to law enforcement responders. The licensee shall continue to satisfy the performance evaluation requirements in paragraph (g) of this section for all armed response personnel, including law enforcement.

(v) Protecting against land and waterborne vehicle bomb assaults. The licensee must be capable of protecting the plant against the design-basis threat vehicle bomb assault. The methods that are relied on to protect against a design-basis threat land vehicle and waterborne vehicle bomb assault must be designed to protect the reactor building and structures containing safety- or security-related systems, and components from explosive effects.

(vi) Access control portals. The licensee must be capable of detecting and denying unauthorized access to persons and pass-through of contraband materials (e.g., weapons, incendiaries, explosives) to protected areas.

(4) The licensee must meet the requirements related to target sets in § 73.55(f).

(5) The licensee must identify and analyze site-specific conditions, including target sets, that may affect the physical protection program needed to implement the requirements of this section. The licensee must account for these conditions in demonstrating compliance with the requirements of this section.

(6) The licensee must establish, implement, and maintain a performance evaluation program to assess the effectiveness of the licensee's implementation of the physical protection program to protect against the design-basis threat of radiological sabotage.

(7) The licensee must establish, implement, and maintain an access authorization program under § 73.56 and must describe the program in the physical security plan.

(8) The licensee must establish, implement, and maintain a cyber security program under § 73.54 or § 73.110 and must describe the program in the cyber security plan.

(9) The licensee must establish, implement, and maintain an insider mitigation program and must describe the program in the physical security plan.

(i) The insider mitigation program must monitor the initial and continuing trustworthiness and reliability of individuals granted or retaining unescorted access or unescorted access authorization to a protected or vital area, and implement defense-in-depth methodologies to minimize the potential for an insider (active, passive, or both) to adversely affect, either directly or indirectly, the licensee's capability to protect against radiological sabotage.

(ii) The insider mitigation program must integrate elements of—

(A) The access authorization program under § 73.56;

(B) The fitness-for-duty program under 10 CFR part 26;

(C) The cyber security program under § 73.54 or § 73.110; and

(D) The physical protection program under this section.

(10) The licensee must have the capability to track, trend, correct, and prevent recurrence of failures and deficiencies in the implementation of the requirements of this section.

(11) Implementation of security plans and associated procedures must be coordinated with other onsite plans and procedures to preclude conflict during both normal and emergency conditions and ensure the adequate management of the safety and security interface.

(c) *Security organization*. The licensee must establish and maintain a security organization that is staffed, trained, qualified, and equipped to implement the physical protection program under the requirements of this section.

(1) The licensee must establish a management system for maintaining and implementing security policies and procedures to implement the requirements of this section and the security plans.

(2) Implementing procedures must document the conduct of security operations, security design and configuration controls, maintenance, training and qualification, and contingency responses.

(3) The licensee must—

(i) Establish a process for the approval of designs, policies, processes, and procedures and changes by the individual with overall responsibility for the physical protection program; and

(ii) Ensure that revisions and changes to the physical protection program and implementing policies, processes, and procedures satisfy the requirements of this

section.

(4) The licensee must retain, under paragraph (j) of this section, all analyses, assessments, calculations, and descriptions of the technical basis for demonstrating compliance with the performance requirements of § 73.100(b). The licensee must protect these records in accordance with the requirements for protecting safeguards information in §§ 73.21 and 73.22.

(5) The licensee may not permit any individual to implement any part of the physical protection program unless the individual has been trained, equipped, and qualified to perform their assigned duties and responsibilities in accordance with the training and qualification plan.

(d) *Search requirements*. The licensee must establish and implement searches of individuals, vehicles, and materials to detect and prevent the introduction into the protected area of firearms, explosives, incendiary devices, or other items and material which could be used to commit radiological sabotage.

(e) *Training and qualification program*. The licensee must establish and maintain a training and qualification program that ensures personnel who are responsible for the physical protection of the facility against radiological sabotage are able to effectively perform their assigned security-related job duties for implementing the requirements of this section and must describe the program in the training and qualification plan.

(f) *Security reviews*. The licensee must establish and implement security reviews to assess the effectiveness of the implementation of the physical protection program. Security reviews must be performed by individuals independent of those personnel responsible for program management and any individual who has direct responsibility for implementing the onsite physical protection program.

(1) The licensee must review each element of the physical protection program at

a frequency commensurate with the importance or significance to safety of plant operations to ensure timely identification and documentation of vulnerabilities, improvements, and corrective actions. The objective of these reviews must be maintaining effective implementation of the engineered and administrative controls required to achieve the physical protection program functions and the management system required to implement programs and requirements in this section.

(2) The licensee must establish and perform self-assessments to ensure the effective implementation of the physical protection program functions of detection, assessment, communication, delay, and interdiction and neutralization to protect against the design-basis threat of radiological sabotage. The licensee must perform design verification and assessments of the capabilities of active and passive engineering systems relied on to protect against the design-basis threat.

(3) Reviews of the security program must include, but are not limited to, an audit of the effectiveness of the physical protection program, security plans, implementing procedures, cyber security programs, safety/security interface activities, the testing, maintenance, and calibration program, and response commitments by local, State, and Federal law enforcement authorities.

(4) The results and recommendations of the onsite physical protection program reviews, management's findings regarding program effectiveness, and any actions taken as a result of recommendations from prior program reviews, must be documented in a report and must be maintained in an auditable form and available for inspection.

(g) *Performance evaluation*. Licensee performance evaluations must include methods appropriate and necessary to assess, test, and challenge the integration of the physical protection program's functions to protect against the design-basis threat, including measures to protect against cyber attack and engineered systems designed to

protect against the design-basis threat standalone ground vehicle bomb attack.

(1) The licensee must establish the frequencies for performance evaluations commensurate with the security significance of the physical protection program.

(2) The licensee must document processes and procedures for implementing the performance evaluations. The licensee must maintain records, including results, findings, and corrective actions identified during the performance evaluations.

(h) *Maintenance, testing, and calibration and corrective actions*.

(1) The licensee must ensure that security structures, systems, and components, including supporting systems, are inspected, tested, and calibrated for operability and performance at intervals necessary and sufficient to meet the requirements of this section.

(2) The licensee must implement corrective actions to ensure resolution of identified vulnerabilities and deficiencies to meet the requirements of this section.

(3) The licensee must establish and implement timely compensatory measures for degraded or inoperable security structures, systems, and components to meet the requirements of this section. Compensatory measures must provide a level of protection that is equivalent to the protection that was provided prior to the degradation or inoperability of the security structures, systems, or components.

(4) The licensee must document processes and procedures and maintain records for implementing the corrective actions, compensatory measures, and maintenance, inspection, testing, and calibration of security structures, systems, and components.

(i) *Suspension of security measures*.

(1) The licensee may suspend implementation of affected requirements of this section in accordance with § 53.740(h) of this chapter under the following conditions:

(i) In an emergency, when action is immediately needed to protect the public

health and safety; and

(ii) During severe weather, when the suspension of affected security measures is immediately needed to protect the personal health and safety of personnel.

(2) Suspended security measures must be reinstated as soon as conditions permit.

(3) The suspension of security measures must be reported and documented in accordance with the provisions of subpart T to this part.

(j) *Records*.

(1) The Commission may inspect, copy, retain, and remove all reports, records, and documents required to be kept by Commission regulations, orders, or license conditions, whether the reports, records, and documents are kept by the licensee or a contractor.

(2) The licensee must maintain all records required to be kept by Commission regulations, orders, or license conditions, until the Commission terminates the license for which the records were developed, and must maintain superseded portions of these records for at least 3 years after the record is superseded, unless otherwise specified by the Commission.

(3) If a contracted security force is used to implement the onsite physical protection program, the licensee's written agreement with the contractor must be retained by the licensee as a record for the duration of the contract.

(4) Review and audit reports must be available for inspection, for a period of 3 years.

162. Add § 73.110 to read as follows:

§ 73.110 Technology-inclusive requirements for protection of digital computer and communication systems and networks

(a) Each holder of a license to operate a commercial nuclear plant under part 53 of this chapter that elects to implement the requirements of this section must establish, implement, and maintain a cyber security program that is commensurate with the potential consequences resulting from cyberattacks, up to and including the design-basis threat as described in § 73.1. The cyber security program must provide reasonable assurance that digital computer and communication systems and networks are adequately protected against cyberattacks that are capable of causing the following consequences:

(1) Adversely impacting the functions performed by digital assets that would prevent a postulated fission product release resulting in offsite doses exceeding the values in § 53.210 of this chapter.

(2) Adversely impacting the functions performed by digital assets used by the licensee for implementing the physical security requirements in § 53.860(a) of this chapter.

(b) To protect digital computer and communication systems and networks associated with the functions described in paragraphs (a)(1) and (2), the licensee must—

(1) Analyze the potential consequences resulting from cyber attacks on digital computer and communication systems and networks and identify those assets that must be protected to demonstrate compliance with paragraph (a) of this section; and

(2) Implement the cyber security program in accordance with paragraph (d) of this section.

(c) The licensee must comply with the requirements in § 73.54(a)(2) for the systems and networks identified in paragraph (b)(1) of this section in a manner that is commensurate with the potential consequences resulting from cyberattacks.

(d) The cyber security program must be designed in a manner that is commensurate with the potential consequences resulting from cyber attacks through the following steps:

(1) Implement security controls to protect the assets identified under paragraph (b)(1) of this section from cyber attacks, commensurate with their safety and security significance;

(2) Apply and maintain defense-in-depth protective strategies to ensure the capability to detect, delay, respond to, and recover from cyberattacks capable of causing the consequences identified in paragraph (a) of this section;

(3) Mitigate the adverse effects of cyber attacks capable of causing the consequences identified in paragraph (a) of this section; and

(4) Ensure that the functions of protected assets identified under paragraph (b)(1) of this section are not adversely impacted due to cyber attacks.

(e) The licensee must implement the following requirements in a manner that is commensurate with the potential consequences resulting from cyber attacks:

(1) As part of the cyber security program, the licensee must comply with the requirements in § 73.54(d)(1), (2), and (4), and must ensure that modifications to assets, identified under paragraph (b)(1) of this section are evaluated before implementation to ensure that the cyber security performance objectives identified in paragraph (a) of this section are maintained.

(2) The licensee must establish, implement, and maintain a cyber security plan that implements the cyber security program requirements of this section.

(i) The cyber security plan must describe how the requirements of this section will be implemented and must account for the site-specific conditions that affect implementation.

(ii) The cyber security plan must include measures for incident response and recovery for cyber attacks. The cyber security plan must include the analysis identified under paragraph (b)(1) of this section and describe how the licensee will—

(A) Apply and maintain defense-in-depth protective strategies as required in paragraph (d)(2) of this section;

(B) Maintain the capability for timely detection and response to cyber attacks;

(C) Mitigate the consequences of cyber attacks;

(D) Correct exploited vulnerabilities; and

(E) Restore affected systems, networks, and/or equipment affected by cyber attacks.

(3) The licensee must develop and maintain written policies and implementing procedures to implement the cyber security plan. Policies, implementing procedures, and other supporting technical information used by the licensee need not be submitted for Commission review and approval as part of the cyber security plan but are subject to inspection by NRC staff on a periodic basis.

(4) The licensee must establish and implement cyber security reviews to assess the effectiveness of the implementation of the cyber security program.

(i) The licensee must review each element of the cyber security program at a frequency commensurate with the importance or significance to safety of plant operations to ensure timely identification and documentation of vulnerabilities, improvements, and corrective actions.

(ii) Cyber security reviews must be performed by individuals independent of those personnel responsible for program management and any individual who has direct responsibility for implementing the cyber security program.

(iii) The licensee must establish and perform self-assessments to ensure the

effective implementation of the cyber security program.

(iv) The results and recommendations of the cyber security program reviews, management's findings regarding program effectiveness, and any actions taken as a result of recommendations from prior program reviews, must be documented in a report and must be maintained in an auditable form and available for inspection.

(5) The licensee must retain all records and supporting technical documentation required to demonstrate compliance with the requirements of this section as a record until the Commission terminates the license for which the records were developed and must maintain superseded portions of these records for at least three (3) years after the record is superseded, unless otherwise specified by the Commission.

163. Add § 73.120 to read as follows:

§ 73.120 Access authorization program for commercial nuclear plants.

(a) *Introduction and scope*. Each applicant for an operating license or a holder of a combined license under 10 CFR part 53 must establish, maintain, and implement an access authorization program before initial fuel load into the reactor. The requirements in this section apply to licensees satisfying the criterion in § 53.860(a)(2) of this chapter.

(b) *Applicability*.

(1) The following individuals must be subject to an access authorization program under this section:

(i) Any individual to whom a licensee intends to grant unescorted access to a commercial nuclear plant protected area, vital area, material access area, or controlled access area where licensed material is used or stored;

(ii) Any individual whose duties and responsibilities permit the individual to take actions by electronic means, either on site or remotely, that could adversely impact the

licensee's or applicant’s operational safety, security, or emergency preparedness;

(iii) Any individual who has responsibilities for implementing a licensee's or applicant's protective strategy, including armed security force officers, alarm station operators, and tactical response team leaders but not including Federal, State, or local law enforcement personnel; and

(iv) The licensee or applicant access authorization program reviewing official or contractor or vendor access authorization program reviewers.

(2) The licensee or applicant may subject other individuals, including employees of a contractor or a vendor who are designated in access authorization program procedures, to an access authorization program that demonstrates compliance with the requirements of this section.

(c) *General performance objectives and requirements*. Each licensee's or applicant’s access authorization program under this section must demonstrate that the individuals who are specified in paragraph (b) of this section are trustworthy and reliable, such that they do not constitute an unreasonable risk to public health and safety or the common defense and security. The licensee’s access authorization program must maintain the capabilities for demonstrating compliance with the following performance requirements:

(1) *Background investigation*. (i)(A) Licensees and applicants must ensure that any individual seeking initial unescorted access or to maintain unescorted access is subject to a background investigation.

(B) Background investigations must include the program elements contained under § 37.25 of this chapter and must also include a credit history evaluation.

(ii) Background investigations must include fingerprinting and an FBI identification and criminal history records check in accordance with § 37.27 of this

chapter.

(iii) Licensees must have the informed and signed consent of the subject individual to initiate a background investigation. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. A signed consent must be obtained prior to any reinvestigation. The subject individual may withdraw his or her consent at any time. Licensees must inform the individual that—

(A) If an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew his or her consent; and

(B) The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

(2) *Behavioral observation*. Licensees, applicants, contractors, and vendors must ensure the access authorization program includes provisions that the individuals specified in paragraph (b) of this section are subject to behavioral observation.

(i) Each person subject to behavioral observation must communicate to the licensee or applicant observed behaviors or activities of individuals that may constitute an unreasonable risk to the health and safety of the public and common defense and security.

(ii) Behavioral observation must include visual observation, in person or remotely by video, to detect and promptly report to plant supervision any concerns arising from behavioral observation, including, but not limited to, concerns related to any questionable behavior patterns or activities of others.

(3) *Self-reporting of legal actions*. Licensees or applicants must inform personnel who are granted and who maintain unescorted access of their responsibilities

to self-report to plant supervision legal actions taken by a law enforcement authority or court of law against the individual that could result in incarceration or a court order or that requires a court appearance, including but not limited to an arrest, an indictment, the filing of charges, or a conviction, but excluding minor civil actions or misdemeanors such as parking violations or speeding tickets, for any individual who has applied for unescorted access or who maintains unescorted access.

(4) *Unescorted access*. Licensees or applicants must grant unescorted access only after the licensee has verified an individual is trustworthy and reliable. A list of persons currently approved for unescorted access to a protected area, vital area, material access area, or controlled access area must be maintained at all times. Unescorted access determinations must be reviewed annually by the reviewing official. Licensees and applicants must complete an FBI criminal history record check update for each individual maintaining unescorted access, within 10 years of the last review.

(5) *Termination of unescorted access.* Licensees and applicants must promptly terminate unescorted access when this access is no longer required or a reviewing official determines an individual is no longer trustworthy and reliable in accordance with this section.

(6) *Determination basis for access*. (i) The licensee’s or applicant’s reviewing official must determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access based on an evaluation of all of the information collected to demonstrate compliance with the requirements of this section.

(ii) Licensees and applicants must provide individuals subject to this section, prior to any final adverse determination, the right to complete, correct, and explain

information obtained as a result of the licensee's background investigation pursuant to § 37.23(g) of this chapter.

(iii) The licensee’s or applicant’s reviewing officials are the only individuals authorized to make unescorted access determination decisions. Each licensee or applicant must name one or more individuals to be reviewing officials pursuant to the requirements of § 37.23(b)(2) of this chapter.

(7) *Review procedures*. Review procedures must be established in accordance with § 37.23(f) of this chapter, to include provisions for the notification in writing of individuals who are denied unescorted access or who are unfavorably terminated.

(8) *Protection of information*. Licensees, applicants, contractors, or vendors must establish and maintain a system of files and procedures in accordance with § 37.31 of this chapter, to ensure personal information is not disclosed to unauthorized persons.

(9) *Access authorization reviews and corrective action*. Licensees and applicants must develop, implement, and maintain procedures for conduct of access authorization reviews and corrective actions in accordance with § 37.33 of this chapter to ensure the continuing effectiveness of the access authorization program and to ensure that the access authorization program and program elements are in compliance with the requirements of this section. Each licensee and applicant must be responsible for the continuing effectiveness of the access authorization program, including access authorization program elements that are provided by the contractors or vendors, and the access authorization programs of any of the contractors or vendors that are accepted by the licensee or applicant.

(10) *Records.* Licensees, applicants, and contractors or vendors must document the processes and procedures for maintaining records used or created to establish an individual’s trustworthiness and reliability or to document access

determinations. Licensees, applicants, and contractor or vendors must—

(i) Retain documentation regarding the trustworthiness and reliability of individual employees for 3 years from the date the individual no longer requires unescorted access;

(ii) Retain a copy of the current access authorization program procedures as a record for 3 years after the procedure is no longer needed. If any portion of the procedure is superseded, retain the superseded material for 3 years after the record is superseded; and

(iii) Retain the list of persons approved for unescorted access for 3 years after the list is superseded or replaced. Records maintained in any database(s) must be available for NRC review.

§ 73.1200 [Amended]

164. In § 73.1200, in paragraphs (o)(5)(i) and (o)(6)(i) add " § 53.1630 of this chapter," after "appendix E to part 50 of this chapter," wherever it appears and in paragraphs (r) and (s) add "53.1630, " after "50.72, " wherever it appears.

§ 73.1205 [Amended]

165. In § 73.1205, add " or § 53.1640" after "§ 50.73" wherever it appears.

166. In appendix B to part 73, revise Definitions introductory text to read as follows:

Appendix B to Part 73 – General Criteria for Security Personnel

* * * * *

Definitions

Terms defined in parts 50, 53, 70, and 73 of this chapter have the same meaning when used in this appendix.

* * * * *

PART 74 – MATERIAL CONTROL AND ACCOUNTING OF SPECIAL NUCLEAR MATERIAL

167. The authority citation for 10 CFR part 74 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 57, 161, 182, 223, 234, 1701 (42 U.S.C. 2073, 2077, 2201, 2232, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

§ 74.13 [Amended]

168. In § 74.13(a), remove “as defined in §§ 50.21 and 50.22” and add in its place “under §§ 50.21, 50.22 or part 53”.

§ 74.31 [Amended]

169. In § 74.31(a), add “, 52, 53,” after “part 50”.

§ 74.41 [Amended]

170. In § 74.41(a), remove “part 50” and add in its place “parts 50, 52, or 53”.

§ 74.51 [Amended]

171. In § 74.51(a), remove “part 50” and add in its place “parts 50, 52, or 53”.

PART 75 – SAFEGUARDS ON NUCLEAR MATERIAL – IMPLEMENTATION OF SAFEGUARDS AGREEMENTS BETWEEN THE UNITED STATES AND THE INTERNATIONAL ATOMIC ENERGY AGENCY

172. The authority citation for 10 CFR part 75 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 63, 103, 104, 122, 161, 223, 234, 1701 (42 U.S.C. 2073, 2093, 2133, 2134, 2152, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

173. In § 75.4, revise the introductory text and the definition for “Facility” to read as follows:

§ 75.4 Definitions.

* * * * *

Unless otherwise defined in this section, the terms defined in §§ 40.4, 50.2, 53.020, and 70.4 of this chapter have the same meaning when used in this part.

* * * * *

Facility means:

(1) * * *

(6) Any plant or location where the possession of more than 1 effective kilogram of nuclear material is licensed pursuant to Parts 40, 50, 52, 53, 60, 61, 63, 70, 72, 76, or 150 of this chapter or an Agreement State license.

* * * * *

PART 95 – FACILITY SECURITY CLEARANCE AND SAFEGUARDING OF NATIONAL SECURITY INFORMATION AND RESTRICTED DATA

174. The authority citation for 10 CFR part 95 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 145, 161, 223, 234 (42 U.S.C. 2165, 2201, 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 44 U.S.C. 3504 note; E.O. 10865, as amended, 25 FR 1583, 3 CFR, 1959–1963 Comp., p. 398; E.O. 12829, 58 FR 3479, 3 CFR, 1993 Comp., p. 570; E.O. 12968, 60 FR 40245, 3 CFR, 1995 Comp., p. 391; E.O. 13526, 75 FR 707, 3 CFR, 2009 Comp., p. 298.

§ 95.5 [Amended]

175. In § 95.5, in the definition for "*License,*" add "53," after "52."

§ 95.39 [Amended]

176. In § 95.39(a), remove "part 52" and add in its place "parts 52 or 53."

PART 140 – FINANCIAL PROTECTION REQUIREMENTS AND INDEMNITY AGREEMENTS

177. The authority citation for 10 CFR part 140 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 161, 170, 223, 234 (42 U.S.C. 2201, 2210, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

178. In § 140.2, revise paragraphs (a)(1) and (2) to read as follows:

§ 140.2 Scope.

(a) * * *

(1) To each person who is an applicant for or holder of a license issued under 10 CFR parts 50, 52, 53, or 54 to operate a nuclear reactor, and

(2) With respect to an extraordinary nuclear occurrence, to each person who is an applicant for or holder of a license to operate a production facility or a utilization facility (including an operating license issued under parts 50 or 53 of this chapter and a combined license under parts 52 or 53 of this chapter), and to other persons indemnified with respect to the involved facilities.

* * * * *

179. Revise § 140.10 to read as follows:

§ 140.10 Scope.

This subpart applies to each person who is an applicant for or holder of a license issued under 10 CFR parts 50, 53 or 54 to operate a nuclear reactor, or is the applicant for or holder of a combined license issued under parts 52, 53, or 54 of this chapter, except licenses held by persons found by the Commission to be Federal agencies or nonprofit educational institutions licensed to conduct educational activities. This subpart also applies to persons licensed to possess and use plutonium in a plutonium processing and fuel fabrication plant.

180. In § 140.11, revise paragraph (b) to read as follows:

§ 140.11 Amounts of financial protection for certain reactors.

* * * * *

(b) In any case where a person is authorized under parts 50, 52, 53, or 54 of this chapter to operate two or more nuclear reactors at the same location, the total primary financial protection required of the licensee for all such reactors is the highest amount

which would otherwise be required for any one of those reactors; provided, that such primary financial protection covers all reactors at the location.

181. In § 140.12, revise paragraph (c) to read as follows:

§ 140.12 Amount of financial protection required for other reactors.

* * * * *

(c) In any case where a person is authorized under parts 50, 52, 53, or 54 of this chapter to operate two or more nuclear reactors at the same location, the total financial protection required of the licensee for all such reactors is the highest amount which would otherwise be required for any one of those reactors; provided, that such financial protection covers all reactors at the location.

* * * * *

182. Revise § 140.13 to read as follows:

§ 140.13 Amount of financial protection required of certain holders of construction permits and combined licenses under 10 CFR parts 52 and 53.

Each holder of a part 50 or 53 construction permit, or a holder of a combined license under parts 52 or 53 of this chapter before the date that the Commission had made the finding under § 52.103(g) or § 53.1452(g) of this chapter, who also holds a license under part 70 of this chapter authorizing ownership, possession and storage only of special nuclear material at the site of the nuclear reactor for use as fuel in operation of the nuclear reactor after issuance of either an operating license under 10 CFR parts 50 or 53, or a combined license under 10 CFR parts 52 or 53, shall, during the period before issuance of a license authorizing operation under 10 CFR parts 50 or 53, or the period before the Commission makes the finding under § 52.103(g) or § 53.1452(g) of this chapter, as applicable, have and maintain financial protection in the amount of $1,000,000. Proof of financial protection shall be filed with the Commission in the

manner specified in § 140.15 of this chapter before issuance of the license under part 70 of this chapter.

183. In § 140.20, revise paragraphs (a)(1)(i) and (ii) to read as follows:

§ 140.20 Indemnity agreements and liens.

(a) * * *

(1)(i) The effective date of the license (issued under parts 50 or 53 of this chapter) authorizing the licensee to operate the nuclear reactor involved; or

(ii) The date that the Commission makes the finding under § 52.103(g) or § 53.1452(g) of this chapter; or

* * * * *

PART 150 – EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

184. The authority citation for 10 CFR part 150 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 53, 81, 83, 84, 122, 161, 181, 223, 234, 274 (42 U.S.C. 2014, 2201, 2231, 2273, 2282, 2021); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

185. In § 150.15, revise paragraphs (a)(7)(iii) and (a)(8) to read as follows:

§ 150.15 Persons not exempt.

(a) * * *

(7) * * *

(iii) Greater than Class C waste, as defined in part 72 of this chapter, in an ISFSI or an MRS licensed under part 72 of this chapter; the GTCC waste must originate in, or be used by, a facility licensed under parts 50, 52, or 53 of this chapter.

(8) Greater than Class C waste, as defined in part 72 of this chapter, that originates in, or is used by, a facility licensed under parts 50, 52, or 53 of this chapter and is licensed under part 30 and/or part 70 of this chapter.

* * * * *

PART 170 – FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

186. The authority citation for 10 CFR part 170 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w) (42 U.S.C. 2014, 2201(w)); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2215; 31 U.S.C. 901, 902, 9701; 44 U.S.C. 3504 note.

187. In § 170.3, revise the definitions for "*Manufacturing License,"* "*Part 55 Reviews,"* "*Power reactor,"* and "*Special projects"* to read as follows:

§ 170.3 Definitions.

* * * * *

Manufacturing license means a license under subpart F of part 52, of this chapter or subpart H of part 53 of this chapter to manufacture a nuclear power reactor(s) to be operated at sites not identified in the license application.

* * * * *

Part 55 Reviews as used in this part means those services provided by the Commission to administer requalification and replacement examinations and tests for reactor operators licensed under 10 CFR part 55 or part 53 of the Commission's regulations and employed by part 50, 52, or 53 licensees. These services also include related items such as the preparation, review, and grading of the examinations and tests.

* * * * *

Power reactor means a nuclear reactor designed to produce electrical or heat energy licensed by the Commission under the authority of section 103 or subsection

104b of the Act, and under the provisions of § 50.21(b), § 50.22, or part 53 of this chapter.

* * * * *

Special projects means specific services provided by the Commission for which fees are not otherwise specified in this chapter. This includes, but is not limited to, contested hearings on licensing actions directly related to U.S. Government national security initiatives (as determined by the NRC), topical report reviews, early site reviews, waste solidification activities, activities related to the tracking and monitoring of shipment of classified matter, services provided to certify licensee, vendor, or other private industry personnel as instructors for 10 CFR parts 55 or 53 reactor operators, reviews of financial assurance submittals that do not require a license amendment, reviews of responses to Confirmatory Action Letters, reviews of uranium recovery licensees' land-use survey reports, and reviews of updated Final Safety Analysis Reports submitted under § 50.71 or § 53.6045 of this chapter. The term special projects does not include activities otherwise exempt from fees under this part. It also does not include those contested hearings for which a fee exemption is granted in § 170.11(a)(2), including those related to individual plant security modifications.

* * * * *

§ 170.12 [Amended]

188. In § 170.12(d)(1)(v), remove “10 CFR 50.71” and add in its place “10 CFR 50.71 or 53.1545”.

§ 170.21 [Amended]

189. In § 170.21, footnote 1, add “10 CFR 53.080,” after “10 CFR 50.12,” inside the parenthetical.

§ 170.41 [Amended]

190. In § 170.41, add “52, 53,” after “40, 50,”.

PART 171 – ANNUAL FEES FOR REACTOR LICENSES AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY THE NRC

191. The authority citation for 10 CFR part 171 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w), 223, 234 (42 U.S.C. 2014, 2201(w), 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2215; 44 U.S.C. 3504 note.

192. Revise § 171.3 to read as follows:

§ 171.3 Scope.

The regulations in this part apply to any person holding an operating license for a test reactor or research reactor issued under part 50 of this chapter, and to any person holding an operating license for a power reactor licensed under 10 CFR parts 50 or 53, or a combined license issued under 10 CFR parts 52 or 53, that has provided notification to the NRC that the licensee has successfully completed power ascension testing. The regulations in this part also apply to any person holding a materials license as defined in this part, a Certificate of Compliance, a sealed source or device registration, a quality assurance program approval, and to a Government agency as defined in this part. Notwithstanding the other provisions in this section, the regulations in this part do not apply to uranium recovery and fuel facility licensees until after the Commission verifies through inspection that the facility has been constructed in accordance with the requirements of the license.

193. In § 171.5, revise the definitions for “Operating license,” and “Power reactor” to read as follows:

§ 171.5 Definitions.

* * * * *

Operating license means having a license issued under § 50.57 or § 53.1387 of this chapter. It does not include licenses that only authorize possession of special nuclear material after the Commission has received a request from the licensee to amend its licensee to permanently withdraw its authority to operate or the Commission has permanently revoked such authority.

* * * * *

Power reactor means a nuclear reactor designed to produce electrical or heat energy and licensed by the Commission under the authority of section 103 or subsection 104b of the Atomic Energy Act of 1954, as amended, and under the provisions of § 50.21(b) or 50.22, or part 53 of this chapter.

* * * * *

194. In § 171.15, revise paragraphs (a), (b)(2)(iii), (c)(1), and (d)(1) to read as follows:

§ 171.15 Annual fees: Non-power production or utilization licenses, reactor licenses, and independent spent fuel storage licenses.

(a) Each person holding an operating license for one or more non-power production or utilization facilities under 10 CFR part 50 that has provided notification to the NRC of the successful completion of startup testing; each person holding an operating license for a power reactor licensed under 10 CFR part 50 or a combined license under 10 CFR part 52, or an operating license or combined license for a commercial nuclear plant under 10 CFR part 53, that has provided notification to the NRC of the successful completion of power ascension testing; each person holding a 10 CFR part 50, 52, or 53 power reactor license that is in decommissioning or possession only status, except those that have no spent fuel onsite; and each person holding a

10 CFR part 72 license who does not hold a 10 CFR parts 50, 52, or 53 license and provides notification under § 72.80(g), shall pay the annual fee for each license held during the Federal fiscal year in which the fee is due. This paragraph (a) does not apply to test or research reactors exempted under § 171.11(b).

(b) * * *

(2) * * *

(iii) Generic activities required largely for NRC to regulate power reactors (e.g., updating parts 50, 52, or 53 of this chapter, operating the Incident Response Center, new reactor regulatory infrastructure). The base annual fee for operating power reactors does not include generic activities specifically related to reactor decommissioning.

(c)(1) The FY 2022 annual fee for each power reactor holding a 10 CFR part 50 operating license or combined license issued under 10 CFR parts 52 or 53 that is in a decommissioning or possession-only status and has spent fuel onsite, and for each independent spent fuel storage 10 CFR part 72 licensee who does not hold a 10 CFR parts 50 or 53 operating license, or a 10 CFR parts 52 or 53 combined license, is $227,000.

* * * * *

(d)(1) Each person holding an operating license for an SMR issued under 10 CFR parts 50 or 53, or a combined license issued under 10 CFR parts 52 or 53, that has provided notification to the NRC of the successful completion of power ascension testing, shall pay the annual fee for all licenses held for an SMR site. The annual fee will be determined using the cumulative licensed thermal power rating of all SMR units and the bundled unit concept, during the fiscal year in which the fee is due. For a given site, the use of the bundled unit concept is independent of the number of SMR plants, the

number of SMR licenses issued, or the sequencing of the SMR licenses that have been issued.

* * * * *

§ 171.17 [Amended]

195. In § 171.17, in paragraph (a) introductory text remove “or 10 CFR part 52” and add in its place, “10 CFR part 52, or 10 CFR part 53”; in paragraphs (a)(1)(ii) and (a)(2) remove “or 52,” wherever it may appear and add in its place, “52, or 53”.

Dated: <Month XX, 20XX>.

For the Nuclear Regulatory Commission.

<**INSERT:** Name,>

<**INSERT:** Title of signing official.>

Attachment 3 to Commissioner Caputo's Comments on SECY-23-0021, "Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31)"

Red-line strikeout version of the Federal Register Notice for the Proposed Rule

AXC Edits

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 1, 2, 10, 11, 19, 20, 21, 25, 26, 30, 40, 50, 51, 53, 55, 70, 72, 73, 74, 75, 95, 140, 150, 170, and 171

[NRC-2019-0062]

RIN 3150-AK31

Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to revise the NRC's regulations by adding a risk-informed, performance-based, and technology-inclusive regulatory framework for commercial nuclear plants in response to the Nuclear Energy Innovation and Modernization Act (NEIMA). The NRC plans to hold a public meeting to promote full understanding of the proposed rule and facilitate public comments.

DATES: Submit comments by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking website:** Go to https://www.regulations.gov and search for Docket ID NRC-2019-0062. Address questions about NRC dockets to Dawn Forder; telephone: 301-415-3407; e-mail: Dawn.Forder@nrc.gov. For technical questions

contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic e-mail reply confirming receipt, then contact us at 301-415-1677.
- **Fax comments to:** Secretary, U.S. NRC at 301-415-1101.
- **Mail comments to:** Secretary, U.S. NRC, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Robert Beall, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-3874; email: Robert.Beall@nrc.gov; or Jordan Hoellman, Office of Nuclear Reactor Regulation, telephone: 301-415-5481; email: Jordan.Hoellman2@nrc.gov. Both are staff of the U.S. NRC, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

EXECUTIVE SUMMARY:

A. Need for the Regulatory Action

On January 14, 2019, the President signed NEIMA into law (Pub. L. 115–439). NEIMA section 103(a)(4) directs the NRC to "complete a rulemaking to establish a technology-inclusive, regulatory framework for optional use by commercial advanced nuclear reactor applicants for new reactor license applications." NEIMA defines a

"technology-inclusive," regulatory framework" as one that is "developed using methods of evaluation that are flexible and practicable for application to a variety of reactor technologies, including, where appropriate, the use of risk-informed and performance-based techniques." NEIMA defines the term ''advanced nuclear reactor," in part, as "a nuclear fission or fusion reactor, including a prototype plant (as defined in sections 50.2 and 52.1 of title 10, Code of Federal Regulations (as in effect on the date of enactment of this Act)), with significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of this Act, including improvements such as—

(A) additional inherent safety features;

(B) significantly lower levelized cost of electricity;

(C) lower waste yields;

(D) greater fuel utilization;

(E) enhanced reliability;

(F) increased proliferation resistance;

(G) increased thermal efficiency; or

(H) ability to integrate into electric and nonelectric applications."

The NRC initially considered establishing the scope of proposed part 53, "Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants," of title 10 of the *Code of Federal Regulations* (10 CFR) as being for "advanced nuclear plants" consisting of one or more "advanced nuclear reactors" as defined in NEIMA. Based on public discussions on the use of the term, the NRC determined that the NEIMA definition, although broad, did not define "significant improvements" with enough specificity to implement in NRC regulations. Additionally, a number of stakeholders suggested that the descriptor, "advanced," implied enhanced safety, while the NEIMA

Commented [A1]: Edited to reflect that the phrase in the NEIMA definition section does not include a comma. Alternatively, this could be corrected by removing the quotation marks.

definition includes ~~"significant~~ improvements~~"~~ in areas other than safety enhancements. In response to this feedback, and to be technology inclusive, the NRC staff determined that the broader term "commercial nuclear plant" would be preferable.

The current application and licensing requirements in 10 CFR part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," were primarily developed to address license requests concerning water-cooled reactors, and to address operational requirements for those types of reactors. This rulemaking responds to NEIMA by creating an alternative regulatory framework for licensing future commercial nuclear plants. The new alternative requirements and implementing guidance would~~ill~~ adopt technology-inclusive approaches and use risk-informed and performance-based techniques to ensure an equivalent level of safety to that of operating commercial nuclear plants while providing flexibility for licensing and regulating a variety of technologies and designs for commercial nuclear reactors.

B. Major Provisions

Major provisions of this proposed rule, supported by accompanying guidance, include the following:

- ~~A~~ A new alternative technology-inclusive, risk-informed, performance-based framework ~~referred to as "Framework A"~~ that includes requirements for licensing and regulating nuclear plants during the various stages of their life cycles.
- ~~A new technology-inclusive framework referred to as "Framework B" that is similar to the current approach to the licensing and regulating of light-water reactors (LWRs) in parts 50 and 52.~~

- A new alternative technology-inclusive, risk-informed, and performance-based framework in 10 CFR part 26, “Fitness for Duty Programs” developed from existing requirements in subpart K, “FFD Programs for Construction,” of part 26.
- A new alternative technology-inclusive and performance-based security framework in 10 CFR part 73, “Physical Protection of Plants and Materials” that includes requirements for protection of licensed activities at commercial nuclear plants.

C. Costs and Benefits

The NRC prepared a draft regulatory analysis to determine the expected quantitative costs and benefits of this proposed rule and associated guidance as well as qualitative factors to be considered in the NRC’s rulemaking decision. The conclusion from the analysis is that this proposed rule and associated guidance would result in net averted costs to the industry and the NRC ranging from $ ~~53.6~~22.0 million using a 7-percent discount rate to $ ~~68.2~~31.9 million using a 3-percent discount rate, using an assumption of one applicant ~~under Framework A, and one applicant under Framework B~~. As the number of applicants increases, so do the estimated averted costs.

The draft regulatory analysis also considered qualitative factors~~aspects~~, such as greater regulatory stability, predictability, and clarity to the licensing process. These benefits would result from incorporating advances in probabilistic risk assessment (PRA) and other risk-informed analyses ~~and codifying regulatory enhancements that currently exist in regulatory guides (RGs)~~. Another qualitative ~~consideration~~ factor is promoting a performance-based regulatory framework that specifies requirements to be met and provides flexibility to an applicant or licensee regarding the information or approach needed to satisfy those requirements.

Commented [A2]: In all cases where acceptable approaches in regulatory guides are proposed for codification, staff should account for the loss of flexibility and the potential need for additional expenditures by applicants in the future proposing innovative approaches to provide an equivalent level of safety in order to obtain exemptions from the single method of providing safety being codified.

Commented [A3]: Edited to conform to the Commission direction of SRM-SECY-14-0087.

For more information, please see the draft regulatory analysis (available in the NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML21165A112).

TABLE OF CONTENTS:

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Please refer to Docket ID NRC-2019-0062 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- **Federal Rulemaking website:** Go to https://www.regulations.gov and search for Docket ID NRC-2019-0062.
- **NRC's ADAMS:** You may obtain publicly available documents online in the ADAMS Public Documents collection at https://www.nrc.gov/reading-rm/adams.html. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by e-mail to pdr.resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in section XIX, "Availability of Documents."

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- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include **Docket ID NRC-2019-0062** in your comment submission. To facilitate NRC review, please distinguish between comments on the proposed rule and comments on the proposed guidance. The NRC cautions you not to include identifying or

contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at https://www.regulations.gov as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

A. NRC Advanced Reactor Readiness

In its "Policy Statement on the Regulation of Advanced Nuclear Power Plants," dated July 8, 1986, the Commission stated that it considered the term "advanced" to apply to reactors that are significantly different from current (i.e., current in 1986) generation LWRs then under construction or in operation, and that "advanced" includes reactors that provide enhanced margins of safety or utilize simplified inherent or other innovative means to accomplish their safety functions. At the time, certain high temperature gas-cooled reactors, liquid metal reactors, and LWRs of innovative design were considered to be "advanced." The 1986 policy statement provided the Commission's policy regarding the review of, and desired characteristics associated with, advanced reactors. The NRC updated this statement in the "Policy Statement on the Regulation of Advanced Reactors," dated October 14, 2008 (Advanced Reactor Policy Statement).

The agency has undertaken many activities related to advanced reactors, including issuing an advance notice of proposed rulemaking titled, “Approaches to Risk-Informed and Performance-Based Requirements for Nuclear Power Reactors,” dated May 4, 2006 (71 FR 26267). These efforts were often done in parallel, and sometimes interwoven, with the NRC’s efforts to improve risk-informed and performance-based approaches within the agency (e.g., the Commission’s policy statement, “Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities,” dated August 16, 1995 (PRA Policy Statement)).

In 2016, the NRC issued “NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light-Water Mission Readiness” (Advanced Reactor Vision and Strategy Document), in response to increasing interest in advanced reactor designs. The NRC considered the Department of Energy’s (DOE) advanced reactor deployment goals in developing the Advanced Reactor Vision and Strategy Document. Since publication of the document, the NRC continues to manage its activities to support the DOE’s deployment goals. The Advanced Reactor Vision and Strategy Document identified initiating and developing a new risk-informed, performance-based, and technology-inclusive regulatory framework as a possible long-term goal. However, the NRC staff’s initial efforts were focused on resolving policy issues and developing guidance for licensing non-LWR technologies under the existing regulatory frameworks (parts 50 and 52). The NRC staff issues annual Commission papers on the status and progress of the NRC staff’s activities related to advanced reactors (e.g., SECY-22-0008, “Advanced Reactor Program Status,” ~~on~~dated January 31, 2022). These Commission papers provide status updates for advanced reactor activities undertaken both prior to and after initiation of this rulemaking.

In 2017, the NRC staff prioritized activities to support the development of technology-inclusive, risk-informed, and performance-based licensing approaches that could be implemented under the existing regulatory framework in parts 50 and 52. One key element of these efforts was the Licensing Modernization Project (LMP), a cost-shared initiative led by nuclear utilities and supported by DOE. The LMP is a technology-inclusive, risk-informed, and performance-based methodology developed for non-LWR designs. The LMP provides a systematic and reproducible process for licensing-basis event (LBE) selection and evaluation; classification of structures, systems, and components (SSCs); and assessment of defense in depth. The LMP refined the DOE's Next Generation Nuclear Plant Program methodologies to reflect interactions with the NRC, to address feedback from industry, and to broaden the scope of the approach to ensure applicability to various non-LWR technologies. The LMP activities led to the publication and submittal of Nuclear Energy Institute (NEI) 18-04, Revision 1, "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," issued August 2019. NEI 18-04 indicates that controlling the frequencies and potential consequences of a wide spectrum of events is the primary focus of the LMP approach.

~~The NRC endorsed the principles and methodology in NEI 18-04, with clarifications, in RG 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors."~~ The NRC staff sought Commission approval of the use of LMP and NEI-18-04 in SECY-19-0117, "Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors," dated December 2, 2019. In that paper, the

staff described the relationship between the LMP and NEI-18-04 and previous relevant Commission decisions, including those described in SECY-93-092, "Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and their Relationship to Current Regulatory Requirements," dated April 8, 1993. The Commission approved the use of the LMP methodology and NEI-18-04 as a reasonable approach for establishing key parts of the licensing basis and content of applications for licenses, certifications, and approvals for non-LWRs in Staff Requirements Memorandum (SRM) SRM-SECY-19-0117, dated May 26, 2020. Although the LMP approach is technology-inclusive, the industry and NRC staff initially focused the LMP's applicability on non-LWRs, both for efficiency and to support near-term non-LWR applications under the existing regulatory framework, such as the Advanced Reactor Demonstration Projects supported by DOE. The NRC endorsed the principles and methodology in NEI 18-04, with clarifications, in RG 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors."

As stated in the part 53 rulemaking plan, SECY-20-0032, the NRC staff developed part 53~~, and specifically Framework A,~~ by building upon recent and ongoing activities such as the LMP approach described in SECY-19-0117. Such an approach supports implementing the NEIMA requirement to use, where appropriate, risk-informed and performance-based techniques, and it also capitalizes on previous initiatives by the industry, DOE, and the NRC, including the LMP. The approach ~~in Framework A~~ highlights the role of risk evaluation~~PRA~~ in risk-informed and performance-based approaches to identifying enhanced safety margins that can be used to justify operational flexibilities. The proposed f~~F~~ramework ~~A~~ is largely based on the

methodology described in SECY-19-0117 and ~~includes~~ facilitates a prominent role for PRA.

As discussed in section II.B, "Stakeholder Views on Part 53 Preliminary Proposed Rule Language," of this document, the NRC conducted extensive public outreach on early versions of the rule text. Those early versions provided an approach to licensing that became the basis for ~~Framework A in~~ the proposed rule. However, stakeholders indicated that some designers might find the role of PRA contemplated by initial versions of the rule~~Framework A~~ unduly restrictive, either because of the simplified scope of their designs or because their business plans contemplated marketing in countries that would require a different, more deterministic, safety analysis. In light of these stakeholder views, the NRC revised the initial discussion drafts of the proposed rule to be a higher level requirement that ~~also developed an alternate approach to licensing in part 53, which became Framework B in the proposed rule. Framework B largely replicates the existing licensing approach in parts 50 and 52 but modifies it to be technology neutral. Although it includes consideration of insights from risk assessments, Framework B~~ would not require a PRA to be used to the extent contemplated ~~by Framework A~~initially. Instead, ~~Framework B~~the proposed rule would require applicants to use a risk evaluation such as ~~insights from~~ a PRA~~,~~ or an alternative evaluation for risk insights (AERI)~~, in a confirmatory role to support the largely deterministic safety analysis and as a possible tool to identify safety margins to justify operational flexibilities. This approach is consistent with how part 52 currently utilizes risk insights. Additionally, the approach to licensing in Framework B, which would require applicants to develop and use principal design criteria (PDCs) similar to those in appendix A in part 50, aligns with existing international standards for designing and licensing advanced reactors.~~

B. Stakeholder Views on Part 53 Preliminary Proposed Rule Language

In SRM-SECY-20-0032, the Commission directed the NRC staff to prepare and release preliminary proposed rule language, followed by public outreach and dialogue, and then further revise the language until the NRC staff had established the rudiments of its proposed rule for Commission consideration. To implement the Commission's direction, the NRC staff undertook an unprecedented program of stakeholder engagement, recognizing the importance of this rulemaking to the advanced reactor community and interested stakeholders from a broad range of backgrounds and organizations.

On November 6, 2020, the NRC published a *Federal Register* notice (85 FR 71002) describing plans for the periodic release of preliminary proposed rule language, meetings with stakeholders, and the ability of stakeholders to provide input during the development of this proposed rule. Sections of the preliminary proposed rule language were subsequently released, and the NRC held numerous public meetings to discuss the preliminary proposed rule language and obtain input from stakeholders. On December 10, 2021, the NRC published a second *Federal Register* notice (86 FR 70423) announcing that the development of the proposed rule and related interactions with stakeholders were being extended until August 31, 2022.

By the close of the public stakeholder interactions on August 31, 2022, the NRC staff had held 24 public meetings since September 2020. The NRC staff also met with the Advisory Committee on Reactor Safeguards (ACRS) in 16 public meetings during this period. By the close of the public engagement period on the preliminary proposed rule language, 126 letters were received on the preliminary proposed rule language. Of these 126 letters, 21 were from non-governmental organizations, 31 were from the public, one was from Congress, and the remaining 73 letters were from NRC licensees,

the NEI, and other industry groups. The letters from stakeholders provided various points of view and suggestions for clarifications, additions, and deletions to the preliminary proposed rule language. In addition, the ACRS wrote four interim letters reports to the Chair on this rulemaking and issued its final letter report on November 22, 2022. ~~The letters from stakeholders provided various points of view and suggestions for clarifications, additions, and deletions to the preliminary proposed rule language.~~ Copies of these letters may be viewed and downloaded from the Federal eRulemaking Web site *http://www.regulations.gov,* under docket number NRC–2019–0062. The inputs received were considered in the development of this proposed rule. However, as described during the various public interactions related to this rulemaking and in supporting documents, the NRC will not formally disposition the questions and suggestions related to the preliminary proposed rule language as it will for public comments received following the publication of this proposed rule.

Commented [A6]: Edited to use the term from the ACRS Bylaws.

Commented [A7]: Edited to be consistent with the usage on the first page of this document and the continued use of that terminology in other portions of this document.

III. Discussion

A. Objective and Applicability

The NRC is proposing to add a new, alternative part to its regulations that would set out a risk-informed, technology-inclusive framework~~s~~ for the licensing and regulation of commercial nuclear plants. Thisese new approach~~es~~ would achieve the following: (1) continue to provide reasonable assurance of adequate protection of public health and safety and the common defense and security; (2) promote regulatory stability, predictability, and clarity; (3) reduce requests for exemptions from the current requirements in parts 50 and 52; (4) establish new requirements to address non-LWR technologies; (5) recognize technological advancements in reactor design; and (6) credit the possible response of some designs of commercial nuclear plants to postulated accidents, including slower transient response times and relatively small and slow

release of fission products. The proposed rule would add 10 CFR part 53; subpart M, "Fitness for Duty Programs for Facilities Licensed Under 10 CFR Part 53," of part 26; § 73.100, "Technology-inclusive requirements for physical protection of licensed activities at commercial nuclear plants against radiological sabotage," § 73.110, "Technology-inclusive requirements for protection of digital computer and communication systems and networks," and § 73.120, "Access authorization program for commercial nuclear plants," and make conforming changes throughout 10 CFR chapter I~~.~~, "Nuclear Regulatory Commission."

B. Need for Changes to the Existing Regulatory Framework

The NRC has long recognized that the licensing and regulation of a variety of nuclear reactor technologies would present challenges because the existing regulatory framework has evolved primarily to address the LWR designs that compose the current operating fleet (widely referred to as Generation II reactors). The NRC has had many interactions with designers of various reactor technologies under development, sometimes collectively referred to as advanced reactors (widely referred to as Generation III/III+ (i.e., evolutionary ~~LWRs~~light-water) and Generation IV (i.e., non-light-water~~LWRs~~) reactors). The interactions have informed the development of policies and guidance to support the potential licensing of new and different types of reactor facilities, some of which may not utilize LWR designs. The NRC issued its Advanced Reactor Policy Statement to provide all interested parties, including the public, with the Commission's views concerning the desired characteristics of advanced reactor designs. The NRC further described its early efforts to establish a technology-inclusive approach to the regulation of nuclear reactors in the advance notice of proposed rulemaking published in 2006. The NRC acknowledged in its "Report to Congress: Advanced Reactor Licensing," issued August 2012, that while the safety philosophy inherent in the

current regulations applies to all reactor technologies, the specific and prescriptive aspects of those regulations clearly focus on the current fleet of LWR facilities.

Congress similarly recognized the potential benefits of developing a regulatory infrastructure to support the development and commercialization of advanced nuclear reactors. Consequently, Congress passed NEIMA in late 2018, and the President signed it into law in January 2019. NEIMA directed the NRC to undertake a~~this~~ rulemaking~~,~~ ~~which would to~~ establish~~es~~ a technology-inclusive regulatory framework for optional use by applicants for new commercial nuclear reactors.

The requirements in part 53 would support a wide variety of potential commercial nuclear reactor technologies. As noted in this discussion, the current regulatory framework in parts 50 and 52 ~~was developed for~~evolved in the context of the current operating reactor fleet dominated by LWRs and as a result includes ~~some~~ provisions specific to LWR technologies. ~~Although~~ While the NRC can license other reactor technologies under the current framework by using existing regulatory flexibilities and the exemption process, there is significant interest in developing a regulatory framework that is flexible enough to accommodate multiple technologies and robust enough to ensure a level of safety equivalent to parts 50 and 52, consistent with the Commission's Advanced Reactor Policy Statement. The Commission reiterated its safety expectations for new reactors in the SRM for SECY-10-0121, "Modifying the Risk-Informed Regulatory Guidance for New Reactors," dated March 2, 2011:

> Because new plant designs incorporate operating experience from current generation reactors, severe accident research, and risk insights from design probabilistic risk assessments, the Commission expects that the advanced technologies incorporated in new reactors will result in enhanced margins of safety. However, the Commission continues to expect (consistent with the 2008 Advanced Reactor Policy Statement), as a minimum, at least the same degree of protection of the public and the environment that is required for current-generation light-water reactors. New reactors with these enhanced margins and safety features should have greater operational flexibility than current reactors.

However, developing a regulatory framework that can accommodate a wide range of technologies while maintaining an acceptable level of safety presents significant regulatory challenges. The existing regulations have been developed over the course of decades and reflect changes to address events discovered through operating experience. In contrast, part 53 is being developed to accommodate technologies that, in some cases, lack significant operating experience. To address these challenges, the NRC drew on well-developed approaches to licensing to produce ~~two technology-neutral and robust regulatory frameworks, described in sections III.C, "10 CFR Part 53 Frameworks," and III.D, "Subpart A – General Provisions," of this document. In terms of providing~~ a regulatory framework that is risk-informed and performance-based, part 53. This new part would provide options for the ~~roles~~ use of risk assessment techniques and design approaches in establishing licensing basis information. The proposed regulatory part would provide a framework ~~that would use PRAs to assess risks, help establish technical requirements, and manage operations is referred to as "Framework A," which would be established primarily in subparts B through K of part 53. Framework A builds on~~ that can support the LMP, which is a technology-inclusive approach to licensing that leverages insights from a detailed PRA to provide applicants with significant design and operation flexibilities.

~~During stakeholder meetings, the NRC learned that not all applicants plan to develop and use the PRA needed for Framework A. Consequently, the NRC also developed an alternative framework, referred to as "Framework B," which would be established primarily in subparts N through U of part 53. This framework would include deterministic and risk-informed acceptance criteria similar to those in parts 50 and 52 but would better address the variety of commercial reactor technologies that may be licensed following this rulemaking. In addition, Framework B would allow an applicant to~~

~~use the AERI provisions in lieu of performing a PRA, provided the applicant can demonstrate its design meets specified criteria related to radiological consequences from bounding events. Framework B also builds on international guidance (e.g., International Atomic Energy Agency (IAEA) guidance) for nuclear reactor licensing.~~

~~*C. 10 CFR Part 53 Frameworks*~~

This rulemaking consists of several major components, including a new part, part 53, to be added to 10 CFR, revisions for part 26 and part 73, and conforming changes throughout 10 CFR chapter I.

~~Proposed § 53.000, "Purpose," would describe the purpose of part 53 and would be equivalent to § 50.1, "Basis, purpose, and procedures applicable." Proposed § 53.010 would provide requirements for the use of either of the two frameworks presented throughout part 53. Proposed § 53.010 is similar to § 2.2, "Subparts," in that it would direct an applicant into the applicable subparts for each framework. Proposed subparts A and X are the only proposed subparts common to both Frameworks A and B.~~

~~Framework A~~Proposed part 53 is ~~comprised of portions of proposed subpart A, subparts B through K, and subpart X of part 53. These provisions are~~ organized to provide high-level performance criteria and to specify requirements to demonstrate compliance with those performance criteria throughout major stages of the life cycle of commercial nuclear plants. This organization reflects a systems-engineering style approach to the design, licensing, operation, and ultimately decommissioning of future commercial nuclear plants. Organizing requirements in this manner also supports performance-based approaches. Required programs (e.g., radiation protection) and monitoring (e.g., technical specification (TS) surveillance) during the operations phase that are similar to those required by part 50 would complement the design and analysis requirements in subpart C. The performance-based approach proposed in ~~Framework A~~

~~of~~ part 53 also includes regulatory requirements that would allow applicants to use a flexible and graded approach to the performance of safety functions based on the role of a particular SSC, human action, or program in limiting the risk of an immediate threat to public health and safety or maintaining the overall risks to the public below accepted standards through balanced measures to prevent and mitigate possible events.

~~Framework B is comprised of portions of proposed subpart A, subparts N through U, and subpart X of part 53 and includes technology-inclusive requirements similar to the traditional requirements in parts 50 and 52, which were developed primarily for LWR designs. Framework B would maintain the traditional role of specific design rules, including use of the single failure criterion as a tool in the reactor safety analysis process, and deterministic approaches to define LBEs and performance requirements for SSCs. The traditional approach in Framework B of would require applicants to define PDCs similar to those required by appendix A to part 50 for LWRs. RG 1.232, "Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors" presents guidance on this topic for select non-LWR technologies.~~

~~Several subparts within proposed part 53 include proposed requirements that would be equivalent under either framework. In these cases, the proposed requirements in Framework B generally reproduce the proposed requirements from Framework A, with minor modifications to account for differences in the frameworks, including framework-specific references. Specifically, subpart O, "Construction and Manufacturing," largely reproduces subpart E; subpart P, "Operation," largely reproduces subpart F; subpart Q, "Decommissioning," largely reproduces subpart G; subpart S, "License Maintenance," largely reproduces subpart I; subpart T, "Reporting," largely reproduces subpart J; and subpart U, "Quality Assurance," largely reproduces subpart K. Unlike most requirements in subpart F, the requirements addressing staffing, training, personnel qualifications, and~~

~~human factors engineering (HFE) would be structured to be common to both frameworks rather than reproducing those sections in each framework.~~

~~Proposed language in subparts F and P that references requirements unique to each framework (e.g., for change control processes) would be used where appropriate. Subpart B, "Safety Requirements"; subpart C, "Design and Analysis"; and subpart D, "Siting," are largely unique to Framework A, and subpart N, "Siting," is largely unique to Framework B. In addition, Framework B, subpart R (on licensing processes) contains elements, including technical requirements, not found in the corresponding subpart H in Framework A.~~

Proposed subpart M of part 26 would be new. ~~and would apply to both Frameworks A and B. However, t~~The requirements in proposed subpart M would be largely consistent with the objective-based fitness for duty (FFD) requirements in current subpart K, "FFD Programs for Construction," of part 26 supplemented by select requirements from subparts A through I, N, and O of part 26. These requirements are designed to ensure program effectiveness, maintain protections afforded to individuals subject to the FFD program, and align with FFD program implementation by part 50 and 52 licensees. The proposed requirements are not entirely equivalent because current subpart K of part 26 only applies during construction of the commercial nuclear plant, whereas proposed subpart M of part 26 would apply during construction, operation, and decommissioning. Furthermore, proposed subpart M of part 26 would allow the use of a variety of biological specimens for drug testing as well as innovative technologies for drug and alcohol screening and testing that are not described or allowed by the requirements in subparts A through K, N, and O of part 26, except under limited conditions. ~~In general, all proposed subpart M of part 26 requirements would apply to~~

both Frameworks A and B, with differences principally occurring in the definitions used in part 26 and references to part 53 requirements.

Proposed revisions to part 73 would establish a new technology-inclusive consequence-based approach for a range of security areas, including physical security, cyber security, and access authorization (AA) for commercial nuclear reactors. The NRC used operating experience to include additional regulatory flexibility for a part 53 licensee's implementation of security requirements.

In addition, this proposed rule would make conforming changes throughout 10 CFR chapter I, such as adding "and part 53" where appropriate to account for the addition of the proposed part 53.

D. Subpart A – General Provisions

Subpart A would provide the general provisions applicable to all applicants and licensees under either of the optional frameworks (Framework A and Framework B) that would be established in part 53 for the issuance, amendment, and termination of licenses, permits, certifications, and approvals for commercial nuclear plants licensed under Section 103 of the Atomic Energy Act of 1954, as amended (AEA) and title II of the Energy Reorganization Act of 1974 (88 Stat. 1242). Subpart A would include purpose, scope, definitions, written communications, employee protections, completeness and accuracy of information, exemptions, standards for review, jurisdictional limits, consideration of attacks and destructive acts by enemies of the United States, and information collection requirements.

The requirements in subpart A would be largely equivalent to the general requirements in part 50 that are applicable to all part 50 applicants and licensees (specifically, §§ 50.1 through 50.13) but would reference the corresponding regulations in part 53 in place of references to part 50.

Discussion of Definitions in Proposed Part 53

Due to fundamental differences in the methodologies in Frameworks A and B, as described in section III.C, "10 CFR Part 53 Frameworks," of this document, the proposed rule would include three definition sections in §§ 53.020, 53.024, and 53.028 to provide terms common to both frameworks, terms specific to Framework A, and terms specific to Framework B, respectively. Section 53.020 would define terms common to both frameworks and would include terms such as: Commercial nuclear plant, Commercial nuclear reactor, Defense in depth, Design features, Event sequence, Licensing basis information, Manufactured reactor, Normal operation, PRA, Quality assurance, Safety function, and Site characteristics. The definitions of most of these terms in § 53.020 would be equivalent to the corresponding terms defined in: (1) §§ 50.2, 52.1, and other NRC regulations; (2) NEI 18-04, as endorsed by RG 1.233; or (3) American Society of Mechanical Engineers (ASME)/American Nuclear Society (ANS) Risk Assessment Standard (RA-S)-1.4-2021, as endorsed for trial use by RG 1.247, "Acceptability of Probabilistic Risk Assessment Results for Non-Light Water Reactor Risk-Informed Activities." This is intended to provide clarity and consistency in terminology among all licensing frameworks where possible and to utilize past and ongoing NRC initiatives to support the licensing of new reactors. Specific deviations from existing definitions are further explained in the following paragraphs.

Regarding the definition of "Commercial nuclear plant" and "Commercial nuclear reactor" in proposed § 53.020, as noted previously, the NRC initially considered establishing the scope of part 53 as being for "advanced nuclear plants." The preliminary proposed rule language defined "advanced nuclear plant" as "a utilization facility consisting of one or more advanced nuclear reactors" as defined in NEIMA. NEIMA defines the term ''advanced nuclear reactor'' as "a nuclear fission or fusion reactor,

including a prototype plant (as defined in sections 50.2 and 52.1 of title 10, Code of Federal Regulations (as in effect on the date of enactment of this Act)), with significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of this Act, including improvements such as — (A) additional inherent safety features; (B) significantly lower levelized cost of electricity; (C) lower waste yields; (D) greater fuel utilization; (E) enhanced reliability; (F) increased proliferation resistance; (G) increased thermal efficiency; or (H) ability to integrate into electric and nonelectric applications."

Based on public discussions on the use of the term, the NRC determined that the NEIMA definition, although broad, did not define "significant improvements" with enough specificity to implement in NRC regulations. Additionally, a number of stakeholders suggested that the descriptor, "advanced," implied enhanced safety, while the NEIMA definition includes "significant improvements" in areas other than safety enhancements. In response to this feedback, and to be technology inclusive, the NRC staff determined that the broader term "commercial nuclear plant" would be preferable. The NEIMA definition of advanced nuclear reactor also includes fusion technologies. Fusion energy systems have not been included, at this time, in the scope of the proposed part 53 but could be addressed in a future revision to part 53 or other NRC regulations.

The NRC proposes to allow use of part 53 by any "commercial nuclear plant." The use of the term "plant" versus "reactor," as used in existing regulations (i.e., § 50.2), recognizes that co-located support facilities and radionuclide sources need to be considered in the licensing of a facility. The phrase "commercial purposes," as used in the definition of "commercial nuclear plant," includes purposes such as providing process heat for a variety of industrial applications (e.g., desalination, oil refining, hydrogen production). The NRC has not compiled a complete list of such commercial

purposes. The definition of "commercial nuclear plant" refers to a "commercial nuclear reactor," which is defined based on the definition of "nuclear reactor" in § 50.2. However, the phrase "in a self-supporting chain reaction" was removed from the definition to enable applying part 53 to accelerator driven systems that use special nuclear material (SNM) but that do not involve self-sustaining chain reactions. Relatedly, "utilization facility" is also defined in § 53.020 based on the definition of that term in § 50.2 but is also revised to refer to a "commercial nuclear plant" as defined in § 53.020.

The NRC considered feedback received during meetings with the public and with the ACRS on preliminary proposed rule language and, as a result, included in the proposed rule a definition of "safety functions" applicable to both frameworks in proposed § 53.020. As discussed in section IV, "Framework A," of this document, for Framework A, § 53.230 would establish a "primary" safety function and then would require applicants to define additional safety functions necessary to retain radioactive materials during LBEs. It would then state that safety functions are required to demonstrate compliance with the safety criteria in subpart B. Safety functions can be performed by any combination of design features, human actions, or programmatic controls and can be specified at the plant level or at the level of a particular barrier or system. Plant-level safety functions, such as reactivity control, fluid (heat removal) systems, and reactor containment, are central to the existing regulatory framework for LWRs. A barrier or system-level safety function could be a specific design criterion stating, for example, that a containment heat removal system must be provided to maintain containment pressure and temperature within acceptable limits.

The NRC proposes to include a definition of "consensus code or standard" in part 53 that is based on the use of these terms in the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Public Law 104-113) and the Office of Management

and Budget (OMB) Circular No. A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities." As required by NTTAA, the NRC undertakes the following activities: (i) consults with voluntary consensus standards bodies; (ii) participates with voluntary consensus bodies in the development of consensus standards; and (iii) uses consensus standards as a means to carry out the NRC's policy objectives. In part 53, the NRC is not proposing to incorporate by reference specific codes and standards as is done under the existing regulations in § 50.55a, "Codes and standards," because some codes and standards are LWR-specific. Part 53 would require that design features must be designed using generally accepted consensus codes and standards but would not incorporate the specific code or standard into the NRC's regulations. During public meetings, significant discussions with stakeholders indicated that future reactor designers were interested in the use of international consensus standards that have not yet been endorsed by the NRC. The definition proposed in part 53 would allow for the use of international codes and standards not previously used in NRC licensing but recognizes that the use of any consensus code or standard would ultimately need to be found acceptable by the NRC, either through generic efforts to endorse a code or standard or on an application-specific basis during an individual licensing review.

The framework-specific definitions in §§ 53.024 and 53.028 of subpart A would define terms that are either applicable under only one of the frameworks or are defined differently in Frameworks A and B (based on the use of a risk-informed, performance-based methodology in Framework A compared to the traditional licensing approach used in Framework B). In general, this would include terms related to event selection and identification, equipment classification, and the way special treatment is applied to equipment identified as risk- or safety-significant. The proposed definitions of

~~"construction" are also framework-specific—they would cover the same concept but be applied to a slightly different scope of activities based on how SSCs are classified under each framework. In Framework A, the definition of "construction" is based on the definition in § 50.10 but modified to apply to safety-related (SR) and non-safety-related but safety-significant (NSRSS) SSCs identified by the design and analysis requirements in subparts B and C to ensure the safety criteria are met. In Framework B, the definition of "construction" is equivalent to the definition in § 50.10.~~

~~Definitions Applicable to Framework A~~

~~Section 53.024 would add definitions that would be applicable to Framework A, such as terms related to event selection (LBEs, design-basis accidents (DBAs), anticipated event sequences, unlikely event sequences, and very unlikely event sequences); equipment classifications (SR, NSRSS, and non-safety-significant SSCs); performance metrics (safety criteria and functional design criteria); and special treatment.~~

~~The regulation would define "safety criteria" in terms of the plant-level performance-based metrics that would be provided in §§ 53.210 and 53.220. The term "functional design criteria" would be defined as metrics for the performance of specific SSCs that are determined from the role of the SSC in meeting the safety criteria. These are new terms that have not previously been defined or used in NRC regulation.~~

~~The term "safety-related SSCs" would refer to those SSCs needed to meet the safety criteria in § 53.210. The term "non-safety-related but safety-significant SSCs" would mean those SSCs that are not SR because they do not perform any function necessary to demonstrate compliance with § 53.210 but warrant special treatment because they are relied on to achieve adequate defense in depth or perform risk-significant functions. The term "special treatment" would be defined as requirements,~~

such as quality assurance and programmatic controls, identified for each design feature to ensure that the safety criteria are satisfied and the safety functions are fulfilled. These requirements would also ensure that SR and NSRSS SSCs will provide defense in depth, or perform risk-significant functions, under service conditions and with SSC reliabilities that are consistent with the analysis required in proposed subpart C. The term "non-safety-significant SSCs" would mean those SSCs that are not SR or NSRSS.

The terms "design-basis accidents," "anticipated event sequences," "unlikely event sequences," and "very unlikely event sequences" would be defined to be different types of "licensing-basis events" and would also be largely equivalent to the LMP's definitions of DBAs, anticipated operational occurrences (AOOs), design-basis events (DBEs), and beyond-design-basis events, respectively. The term "design-basis accidents" would be defined as postulated event sequences that are used to set functional design criteria and performance objectives for the design of SR SSCs through deterministic analyses. DBAs would be derived from the unlikely event sequences from the PRA and then analyzed in a conservative approach by prescriptively assuming that only SR SSCs are available to mitigate postulated accident scenarios. Within the LMP methodology, event sequences with mean frequencies of 1×10-2/plant-year and greater would be classified as anticipated event sequences. Within the LMP methodology, infrequent event sequences with mean frequencies of 1×10-4/plant-year to 1×10-2/plant-year would be classified as unlikely event sequences. "Very unlikely event sequences" would be less likely to occur than unlikely event sequences. Within the LMP methodology, rare event sequences with frequencies of 5×10-7/plant-year to 1×10-4/plant-year would be classified as very unlikely event sequences. While the proposed terminology for these event sequences would create some differences between Framework A and the LMP, Framework A would use new terms for these event

sequences specifically to avoid conflicts with terms already used within part 50 and part 52 to represent different concepts. Further, because some stakeholder comments demonstrated confusion related to the history of beyond-design-basis accidents terminology, these definitions seek to clarify the event categories in Framework A. The sections of this preamble related to subparts B and C provide additional discussion of LBEs.

Definitions Applicable to Framework B

Section 53.028 would add definitions that would be applicable to Framework B. The term "anticipated operational occurrence" would be the term for an event class unique to Framework B, within part 53. This term would be comparable to the term "anticipated event sequence" in Framework A. However, "anticipated operational occurrence" is used in Framework B to mirror the traditional licensing approach under part 50 and part 52 and to allow Framework B applicants and licensees to use certain part 50 guidance where applicable that use this event terminology. Additionally, use of "anticipated operational occurrence" in Framework B, as opposed to "anticipated event sequence," recognizes that the frequency component of this type of event is not used in Framework B. The definition for "anticipated operational occurrence" would be equivalent to that in appendix A to part 50, with changes that would eliminate existing examples of AOOs that are not technology inclusive. Similarly, the definition for "construction" would be equivalent to that in § 50.10(a) with conforming changes made for cross references in Framework B. The definitions for "design bases" and "reactor coolant pressure boundary" in Framework B would be equivalent to their definitions in § 50.2.

The term "functional containment" would be defined in § 53.028 to support its use throughout Framework B by non-LWR applicants and licensees that may need or elect

to use a functional containment approach in lieu of the traditional essentially leak-tight containment structure used by LWRs. The proposed definition for functional containment is consistent with the definition for the same term from SECY-18-0096, "Functional Containment Performance Criteria for Non-Light-Water Reactors."

The term "safety-related SSCs" is used in both frameworks with different definitions. The proposed rule would provide a specific definition in § 53.028 for use of this term in Framework B. In Framework B, the term would be used in a more deterministic sense consistent with the existing regulatory frameworks in part 50 and part 52. The definition of this term has been bifurcated in Framework B to ensure technology inclusiveness and consistency with the existing regulatory frameworks. For LWRs, the definition of this term would be equivalent to the definition in § 50.2. For non-LWRs, a new portion of the definition would be introduced that is broader to accommodate a wider range of technologies. This portion of the definition would denote that SR SSCs for non-LWRs are those SSCs that are used to mitigate the consequences of a DBA, including those SSCs that may be relied on as part of a functional containment.

Other General Provisions

Section 53.040 would govern written communications and how applications and other required information must be submitted to the NRC. These requirements would be equivalent to those in § 50.4.

Section 53.050 would establish requirements for enforcement action to which a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, or an employee of any of them may be subject for engaging in deliberate misconduct. These requirements would be equivalent to those in § 50.5.

~~Section 53.060 would prohibit discrimination against an employee of a holder or applicant for an NRC license, permit, design certification (DC), or design approval, or a contractor or subcontractor of a holder or applicant for an NRC license, permit, DC, or design approval for engaging in certain protected activities. Section 53.060 also would prescribe a procedure for seeking a remedy for an employee who believes he or she has been discriminated against for engaging in such protected activities. These requirements would be equivalent to those in §§ 50.7 and 52.5.~~

~~Section 53.070 would govern the completeness and accuracy of information provided to the NRC. These requirements would be equivalent to those in §§ 50.9 and 52.6.~~

~~Section 53.080 would govern exemptions from the requirements of the regulations in this part. These requirements would be equivalent to those in §§ 50.12 and 52.7.~~

~~Paragraphs (a) through (d) of § 50.90 would establish requirements for standards that the NRC would consider in determining whether a construction permit (CP), operating license (OL), early site permit (ESP), combined license (COL), or manufacturing license (ML) under part 53 would be issued to an applicant. These requirements would be equivalent to those in §§ 50.40, 50.42, 50.43 and 50.22, respectively. Requirements equivalent to those in §§ 50.41 and 50.21 would not be included in part 53 because they apply to Class 104 licenses, and part 53 would not apply to those licenses.~~

~~Section 53.100 would require that no license issued under part 53 would cover activities which are not under or within the jurisdiction of the United States. These requirements would be equivalent to those in § 50.53.~~

Section 53.110 would state that licensees and applicants would not be required to provide design features or other measures for the specific purpose of protection against the effects of attacks and destructive acts by enemies of the United States directed against the facility or deployment of weapons incident to U.S. defense activities. These requirements would be equivalent to those in § 50.13.

Section 53.115 would establish requirements for rights related to SNM. These requirements would be equivalent to those in § 50.54(b) and (c).

Section 53.117 would establish requirements for license suspension and rights of recapture of the material or control of the facility in a state of war or national emergency declared by Congress. These requirements would be equivalent to those in § 50.54(d).

Section 53.120 would establish requirements for information collection requirements and OMB approval. These requirements would be equivalent to those in § 50.8.

E. Subpart X – Enforcement

Subpart X would contain two provisions, § 53.9000 and § 53.9010, which are analogous to provisions contained in other parts of 10 CFR Chapter I imposing requirements on regulated entities. Section 53.9000 would provide notice of the Commission's authority under the AEA to obtain injunctions or other court orders for the enumerated violations. Paragraph (a) of § 53.9010 would provide notice to all persons and entities subject to part 53 that they are subject to criminal sanctions for willful violations, attempted violations, or conspiracy to violate certain regulations under part 53. Criminal sanctions would not apply to the regulations listed in paragraph (b). The regulations for which criminal penalties would apply are limited to those that establish either a regulatory obligation or prohibition.

IV. ~~Framework A~~Part 53

New Requirements in 10 CFR Part 53

Proposed § 53.000, "Purpose," would describe the purpose of part 53 and would be equivalent to § 50.1, "Basis, purpose, and procedures applicable."

Subpart A – General Provisions

Subpart A would provide the general provisions applicable to all applicants and licensees that would be established in part 53 for the issuance, amendment, and termination of licenses, permits, certifications, and approvals for commercial nuclear plants licensed under Section 103 of the Atomic Energy Act of 1954, as amended (AEA) and title II of the Energy Reorganization Act of 1974 (88 Stat. 1242). Subpart A would include purpose, scope, definitions, written communications, employee protections, completeness and accuracy of information, exemptions, standards for review, jurisdictional limits, consideration of attacks and destructive acts by enemies of the United States, and information collection requirements.

The requirements in subpart A would be largely equivalent to the general requirements in part 50 that are applicable to all part 50 applicants and licensees (specifically, §§ 50.1 through 50.13) but would reference the corresponding regulations in part 53 in place of references to part 50.

Discussion of Definitions in Proposed Part 53

Section 53.020 would define terms used in part 53 and would include terms such as: Commercial nuclear plant, ~~Commercial n~~Nuclear reactor, Defense in depth, Design features, Event sequence, Licensing basis information, Manufactured reactor, Normal operation, PRA, Quality assurance, Safety function, and Site characteristics. The definitions of most of these terms in § 53.020 would be equivalent to the corresponding terms defined in: (1) §§ 50.2, 52.1, and other NRC regulations; (2) NEI 18-04, as

endorsed by RG 1.233; or (3) American Society of Mechanical Engineers (ASME)/American Nuclear Society (ANS) Risk Assessment Standard (RA-S)-1.4-2021, as endorsed for trial use by RG 1.247, "Acceptability of Probabilistic Risk Assessment Results for Non-Light Water Reactor Risk-Informed Activities." This is intended to provide clarity and consistency in terminology among all licensing frameworks where possible and to utilize past and ongoing NRC initiatives to support the licensing of new reactors. Specific deviations from existing definitions are further explained in the following paragraphs.

Regarding the definition of "Commercial nuclear plant" and "Commercial nuclear reactor" in proposed § 53.020, as noted previously, the NRC initially considered establishing the scope of part 53 as being for "advanced nuclear plants." The preliminary proposed rule language defined "advanced nuclear plant" as "a utilization facility consisting of one or more advanced nuclear reactors" as defined in NEIMA. NEIMA defines the term ''advanced nuclear reactor'' as "a nuclear fission or fusion reactor, including a prototype plant (as defined in sections 50.2 and 52.1 of title 10, Code of Federal Regulations (as in effect on the date of enactment of this Act)), with significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of this Act, including improvements such as— (A) additional inherent safety features; (B) significantly lower levelized cost of electricity; (C) lower waste yields; (D) greater fuel utilization; (E) enhanced reliability; (F) increased proliferation resistance; (G) increased thermal efficiency; or (H) ability to integrate into electric and nonelectric applications."

Based on public discussions on the use of the term, the NRC determined that the NEIMA definition, although broad, did not define "significant improvements" with enough specificity to implement in NRC regulations. Additionally, a number of stakeholders

suggested that the descriptor, “advanced,” implied enhanced safety, while the NEIMA definition includes “significant improvements” in areas other than safety enhancements. In response to this feedback, and to be technology inclusive, the NRC staff determined that the broader term “commercial nuclear plant” would be preferable. The NEIMA definition of advanced nuclear reactor also includes fusion technologies. Fusion energy systems have not been included, at this time, in the scope of the proposed part 53 but could be addressed in a future revision to part 53 or other NRC regulations.

The NRC proposes to allow use of part 53 by any “commercial nuclear plant.” The use of the term "plant” versus “reactor,” as used in existing regulations (i.e., § 50.2), recognizes that co-located support facilities and radionuclide sources need to be considered in the licensing of a facility. The phrase “commercial purposes,” as used in the definition of “commercial nuclear plant,” includes purposes such as providing process heat for a variety of industrial applications (e.g., desalination, oil refining, hydrogen production). The NRC has not compiled a complete list of such commercial purposes. The definition of “commercial nuclear plant” refers to a “nuclear reactor,” which is defined based on the definition of “nuclear reactor” in § 50.2. However, the phrase “in a self-supporting chain reaction” was removed from the definition to enable applying part 53 to accelerator driven systems that use special nuclear material (SNM) but that do not involve self-sustaining chain reactions. The definition of “nuclear reactor” in proposed § 53.020 includes an exception for fueled manufactured reactors that have redundant means in place to prevent criticality to support the Commission finding that they are not utilization facilities. Relatedly, “utilization facility” is also defined in § 53.020 based on paragraph (1) of the definition of that term in § 50.2, omitting reference to accelerator driven systems in paragraph (2) of that definition as allowed by the change

to the definition for “nuclear reactor.” but is also revised to refer to a “commercial nuclear plant” as defined in § 53.020.

The NRC considered feedback received during meetings with the public and with the ACRS on preliminary proposed rule language and, as a result, included in the proposed rule a definition of “safety functions” applicable to both frameworks in proposed § 53.020. As discussed in section IV, “Framework A,” of this document, for Framework A, § 53.230 would establish a “primary” safety function and then would require applicants to define additional safety functions necessary to retain radioactive materials during LBEs. It would then state that safety functions are required to demonstrate compliance with the safety criteria in subpart B. Safety functions can be performed by any combination of design features, human actions, or programmatic controls and can be specified at the plant level or at the level of a particular barrier or system. Plant-level safety functions, such as reactivity control, fluid (heat removal) systems, and reactor containment, are central to the existing regulatory framework for LWRs. A barrier or system-level safety function could be a specific design criterion stating, for example, that a containment heat removal system must be provided to maintain containment pressure and temperature within acceptable limits.

The NRC proposes to include a definition of “consensus code or standard” in part 53 that is based on the use of these terms in the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Public Law 104-113) and the Office of Management and Budget (OMB) Circular No. A-119, “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.” As required by NTTAA, the NRC undertakes the following activities: (i) consults with voluntary consensus standards bodies; (ii) participates with voluntary consensus bodies in the development of consensus standards; and (iii) uses

Commented [A8]: Deleted as unnecessary and to eliminate the inconsistency with the definition provided in the draft proposed rule, which referred to a "commercial nuclear reactor" vice a "commercial nuclear plant."

consensus standards as a means to carry out the NRC's policy objectives. In part 53, the NRC is not proposing to incorporate by reference specific codes and standards as is done under the existing regulations in § 50.55a, "Codes and standards," because some codes and standards are LWR-specific. Part 53 would require that ~~design features must be designed~~applicants describe their use~~ing~~ of generally accepted consensus codes and standards but would not incorporate the specific code or standard into the NRC's regulations. During public meetings, significant discussions with stakeholders indicated that future reactor designers were interested in the use of international consensus standards that have not yet been endorsed by the NRC. The definition proposed in part 53 would allow for the use of international codes and standards not previously used in NRC licensing but recognizes that the use of any consensus code or standard would ultimately need to be found acceptable by the NRC, either through generic efforts to endorse a code or standard or on an application-specific basis during an individual licensing review.

~~The framework-specific definitions in §§ 53.024 and 53.028 of subpart A would define terms that are either applicable under only one of the frameworks or are defined differently in Frameworks A and B (based on the use of a risk-informed, performance-based methodology in Framework A compared to the traditional licensing approach used in Framework B). In general, this would include terms related to event selection and identification, equipment classification, and the way special treatment is applied to equipment identified as risk- or safety-significant. The proposed definitions of "construction" are also framework-specific—they would cover the same concept but be applied to a slightly different scope of activities based on how SSCs are classified under each framework. In Framework A, the definition of "construction" is based on the definition in § 50.10 but modified to apply to safety-related (SR) and non-safety-related~~

~~but safety-significant (NSRSS) SSCs identified by the design and analysis requirements in subparts B and C to ensure the safety criteria are met. In Framework B, the definition of "construction" is equivalent to the definition in § 50.10.~~

Section 53.0204~~ would also add definitions that would be applicable to Framework A,~~ such as terms related to event selection (LBEs, design-basis accidents (DBAs), anticipated event sequences, unlikely event sequences, and very unlikely event sequences); equipment classifications (SR, NSRSS, and non-safety-significant SSCs); performance metrics (safety criteria and functional design criteria); and special treatments.

The regulation would define "safety criteria" in terms of the plant-level performance-based metrics that would be provided in or established under §§ 53.210 and 53.220. The term "functional design criteria" would be defined as metrics for the performance of specific SSCs that are determined from the role of the SSC in meeting the safety criteria. These are new terms that have not previously been defined or used in NRC regulation.

The term "safety-related structures, systems, and components~~SSCs~~" would refer to those SSCs needed to meet the safety criteria in § 53.210. The term "non-safety-related but safety-significant structures, systems, and components~~SSCs~~" would mean those SSCs that are not SR because they do not perform any function necessary to demonstrate compliance with § 53.210 but warrant special treatment because they are relied on to achieve adequate defense in depth or perform risk-significant functions. The term "special treatments" would be defined as ~~requirements~~items, such as quality assurance and programmatic controls, identified for each design feature to ensure that the safety criteria are satisfied and the safety functions are fulfilled. These ~~requirements~~treatments would also ensure that SR and NSRSS SSCs will provide

defense in depth, or perform risk-significant functions, under service conditions and with SSC reliabilities that are consistent with the analysis required in proposed subpart C. The term “non-safety-significant SSCs” would mean those SSCs that are not SR or NSRSS.

The terms “design-basis accidents,” “anticipated event sequences,” “unlikely event sequences,” and “very unlikely event sequences” would be defined to be different types of “licensing-basis events” and would also be largely equivalent to the LMP’s definitions of DBAs, anticipated operational occurrences (AOOs), design-basis events (DBEs), and beyond-design-basis events, respectively. The term “design-basis accidents” would be defined as postulated event sequences that are used to set functional design criteria and performance objectives for the design of SR SSCs through deterministic analyses. DBAs would be derived from the unlikely event sequences from the risk evaluation~~PRA~~ and then analyzed in a conservative approach by prescriptively assuming that only SR SSCs are available to mitigate postulated accident scenarios. Within the LMP methodology, event sequences with mean frequencies of 1×10^{-2}/plant-year and greater would be classified as anticipated event sequences. Within the LMP methodology, infrequent event sequences with mean frequencies of 1×10^{-4}/plant-year to 1×10^{-2}/plant-year would be classified as unlikely event sequences. “Very unlikely event sequences” would be less likely to occur than unlikely event sequences. Within the LMP methodology, rare event sequences with mean frequencies of 5×10^{-7}/plant-year to 1×10^{-4}/plant-year would be classified as very unlikely event sequences. While the proposed terminology for these event sequences would create some differences between ~~Framework A~~part 53 and the LMP, ~~Framework A~~part 53 would use new terms for these event sequences specifically to avoid conflicts with terms already used within part 50 and part 52 to represent different concepts. Further, because some stakeholder

comments demonstrated confusion related to the history of beyond-design-basis accidents terminology, these definitions seek to clarify the event categories ~~in Framework A~~. The sections of this document~~preamble~~ related to subparts B and C provide additional discussion of LBEs.

Other General Provisions

Section 53.040 would govern written communications and how applications and other required information must be submitted to the NRC. These requirements would be equivalent to those in § 50.4.

Section 53.050 would establish requirements for enforcement action to which a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, or an employee of any of them may be subject for engaging in deliberate misconduct. These requirements would be equivalent to those in § 50.5.

Section 53.060 would prohibit discrimination against an employee of a holder or applicant for an NRC license, permit, design certification (DC), or design approval, or a contractor or subcontractor of a holder or applicant for an NRC license, permit, DC, or design approval for engaging in certain protected activities. Section 53.060 also would prescribe a procedure for seeking a remedy for an employee who believes he or she has been discriminated against for engaging in such protected activities. These requirements would be equivalent to those in §§ 50.7 and 52.5.

Section 53.070 would govern the completeness and accuracy of information provided to the NRC. These requirements would be equivalent to those in §§ 50.9 and 52.6.

Section 53.080 would govern exemptions from the requirements of the regulations in this part. These requirements would be equivalent to those in §§ 50.12 and 52.7.

~~Paragraphs (a) through (d) of §~~Section 53.90 would establish requirements for standards that the NRC would consider in determining whether a construction permit (CP), operating license (OL), early site permit (ESP), combined license (COL), or manufacturing license (ML) under part 53 would be issued to an applicant. These requirements would be equivalent to those in §§ 50.40, 50.42, 50.43 and 50.22, respectively. Requirements equivalent to those in §§ 50.41 and 50.21 would not be included in part 53 because they apply to Class 104 licenses, and part 53 would not apply to those licenses.

Section 53.100 would require that no license issued under part 53 would cover activities which are not under or within the jurisdiction of the United States. These requirements would be equivalent to those in § 50.53.

Section 53.110 would state that licensees and applicants would not be required to provide design features or other measures for the specific purpose of protection against the effects of attacks and destructive acts by enemies of the United States directed against the facility or deployment of weapons incident to U.S. defense activities. These requirements would be equivalent to those in § 50.13.

Section 53.115 would establish requirements for rights related to SNM. These requirements would be equivalent to those in § 50.54(b) and (c).

Section 53.117 would establish requirements for license suspension and rights of recapture of the material or control of the facility in a state of war or national emergency declared by Congress. These requirements would be equivalent to those in § 50.54(d).

Section 53.120 would establish requirements for information collection requirements and OMB approval. These requirements would be equivalent to those in § 50.8.

Subpart B – Technology-Inclusive Safety Requirements

Proposed subpart B, "Technology-Inclusive Safety Requirements," would provide technology-inclusive safety criteria that would serve as performance standards for the subsequent performance-based requirements used throughout ~~Framework A of~~ part 53. Subsequent subparts would define how specific activities during various stages of the life cycle of a commercial nuclear plant contribute to satisfying these high-level performance standards. The performance standards in subpart B would also establish a means to determine appropriate regulatory controls for SSCs, human actions, and programs in the following subparts ~~in Framework A~~. For example, the classification of SR SSCs would be built upon the proposed safety criteria in § 53.210, "Safety criteria for design-basis accidents." The more detailed requirements for those SSCs would then be further defined in the design and analysis requirements in subpart C, "Design and Analysis Requirements." The activities for manufacturing, constructing, and maintaining the SR SSCs would be governed by subpart E, "Construction and Manufacturing Requirements," and subpart F, "Requirements for Operation."

Requirements for NSRSS SSCs warranting special treatment would likewise be determined under~~in accordance with~~ § 53.220, "Safety criteria for licensing-basis events other than design-basis accidents," in subpart B and § 53.460, "Safety categorization and special treatment," in subpart C. Regulatory requirements related to the NSRSS SSCs would be distinguished from the regulatory requirements for SR SSCs throughout ~~Framework A of~~ part 53. Part 53~~Framework A~~ would afford more flexibility to applicants and licensees regarding how NSRSS SSCs would be used in the design and maintained during plant operations, as compared to SR SSCs.

~~Section 53.200 would provide the overall safety objectives for Framework A of this part. These objectives would be to ensure the following: (1) commercial nuclear~~

plants are designed, constructed, operated, and decommissioned to limit the possibility of an immediate threat to the public health and safety; and (2) additional measures are taken as may be appropriate when considering potential risks to public health and safety. The first safety objective would be taken, in part, from the long-standing principles used for determining the content of TS (see Technical Specifications, Final Rule (60 FR 36953, 36955) (citing the Atomic Safety and Licensing Appeal Board in Portland General Electric Co. (Trojan Nuclear Plant), ALAB-531, 9 NRC 263, 273 (1979))). The first safety objective would also support establishing a common performance standard for the plant SSCs categorized as SR and for the human actions and programmatic controls needed to address DBAs. The use of a safety objective rooted in established standards would help maintain consistency across Framework A, from the classification of SR SSCs to the content of TS that control those SR SSCs during the operation of a commercial nuclear plant. The second safety objective would consider potential risks to public health and safety beyond immediate threats—an approach that would ensure that commercial nuclear plants licensed under part 53 are at least as safe as those previously licensed by the NRC, consistent with the Commission's Advanced Reactor Policy Statement.

The collective set of performance-based requirements in Framework A would be sufficient, if met, for the NRC to make the findings required to grant an application for a utilization facility under Section 182 of the AEA that the utilization of SNM will be in accord with the common defense and security and will provide adequate protection to the health and safety of the public. This construct would be similar to existing NRC regulations, which the Commission has said on many occasions do not specifically define "adequate protection." However, compliance with NRC regulations may be presumed to assure adequate protection at a minimum. The requirements throughout

~~Framework A that support demonstrating compliance with the second safety objective would be similar to current regulations that both contribute to assuring adequate protection of public health and safety and are desirable to promote the common defense and security or to protect health or to minimize danger to life or property under Section 161 of the AEA.~~

~~Consistent with historical practice, Sections 182 and 161 of the AEA are cited as authorizing legislation within this proposed rule. However, specific language from the AEA would not be incorporated into the safety objectives or safety criteria in part 53. This is because, again consistent with historical practice, the NRC would not be defining "adequate protection" through the individual safety requirements in part 53. Rather, Framework A would enable the NRC to make its required findings under the AEA by providing sufficient performance standards, safety criteria, and related requirements on how applicants must demonstrate compliance with subpart B and other subparts.~~

Section 53.210 would provide safety criteria for DBAs that would be required to be identified under § 53.240 and analyzed under~~in accordance with~~ § 50.450(f) in subpart C of part 53. Subsequent sections in part 53~~Framework A~~ would require that the SSCs relied upon to demonstrate compliance with the criteria in § 53.210 be classified as SR. The use of SR SSCs and the 25 rem reference values for potential radiological consequences would align with traditional deterministic approaches for LWRs from §§ 50.34, 52.79, and 100.1 for evaluating the effectiveness of plant design features with respect to postulated reactor accidents so as to limit the possibility of an immediate threat to public health and safety. A footnote similar to that included in § 50.34(a)(1)(ii)(D)(*1*) and § 52.79(a)(1)(vi)(A) would be included in § 53.210 to explain that the use of the 25 rem value would not be intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident

conditions. Rather, this dose value has been set forth in this proposed section as a reference value~~,~~ that~~which~~ would be used in the evaluation of plant design features with respect to DBAs to verify that the proposed designs would provide assurance of low risk of public exposure to radiation in the event of an accident. The inclusion of the safety criteria for DBAs in subpart B would provide a logical structure supporting the identification and treatment of SR SSCs and establishing the corresponding functional design criteria for those SSCs.

Section 53.220 would require the applicant or licensee to identify~~provide~~ safety criteria for LBEs other than DBAs that would be required to be identified under § 53.240 and analyzed under~~in accordance with~~ § 53.450(e) in subpart C. Whereas § 53.210 and the related requirements for SR SSCs would provide that a defined success path exists for DBAs, the safety criteria for LBEs other than DBAs would establish the connections between SSC design, human actions, and programmatic controls and a broader set of potential internal and external hazards. These safety criteria would also address defense-in-depth matters such as a balanced consideration of prevention and mitigation. The safety criteria in § 53.220(b) c~~w~~ould include a cumulative risk measure and support a performance-based approach to developing an appropriate combination of design features and programmatic controls to prevent or mitigate LBEs other than DBAs.

~~It is worth noting that the evaluation of plant risks as represented by a comparison of analysis results to cumulative risk measures would be one of several performance standards used in subpart B.~~ The proposed use of multiple performance standards, including deterministic criteria and defense-in-depth measures, reflects an integrated decision-making process similar to that described in RG 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” Revision 3. The NRC initially considered establishing

the quantitative health objectives from “Safety Goals for the Operation of Nuclear Power Plants; Policy Statement; Republication” (51 FR 30028; August 21, 1986) as the safety criteria under § 53.220 but consistent with longstanding Commission Policy on the subject as discussed in SECY-89-102, “Implementation of the Safety Goals,” determined that while the use of “partitioned” objectives such as consequence estimates from PRA level calculations can be useful in making regulatory decisions and improving regulatory practices, the Commission determination that “partitioned objectives are not to be imposed as requirements themselves but may be useful as a basis for regulatory guidance” remains valid.

~~The RG 1.233, “Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light Water Reactors,” describes an example of an acceptable approach for identifying and analyzing LBEs under part 50 and part 52, including the use of the quantitative health objectives (QHOs) stated in the NRC’s policy statement, “Safety Goals for Nuclear Power Plant Operation,” dated August 4, 1986 (51 FR 28044), as corrected and republished August 21, 1986 (51 FR 30028) (Safety Goals Policy Statement), as a cumulative risk measure. The QHOs from the Safety Goals Policy Statement, which would form the basis of § 53.220(b), are a well-established cumulative risk measure used in NRC risk-informed decision-making. Section 53.220(b) in combination with the other proposed requirements in subparts B and C would bring the approach endorsed in RG 1.233 for parts 50 and 52 into part 53. Additionally, the QHOs are a logical performance metric to support the risk management approaches in the various subparts comprising proposed Framework A. The derivation of the values proposed in § 53.220(b) was originally documented in the Safety Goals Policy Statement. The Commission stated in the SRM for SECY-10-0121 that “…the~~

existing safety goals, safety performance expectations, subsidiary risk goals and associated risk guidance …, key principles and quantitative metrics for implementing risk-informed decision-making, are sufficient for new plants…".

The Commission stated in the introduction of the Safety Goals Policy Statement that improvements to then-current regulatory practices could lead to a more coherent and consistent regulation of nuclear power plants, a more predictable regulatory process, a better public understanding of the regulatory criteria that the NRC applies, and public confidence in the safety of operating plants. Accordingly, the Commission announced the safety goals with a focus on the risks to the public from nuclear power plant operation. Following the issuance of the Safety Goals Policy Statement, the NRC has used the cumulative risk measures provided in the safety goals within the criteria for many decisions involving safety judgments during the licensing and regulation of operating reactors and proposed nuclear reactor designs. As described in NUREG-0880, the values used in § 53.220(b) would be expressed in terms of a biologically average individual in terms of age and other risk factors. Although the QHOs are defined in terms of fatality risks, the Commission continues to make clear that no death attributable to nuclear power plant operation will ever be "acceptable" in the sense that the Commission would regard it as a routine or permissible event. The QHOs as used in this proposed rule would establish acceptable risks, not acceptable deaths.

Applicants under the proposed Framework A could choose to develop and seek NRC approval to use surrogate measures to show that particular designs or plants satisfy the QHO-related safety criteria in proposed § 53.220(b). Such surrogate measures could be used in a manner similar to the use of core damage frequency and conditional containment failure probability for LWRs within the safety goal evaluation

~~process in NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission."~~

Section 53.230 would require safety functions needed to ensure that the safety criteria under~~in~~ §§ 53.210 and 53.220 can be met if a commercial nuclear plant experiences an LBE. Section 53.230 would specify that limiting the release of radioactive materials from the facility is the primary safety function, and therefore, limiting potential offsite consequences (i.e., dose to a hypothetical individual) would be used as the primary performance metric ~~for Framework A~~ throughout part 53. The additional or subsidiary safety functions needed to limit the release of radionuclides may include, without limitation, controlling processes related to reactivity, heat generation, heat removal, and chemical interactions. This proposed rule provides flexibility to applicants and licensees in identifying, implementing, and maintaining the safety functions supporting retention of radionuclides for commercial nuclear plants of varying sizes and technologies.

Proposed § 53.240 would require applicants to identify and address LBEs. LBEs are unplanned events, resulting from both internal and external hazards, that are used in the design and analyses required under part 53 for licensing commercial nuclear plants. This ensures estimates of offsite consequences from analyses performed under~~in accordance with~~ proposed § 53.450 are below the safety criteria identified under~~in~~ proposed §§ 53.210 and 53.220 and that SSCs, personnel, and programs address the safety functions from proposed § 53.230. Including a high-level performance requirement related to the identification and analysis of LBEs in subpart B would reflect the historical and continuing importance of evaluating unplanned events as part of the licensing of commercial nuclear plants. Proposed § 53.240 would require identification and analysis of LBEs under~~in accordance with~~ § 53.450, which would require a ~~PRA~~risk

evaluation. Examples of acceptable methods of using ~~PRAs~~ risk evaluations to identify and assess LBEs would be the methodology in RG 1.233, as discussed in Draft Regulatory Guide (DG)-1413, "Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants."

Section 53.250 would establish defense-in-depth requirements based on the longstanding philosophy of providing defense in depth to address uncertainties about the design, operation, and performance of commercial nuclear plants. For example, parts 50 and 52 address defense in depth through layered prescriptive technical requirements (e.g., fuel performance, cladding integrity, reactor coolant system integrity, containment performance) for LWRs. In contrast, the flexibility afforded to applicants in how they propose to demonstrate compliance with the high-level safety criteria within part 53~~Framework A~~ would necessitate this specific requirement to ensure defense in depth is provided. The requirements in this section would state that no single engineered design feature, human action, or programmatic control, no matter how robust, should be exclusively relied upon to address LBEs other than DBAs. The phrase "engineered design feature" would not preclude the possible crediting of inherent characteristics within the design and analysis for commercial nuclear reactors. While defense in depth would only be assessed for LBEs other than DBAs, the need to ensure dedicated success paths for DBAs would contribute to the overall defense in depth for each commercial nuclear plant under part 53~~Framework A~~.

Section 53.260 would govern normal operations and ~~would consist of two requirements. First, it would~~ establish a level of safety based on current requirements in 10 CFR part 20, "Standards for Protection Against Radiation," which limits doses to members of the public. ~~Second, it would include requirements equivalent to those in part 20 and § 50.34a that ensure doses will be and are maintained as low as~~ (is) reasonably

~~achievable (ALARA) for normal operations. ALARA doses would be achieved through the use of an appropriate combination of design features and programmatic controls.~~

~~The ALARA requirements in § 50.34a, appendix I to part 50 for LWR effluents, and part 20 allow applicants and licensees to take into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations when determining doses to be ALARA. These same considerations would apply to the proposed requirements in part 53, which would also emphasize that ALARA doses would be achieved through a combination of design choices and programmatic controls with an appropriate consideration of potential costs. Given the variety of potential commercial reactor technologies, this provision affords applicants the flexibility to propose an appropriate balance between programmatic controls, such as operational programs, and design features to demonstrate that the ALARA principle has been met for their facility. That said, the proposed part 53 requirements related to ALARA in combination with the established regulations in part 20, including references to the U.S. Environmental Protection Agency (EPA) regulations in part 190 to title 40 (Protection of Environment), will ensure that public doses resulting from the normal operation of commercial nuclear plants are well below the limit of 0.1 rem per year.~~

Section 53.270 would provide for the protection of plant workers. This section would include the part 20 limits on occupational exposures to ensure that protection of plant workers is addressed within the high-level safety criteria for part 53. ~~Similar in content and rationale to the discussion in the preceding section for proposed § 53.260 to maintain doses to the public ALARA, the proposed § 53.270 would require applicants and licensees to identify and provide a combination of design features and programmatic controls to ensure occupational doses are ALARA. The experience at the current~~

~~generation of nuclear plants has demonstrated the efficacy of combinations of plant design features and programmatic controls for limiting dose to plant workers. The need to give special consideration to limiting occupational exposures during all phases of the life cycle of future commercial nuclear plants is especially important given the wide variety of potential reactor technologies and designs that could be licensed under Framework A of part 53.~~

Subpart C – Design and Analysis Requirements

This subpart would provide requirements for the design of commercial nuclear plants and the supporting analyses, including the analyses of LBEs, to demonstrate that the performance standards in proposed subpart B can be satisfied. The sections within subpart C would reflect the overall hierarchy throughout part 53~~Framework A~~, which would cover: (1) plant-level safety criteria (§§ 53.210, 53.220, and 53.470); (2) safety functions (§ 53.230) needed to demonstrate compliance with the safety criteria; (3) design features (§ 53.400), human actions, and programmatic controls needed to fulfill the safety functions; and (4) functional design criteria (§§ 53.410 and 53.420) that must be defined for each design feature relied on to demonstrate the safety criteria (§§ 53.210~~,~~ and 53.220~~, and 53.470~~) are met. Subpart C would also contribute to the logic and structure of part 53~~Framework A~~ by distinguishing between SR SSCs and NSRSS SSCs and licensee-controlled programs that address LBEs other than DBAs. Specifically, SR SSCs, human actions, and programmatic controls needed to protect against DBAs are used to satisfy the safety objective of limiting the possibility of an immediate threat to the public health and safety. NSRSS SSCs, human actions, and licensee-controlled programs that address LBEs other than DBAs generally make up the appropriate measures considering potential risks to public health and safety.

Section 53.400 would establish a requirement that design features be provided for each commercial nuclear plant to satisfy the safety criteria and fulfill safety functions from proposed subpart B during LBEs. Other sections in subpart C would, in turn, further address the necessary capabilities and reliabilities for SSCs by establishing functional design criteria, fulfilling design requirements, performing analyses of LBEs, performing other supporting analyses, and categorizing SSCs based on their roles in preventing or mitigating LBEs.

Section 53.410 would require that functional design criteria be defined for design features relied upon to demonstrate that the consequences from DBAs would be below the criteria in § 53.210 through analyses performed under~~in accordance with~~ § 53.450(f), which includes insights from both PRAs and deterministic analyses. Other sections within part 53~~Framework A~~ would establish appropriate controls on these design features (e.g., safety classification, protection from external hazards, quality assurance, and TS) to ensure the functional design criteria are satisfied. The performance requirements for the SSCs needed to address DBAs and the corresponding human actions and programmatic controls would contribute to ensuring that a commercial nuclear plant licensed under part 53~~Framework A~~ would demonstrate compliance with the safety objective that the plant poses no immediate threat to public health and safety.

Section 53.415 would require that SR SSCs be protected against or designed to withstand the effects of natural phenomena (e.g., earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches) and constructed hazards (e.g., from dams, transportation routes, and military or industrial facilities). Specifically, § 53.415 would require that SR SSCs remain capable of performing the safety functions stated in § 53.230 for which they are credited up to the design-basis external hazard levels as determined under § 53.510. As used in § 53.415 and subpart D of part 53, a hazard level would refer to

such things as the magnitude and recurrence rate of an earthquake and the resultant ground motions, the height of a flood, the force of hurricane winds, or the concentrations of chemicals resulting from a release from a nearby facility. These requirements would support either traditional deterministic approaches for determining and protecting against external hazards or probabilistic approaches that are being developed for seismic and some other external hazards.

Section 53.420 would require that functional design criteria be defined for design features that play a significant role in demonstrating that the safety criteria for LBEs other than DBAs are satisfied. The analyses required for this demonstration would be described in proposed § 53.450(e), which would require that those events be identified and assessed using a ~~PRA~~ risk evaluation methodology. The SSCs determined to be safety significant (i.e., either SR or NSRSS) would have associated special treatment requirements as specified in § 53.460. Special treatment would be defined in subpart A of part 53 and generally refers to measures (e.g., quality assurance, testing, monitoring) taken beyond the procurement and installation of commercial grade products to provide confidence that the SSC will comply with the applicable functional design criteria. The inclusion of a systematic approach to identifying the functional design criteria for SSCs and tailoring the special treatments to specific LBEs and safety functions is an important contributor to satisfy the safety objectives in ~~proposed § 53.200~~the Atomic Energy Act. As explained above, other sections in part 53~~Framework A~~ that address DBAs would require protection against an immediate threat to public health and safety. Therefore, designers and licensees for commercial nuclear plants would be provided flexibility on how LBEs other than DBAs are either prevented or mitigated and how the ~~cumulative~~ plant risks remain below the safety criteria in § 53.220.

Section 53.425 would establish requirements for design features and related functional design criteria limiting the release of radionuclides during normal operations to satisfy the criteria in ~~§ 53.260 of subpart B~~part 20. Section 53.430 would provide similar requirements for design features and related functional design criteria for protection of plant workers to meet the safety criteria in ~~§ 53.270~~part 20. ~~Both sections would also include requirements to establish functional design criteria for SSCs contributing to achieving doses ALARA when considering the state of technology, the economics of improvements in relation to benefits to the public or worker health and safety, and other societal and socioeconomic considerations. These ALARA requirements would recognize the roles of both design features and programmatic controls in reaching desired objectives. The development of an integrated approach to maintaining doses to the public and workers ALARA during normal operations would present a particular challenge to applicants seeking only an approval or certification of the design of a commercial nuclear plant. Design features are an essential element in limiting doses resulting from normal operations and would need to be considered. A performance-based approach to the design and the associated NRC review of the design can consider proposed combinations of design features and programmatic controls for maintaining doses ALARA. In addition, s~~Similar to existing regulations, the NRC considers that ~~applicants~~ licensees would generally comply the requirements of part 20 to keep doses as loss as is reasonably achievable~~with § 53.425(b)~~ by meeting a design objective~~performance goal~~ of keeping doses to the public from routine plant effluents less than 10 millirem per year. This goal is similar to that provided by appendix I to part 50 and would assist designers, applicants, and licensees in performing the evaluations of possible reductions in public dose from routine effluents when considering costs and other factors. As emphasized in existing regulations in part 50, the design objective of

keeping doses to the public from routine plant effluents less than 10 millirem per year should not be construed as a radiation protection standard. The NRC anticipates that future guidance will continue to reflect this performance goal.

Section 53.440 would address various design requirements that warrant specific mention to ensure that the design features required by § 53.400 comply with the functional design criteria required by §§ 53.410 and 53.420. These requirements would be met through design practices, consideration of testing and operating experience, and various assessments of LBEs and other potential challenges to commercial nuclear plants. Discussions of some of the key design requirements included in this section follow.

~~§ 53.440(a): An essential element to ensuring a proposed design can comply with the performance criteria in proposed part 53 would be that the abilities of design features to fulfill their safety functions are demonstrated by a combination of analyses, test programs, prototype testing, and operating experience. This requirement closely aligns with the language in § 50.43(e) and is proposed in part 53 as the same foundational requirement.~~

~~§ 53.440(b): The design and licensing of commercial nuclear plants should use generally accepted consensus codes and standards. Such codes and standards ensure sufficient testing and qualification of materials and equipment and provide defined processes, specifications, and acceptance criteria for use by designers and suppliers. The NRC would indicate acceptance of consensus codes and standards used in the design and licensing of a specific commercial nuclear plant either through the NRC's generic endorsement of a code or standard (i.e., through regulatory guidance), including any limitations or conditions, that can be referenced within an~~

Commented [A9]: The language in 50.43(e) has been incorporated in the review standards in 53.090(c)(5), renumbered in these edits as 53.090(d) to make them applicable to commercial nuclear plants not producing commercial power. As a result, 53.440(a) is redundant and should be eliminated.

~~application, or through the review of a referenced code or standard as part of the review of a specific application.~~

Commented [A10]: Deleted to avoid an inappropriate delegation of Commission authority to determine what is acceptable and to avoid conflict with the Principle of Good Regulation of Clarity.

- § 53.440(c): The design requirements in subpart C would require the materials used for SR and NSRSS SSCs to be qualified for their service conditions over the plant lifetime.
- § 53.440(d): The requirements in § 53.440 would include the need to consider possible degradation mechanisms for materials and equipment to inform ~~both~~ the design process ~~and the development of integrity assessment programs to be executed during plant operations in accordance with subpart F of part 53~~. The inclusion of requirements related to designing ~~and monitoring~~ for possible degradation mechanisms reflects important lessons learned from the history of LWRs as well as operating experience with structures and systems in ~~countless~~ other engineering endeavors.

Commented [A11]: Similar to the environmental qualification of electrical equipment important to safety under 50.49, any special treatment programs such as the draft proposed integrity assessment program should be expected to come out of the risk evaluations if they are needed. In light of the design requirements proposed in 53.440(c) for SSC material qualification for service conditions throughout the plant lifetime, it does not appear that there will be a need for such a program.

- § 53.440(e) and (f): The design requirements in subpart C would state specific design requirements similar to existing requirements in parts 50, 52, and 73 for protections against fires and explosions and consideration of safety and security together in the design process.
- § 53.440(g) and (h): Specific design requirements are proposed to ensure that commercial nuclear reactors under part 53 have the capability to ~~achieve and maintain subcriticality~~reliable control reactivity and provide long-term cooling. The requirements would be included to address the potential that some reactor designs may be able to achieve a stable end state for the purpose of event analyses but might need further actions to completely shut down and service the facility.
- § 53.440(i): The design, analysis, and development of programmatic controls under part 53 would consider the number of reactor units and other significant inventories of radioactive materials contributing to the risks to public health and safety.

This would reflect the definition of “commercial nuclear plant” in subpart A and reinforce that the evaluation of LBEs is performed on a plant-wide basis. This aspect of part 53~~Framework A~~ would be different from parts 50 and 52, which generally define safety requirements on the assumption of events involving only individual reactor units.

- § 53.440(j): A design requirement is proposed to provide a technology-inclusive requirement that would be equivalent to the requirements in § 50.150 to address the possible impact of a large commercial aircraft.
- § 53.440(k): The inclusion of a specific proposed requirement to address the risks to public health from potential chemical hazards of licensed material is appropriate given the diversity of reactor technologies and designs that might be licensed under part 53. The requirement in part 53 would be similar to the existing requirements in 10 CFR part 70, “~~”~~Domestic Licensing of Special Nuclear Material,” that address both potential radiological and chemical hazards for licensed materials at fuel cycle facilities.
- § 53.440(l): Provisions are proposed to require that measures be taken during the design of commercial nuclear plants to minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the generation of radioactive waste in accordance with § 20.1406.
- § 53.440(m): A design requirement is proposed to provide a technology-inclusive equivalent to the requirements in § 50.68 by including options for commercial nuclear plants to either have a monitoring system capable of detecting a criticality as described in § 70.24 or to have restrictions on SNM handling and storage that would prevent inadvertent criticality events.
- § 53.440(n): The design would need to reflect state-of-the-art human factors principles for safe and reliable performance in all settings that human activities are

expected for performing or supporting the continued availability of plant safety or emergency response functions.

HFE is essential to facilitate the role of personnel in facility safety in a manner that is both effective and reliable. The NRC proposes to adapt § 53.~~73~~440(~~a~~n)(1) from the HFE design requirements of § 50.34(f)(2)(iii). A key difference would be that the requirement would now be focused on settings where personnel fulfill their safety or emergency response roles wherever they may occur. The NRC additionally proposes to include within the scope of this requirement activities for assuring the continued availability of plant equipment that is needed for safety, and envisions that this may encompass relevant maintenance, inspections, and testing as well. The NRC intends that this requirement would be associated with staff guidance for conducting scalable reviews of HFE that is planned to accompany part 53.

Human-system interfaces provide vital information to operators across a spectrum of operating conditions that can range from normal operations through severe accident conditions. The specific types of information that must be available to support operations staff during such conditions include, in part, those associated with safety function parameters, safety system status, possible core damage states, barrier integrity, and radioactive leakage. Due to the importance of such information, the NRC proposes under § 53.44~~73~~0(n~~b~~)(2) to require such human-system interface design features for all facilities, irrespective of other flexibilities proposed under part 53. Therefore, the NRC proposes to adapt specific post-Three Mile Island requirements of § 50.34(f) in a technology-inclusive manner as detailed in the following:

- Paragraph (n~~b~~)(2~~4~~)(i) would be adapted from § 50.34(f)(2)(iv).
- Paragraph (n~~b~~)(2)(ii) would be adapted from § 50.34(f)(2)(v).

- Paragraph (n~~b~~)(2~~3~~)(iii) would be adapted from § 50.34(f)(2)(xi), 50.34(f)(2)(xii), and 50.34(f)(2)(xxi).
- Paragraph (n~~b~~)(24)(iv) would be adapted from § 50.34(f)(2)(xvii), 50.34(f)(2)(xviii), 50.34(f)(2)(xix), and 50.34(f)(2)(xxiv).
- Paragraph (n~~b~~)(2~~5~~)(v) would be adapted from § 50.34(f)(2)(xxvi).
- Paragraph (n~~b~~)(2~~6~~)(vi) would be adapted from § 50.34(f)(2)(xxvii).

~~In addition to the requirements of § 53.730(b)(1) through (6), a further set of human-system interface design requirements applicable only to those facilities that will be staffed by GLROs would be provided under § 53.730(b)(7). This prescriptive set of design requirements for those facilities which demonstrate compliance with the criteria of § 53.800 would recognize that the application of HFE under § 53.730(a) is anticipated to be significantly reduced at such facilities in the absence of an expected operator role for the fulfillment of safety functions. However, it should be noted that the capability for an immediately initiated, manual reactor shutdown would be conservatively mandated irrespective of any other design considerations.~~

- § 53.440(o): Load following where plant output automatically changes in response to externally originated instructions or signals is not permitted under the existing regulations of § 50.54. However, new technological considerations and concepts of operation may justify such an operational approach under appropriate circumstances. The NRC recognizes that, beyond electrical power generation, load following may also affect other applications of plant output, such as hydrogen production, desalination, or district heating. For load following to be permissible, measures must be in place to provide assurance that plant output considerations are not permitted to lead to challenges to safe reactor operations. These measures may consist of automated control systems, automatic protective features, or the continuous oversight and

Commented [A12]: Design requirements for load following have been moved from 53.740(f) to 53.440(o) to follow the systems engineering model used for the structure of part 53.

immediate intervention capability of an appropriately qualified and authorized individual. Section 53.~~7~~440(~~f~~o) would provide the measures to allow for load following under § 740(f)~~, provided that appropriate measures are in place~~. In considering the acceptability of the measures associated with load following, the NRC expects that any automatic protection relied upon would be separate from that credited for reactor protection purposes and would employ setpoints that are set so as to prevent actuation of the reactor protection system while accomplishing its functions to the extent practical.

Section 53.450 would establish analysis requirements and would center upon the use of a risk evaluation such as a PRA in combination with other generally accepted approaches for systematically evaluating engineered systems. The reliance on ~~PRAs~~ risk evaluation as a key component in the proposed analysis requirements for part 53~~Framework A~~ would reflect the decades of improvements in risk~~PRA~~ methodologies and the increasing use of risk~~PRA~~ techniques in the design, licensing, and oversight of both operating and future nuclear reactors. Part of the Commission's PRA Policy Statement is that the use of PRA technology should be increased in all regulatory matters to the extent supported by the state of the art in PRA methods and data and in a manner that complements the NRC''s deterministic approach and supports the NRC''s traditional defense-in-depth philosophy. The need to supplement PRA insights with other engineering approaches and judgments reflects the NRC's longstanding policy described in the SRM to SECY-98-144, "Staff Requirements—SECY-98-144—White Paper on Risk-Informed and Performance-Based Regulations," dated February 24, 1999, for regulatory decision-making to be risk-informed but not solely based on numerical results of a risk assessment (i.e., not a risk-based approach). Part 53 would maintain a role for NRC's traditional deterministic approaches (particularly for DBAs) and

defense-in-depth philosophy by including specific requirements utilizing these regulatory tools in subparts B and C.

~~PRA~~ Risk assessment would be used in combination with other techniques in part 53~~Framework A~~ to identify and categorize LBEs, classify SSCs, and evaluate defense in depth. This increased role for the ~~PRA~~ risk evaluation necessitates that it would be developed, performed, and maintained ~~in accordance with NRC-approved standards and practices (see § 53.450(c) and (d))~~. The computer codes used to model the plant response and the behavior of the barriers to the release of radionuclides would need to be qualified for the range of conditions being simulated across a wide range of unplanned events. These analyses would need to use realistic approaches and address uncertainties associated with states of knowledge, modeling, and performance of SSCs.

Commented [A13]: Deleted to reflect the need to follow the OFR requirements for incorporation by reference of any documents external to the Code of Federal Regulations the agency would require an applicant or licensee to comply with. This reflects the edits to 53.450.

The categories of LBEs used in part 53~~Framework A~~ would include anticipated event sequences, unlikely event sequences, and very unlikely event sequences. The unlikely event sequences would include those events with estimated frequencies well below the frequency of events expected to occur during the lifetime of a commercial nuclear plant. An important aspect of the analysis requirements is that, under proposed § 53.450(e), the analyses of LBEs other than DBAs would ~~not only~~ be used to ~~show the performance criteria of § 53.220 are satisfied but to also~~ show that evaluation criteria defined under § 53.220 for each LBE or category of LBEs would ~~also~~ be satisfied. Such evaluation criteria for specific LBEs or categories of LBEs would be defined in terms of limits on the release of radionuclides or maintaining the integrity of one or more barriers used to limit the release of radionuclides and reflect a graded approach of allowing lesser potential consequences from more frequent events. An example of such evaluation criteria for a range of LBEs that could likely be expanded for part 53 is provided in RG 1.233. Another proposed requirement for the proposed § 53.450(e)

analyses is that the methodology would need to include a means to identify event sequences deemed risk-significant such that those event sequences can be given special attention within other sections of part 53.

Part 53~~Framework A~~ would maintain an important role for a deterministic analysis of DBAs in the performance criteria of § 53.210 and the related analytical requirements in § 53.450(f). The analysis of DBAs would be required to address event sequences drawn from those with estimated frequencies below the expected lifetime of a generation of reactors (e.g., event sequences with frequencies as low as one in ten thousand years). As proposed in this section, DBAs would need to be analyzed using deterministic methods and ensure a safe, stable end state with reliance upon only SR SSCs and human actions, if needed, to be performed by operators licensed under the provisions of §§ 53.760 through 53.7780~~95~~ and part 55.

While the DBAs analyzed under part 53~~Framework A~~ would be similar to the traditional DBAs analyzed under parts 50 and 52, there are important distinctions between their ~~overall~~ roles ~~of DBA analyses in part 50 and proposed Framework A~~. In part 53~~Framework A~~, the role of the DBA analysis would be more narrowly focused on selecting SR SSCs and determining functional design criteria for those SSCs to ensure the commercial nuclear plant poses no immediate threat to public health and safety. The overall control of risks posed by commercial nuclear plants under part 53~~Framework A~~ would be provided by the analyses of and measures taken for both DBAs and other LBEs, including very unlikely event sequences. This would contrast with the traditional deterministic approach in part 50 wherein the analyses of DBEs such as DBAs were used to provide bounding assessments, incorporate standard design rules such as principal design criteria based upon the general design criteria of appendix A to part 50 coupled with assumptions related to single failures~~, and~~ to define conservative

performance requirements for SR SSCs. Limitations related to the traditional deterministic approach were addressed in part 50 through case-by-case assessments and specific actions for beyond-design-basis events such as anticipated transients without scram (ATWS) and station blackout (SBO).

Section 53.450 would also include provisions to ensure that analyses are performed to support the design requirements of § 53.440(e) on fire protection, § 53.440(j) on aircraft impact assessments, and § 53.425 on controlling effluents ~~and otherwise maintaining the dose to individual members of the public ALARA~~. The proposed analysis requirements related to fire protection would support either a traditional, deterministic approach or a more risk-informed approach where the risks from fires are addressed within the identification and analyses of LBEs.

Section 53.460 would establish criteria for the safety classification of SSCs and determination of appropriate special treatments. As noted in subpart A, the term "special treatments" would be defined to mean those ~~requirements~~items, such as measures taken to satisfy functional design criteria, quality assurance, environmental qualification of electrical equipment, integrity assessment, and programmatic controls, which provide assurance that certain SSCs will provide defense in depth or perform risk-significant functions. These requirements would also provide confidence that the SSCs will perform under the service conditions and with the reliability credited in the analysis performed in accordance with § 53.450 to satisfy the safety criteria in §§ 53.210 and 53.220. The terminology used in part 53 would include the following categories for SSC classification: (1) SR; (2) NSRSS; and (3) non-safety significant. Requirements for SR SSCs would be defined in other sections of part 53 and would include using technical specifications~~TS~~ for controls during operation and the application of quality assurance requirements from appendix B to part 50~~subpart K~~.

Requirements for NSRSS SSCs would include the need to identify necessary special treatments such as performance measures on reliability. Licensees would generally be afforded flexibility in maintaining and changing special treatments ~~requirements~~ for SSCs categorized as NSRSS. Non-safety-significant SSCs would be addressed under normal licensee programs for commercial grade equipment and typical industry practices for general plant design and maintenance.

~~Section 53.470 would allow an applicant or licensee to seek operational flexibilities by adopting more restrictive criteria than those provided in § 53.220 and that might otherwise be used in the analysis of LBEs under § 53.450(e). Such an approach might be taken to ensure sufficient safety margins to gain operational flexibilities in areas such as justifying siting in relation to population centers or staffing levels. As an example, an applicant or licensee could propose to justify siting proposals by adopting alternate criteria for very unlikely event sequences. Such alternate criteria could require calculated consequences for an individual at the exclusion area boundary to be less than one rem total effective dose equivalent (TEDE). This section would establish requirements to ensure that, if more restrictive evaluation criteria than those required by a methodology were used to justify operational flexibilities, then the analysis, design features, and programmatic controls would be established and maintained accordingly.~~

Section 53.480 would establish seismic design considerations. This proposed section would relate to the safety criteria in subpart B, the analytical requirements related to external hazards in § 53.450, and subpart D, “Siting Requirements.” For licenses issued under ~~Framework A of~~ part 53, this section in subpart C would support a variety of approaches to seismic design. For example, a design for a commercial nuclear plant could show that SSCs are able to withstand the effects of earthquakes by adopting an approach similar to that in appendix S to part 50. Alternatively, an applicant could

follow the more recent risk-informed alternatives afforded by standards development organizations (e.g., American Society of Civil Engineers (ASCE)/Structural Engineering Institute (SEI) 43-19, “Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities.”) Because the agency has not endorsed ASCE/SEI-43-19, an applicant can propose to use ASCE/SEI 43-19 on an application specific basis to meet § 53.480 and the NRC would~~ill~~ evaluate the adequacy of the standard as applied in that application. The design could also be done with the full integration of seismic PRAs into the design and licensing of a particular commercial nuclear plant. This section has been developed to accommodate a variety of potential risk-informed, performance-based seismic design approaches. The analyses required by § 53.450 would need to address seismic hazards as well as other external hazards. The expected responses of SSCs to a range of seismic events would be included in the analyses when ensuring that the safety criteria defined under~~in~~ § 53.220 would be met. The potential SSC responses to seismic hazards could be addressed in the analyses using a fragility model (conditional probability of its failure at a given hazard input level), a high confidence of low probability of failure value, or other method endorsed or otherwise found acceptable by the NRC.

Subpart D – Siting Requirements

Proposed subpart D ~~in Framework A~~ would state requirements for the siting of commercial nuclear plants and would serve the role provided by 10 CFR part 100, “Reactor Site Criteria,” for nuclear reactors licensed under parts 50 and 52. As reflected in proposed § 53.500, the reason for establishing siting requirements would remain the same as it has been historically~~, which is~~ to ensure that licensees and applicants assess what impact the site environs may have on a commercial nuclear plant (e.g., external hazards) and, conversely, what potential adverse health and safety impacts a

commercial nuclear plant may have on nearby populations in view of the site characteristics.

Proposed § 53.510 would require that design-basis external hazard levels be identified and characterized based on site-specific assessments of natural and ~~constructed~~ man-related hazards with the potential to adversely affect plant functions. The site-specific assessments would be used in the proposed § 53.415, which would require that SR SSCs be designed to withstand the effects of natural phenomena and ~~constructed~~ man-related hazards of levels or severities up to design-basis external hazard levels. The design-basis levels for external hazards relevant to a site would need to account for uncertainties and variabilities in data, models, and methods used to characterize those hazards. Existing approaches could be used to demonstrate compliance with this requirement. The historical importance of assessing seismic events as risks to commercial nuclear plants and the associated development of risk-informed approaches to address seismic events would be reflected in proposed § 53.480, "Earthquake engineering," and specific requirements in subpart C. The NRC staff describes in the pre-decisional ~~DG entitled~~draft regulatory guide, "Technology-Inclusive, Risk-Informed, and Performance-Based Methodology for Seismic Design of Commercial Nuclear Plants," issued on October 3, 2022, its efforts to develop a graded approach for seismic design by grouping SSCs into different seismic design categories (SDCs) based on~~in accordance with~~ their risk significance. ~~While the agency has not endorsed ASCE/SEI 43-19, an applicant can propose to use ASCE/SEI 43-19 on an application specific basis to meet § 53.480 and the NRC will evaluate the adequacy of the standard as applied in that application. The NRC staff will continue to review ASCE/SEI 43-19 as part of its efforts to further develop guidance in this area. The approach described in RG 1.208, "A Performance-Based Approach to Define the Site-Specific Earthquake Ground~~

Commented [A14]: Deleted as redundant to the discussion of ASCE/SEI 43-19 in 53.480.

~~Motion," would be an acceptable way to develop site-specific ground motion response spectra for SSCs under appendix S to part 50, which corresponds to SSCs that are categorized as the highest seismic design category (SDC-5) in ASCE/SEI 43-19.~~

The evaluation of seismic hazards under subpart D would need to be sufficient to inform a site-specific design (e.g., a CP or custom COL) or confirm the use of a standard design ~~(e.g., a standard DC)~~ for a ~~subject~~ commercial nuclear plant under § 53.480 and other sections of subpart C. ~~A risk-informed approach could use several design-basis ground motions (DBGMs) to assess SSCs in various SDCs (i.e., one DBGM per SDC).~~ Section 53.510(d) would state that geologic and seismic siting factors must also include related hazards such as seismically induced flooding ~~and volcanic activity~~ that may affect the design and operation of a proposed commercial nuclear plant for the proposed site.

Section 53.520 would require applicants to identify and assess site characteristics related to topics which might include meteorology, geology, hydrology, or other areas in the design and analyses required under subpart C.

Proposed section 53.530 would set requirements for population-related considerations and maintain requirements and definitions similar to those currently in part 100 for an exclusion area, low population zone, and population center distance. The NRC recognizes that some applicants may propose to essentially collapse the exclusion area and low population zone to the site boundary. This approach would rest on a demonstration that the calculated consequences of DBAs remain below the proposed dose guidelines used in part 53~~Framework A~~, which are the same as those in the existing regulations in parts 50, 52, and 100. The proposed definitions in § 53.020 would allow such configurations, assuming they were justified by the design and analyses from subpart C. This approach should provide flexibility to justify alternative exclusion areas

Commented [A15]: Deleted as inapposite here because this relates to the acceptability of an approach in part 50 rather than part 53.

Commented [A16]: Deleted as improper and unnecessary because the term "standard design certification" refers to the Commission approval through a rule of a standard design and does not refer to the design itself.

Commented [A17]: Staff should address this in guidance.

Commented [A18]: Deleted to reflect the absence of mention of volcanic activity in the draft proposed 53.510(d) provided in SECY-23-0021.

and low population zones without foreclosing the option for an applicant to define more conventional exclusion areas and low population zones outside of a defined site boundary. The NRC's long-standing preference for siting reactors in areas of low population density would be maintained in part 53~~Framework A~~ by using the current language from part 100 in proposed § 53.530(c). The NRC ~~currently~~ plans to revise guidance related to population densities surrounding a commercial nuclear plant to reflect Commission direction in SRM-SECY-20-0045, "Population Related Siting Considerations for Advanced Reactors." Site-related requirements in part 20 (restricted area) and part 73 (protected and owner-controlled areas) would remain applicable to commercial nuclear plants licensed under part 53.

Commented [A19]: Deleted as unnecessary.

Proposed section 53.540 would require that site characteristics be appropriately considered in other activities such as the design and analysis performed under proposed subpart D, the emergency planning and security programs under proposed subpart F, and the facility safety program under proposed subpart F.

Subpart E – Construction and Manufacturing Requirements

The proposed part 53 language would establish construction and manufacturing requirements in subpart E ~~for Framework A and in subpart O for Framework B~~. ~~The two subparts would essentially be the same but would be included separately within the frameworks to support clarity and ease of use due to the differences in the internal references between Framework A and Framework B.~~ The proposed language for construction-related activities would largely reflect current requirements in part 50 without any fundamental changes. Limited changes would be made in several places, as described in the following paragraphs, to be technology-neutral and for consistency with the organization and language of part 53. The proposed language for requirements for manufacturing activities would largely mirror those for construction-related activities.

However, the proposed manufacturing requirements have been updated from the current requirements in subpart F of part 52 to better accommodate the possible factory fabrication of manufactured reactors. The manufacturing of specific components outside the scope of an ML would not be addressed by these proposed subparts.

Sections 53.600 ~~and 53.4100 within Frameworks A and B, respectively,~~ would establish that subpart E provides the overall construction and manufacturing requirements for CPs, OLs, COLs, MLs, and limited work authorizations (LWAs). ~~These sections would connect the construction and manufacturing requirements to the safety criteria, quality assurance requirements, and other requirements located in other subparts in Frameworks A and B. These requirements would require that construction and manufacturing activities be managed and conducted such that when combined with associated design features and programmatic controls, the constructed plant would satisfy the relevant requirements in subpart B in Framework A and subpart R in Framework B.~~

Section~~s~~ 53.605 ~~and 53.4105 in Frameworks A and B, respectively,~~ would establish requirements for the reporting of defects and instances of noncompliance during construction~~. Both sections would provide~~ equivalent ~~requirements~~ to those in § 50.55(e).

Section~~s~~ 53.610(a) ~~and 53.4110(a) in Frameworks A and B, respectively,~~ would establish the requirement to have in place a construction experience program corresponding to the requirements of § 50.34(f)(3)(i)~~well-defined command and control structure to manage construction activities. The requirements would generally reflect current requirements, with an emphasis on the quality assurance programs for complying with the requirements in proposed subparts K and U, which would both be equivalent to appendix B to part 50. The proposed § 53.610(a)(6) would require~~

~~programmatic controls for implementing special treatment for NSRSS SSCs to align with requirements in other subparts in Framework A. The sections in both frameworks would also refer to other NRC regulations to address matters such as requirements to have a FFD program, a radiation protection program if radioactive materials are brought onto the site, and security programs to protect sensitive information and cyber threats.~~

Section~~s~~ 53.610(b) ~~and 53.4110(b)~~ would provide requirements governing construction activities, including the equivalent of the requirement in § 50.10(e) that prohibits starting construction until the NRC has authorized the activities by issuing a CP, COL, ESP, or LWA. Section~~s~~ 53.610(b)(1)(iii) ~~and 53.4110(b)(1)(iii)~~ would require procedures to be in place prior to beginning construction to ensure that construction-related activities do not undermine important features such as slope stability and that construction-related activities such as backfilling of excavated portions of the site appropriately address potential pre-construction activities such as the emplacement of retaining walls or drainage systems. Other requirements in these paragraphs would be equivalent to requirements in parts 50 and 52 ~~with appropriate references to other parts for items such as possession of byproduct material or SNM,~~ for protecting operating units from construction activities for commercial nuclear plants with multiple reactor units~~,~~ and having a redress plan in case LWA activities are terminated.

Sections 53.610(c) ~~and 53.4110(c)~~ would address inspection and acceptance activities ~~by including requirements in part 53 equivalent to specific quality assurance criteria in appendix B to part 50 and inspections, tests, analyses, and acceptance criteria (ITAAC) in part 52 for COLs~~ for manufactured reactors delivered to a site for installation under a COL.

Section 53.615 would establish a requirement corresponding to the requirements of §§ 50.30(d) and 50.55(d) for a CP holder to submit additional information to bring the

application up to date and apply for an operating license at or about the time of completion of construction.

Section~~s~~ 53.620(a) ~~and 53.4120(a)~~ would include proposed requirements covering the activities performed under an ML issued under ~~either Framework A or Framework B, respectively~~part 53. Provisions related to MLs were first adopted by the NRC in 1973 through the addition of appendix M to part 50. The regulation supported the manufacture of a nuclear power reactor to be incorporated into a commercial nuclear plant under a CP and operated under an OL at a different location from the place of manufacture.[1] The regulations and processes for MLs were changed substantially in the part 52 rulemaking in 2007 (72 FR 49352). The most important shift in the ML concept in that rulemaking was that a final reactor design, which would be equivalent to that required for a standard DC under part 52 or an OL under part 50, must be submitted and approved before issuance of an ML. The rationale for that change was that approval of a final design ensures early consideration and resolution of technical matters before there is any substantial commitment of resources associated with the actual manufacture of the reactor, which greatly enhances regulatory stability and predictability.

The proposed part 53 sections in subpart~~s~~ E ~~and O~~ for manufacturing and in subpart~~s~~ H ~~and R~~ for licensing matters would maintain requirements equivalent to those in part 52 for MLs. The NRC approval of a standard~~ized~~ design and related manufacturing processes, coupled with a stable workforce and established procedures, has the potential for maintaining and even improving the quality and consistency of manufacturing, as compared to the traditional method of constructing reactors onsite by a variety of contractors and subcontractors.

Commented [A20]: Edited to use the defined term.

[1] On December 17, 1982, the NRC issued "Manufacturing License ML-1 to Offshore Power Systems for the manufacture of a maximum of eight floating nuclear plants," dated September 30, 1982, but the project was subsequently canceled.

Subparts E and O would include requirements that would apply to portions of a manufactured reactor in recognition that some activities covered by an ML may occur at different fabrication facilities. As with the preceding sections on construction, §§ 53.620 and 53.4120 would establish the requirements to have in place programs, procedures, and a well-defined command and control structure to manage manufacturing-related activities.

Section 53.620(b) in subpart E and § 53.4120(b) in subpart O would propose requirements for executing the manufacturing activities following receipt of an ML in Frameworks A and B, respectively. Information about the design and manufacturing processes should be provided by the applicant. The importance of the ML is reflected in several of the proposed requirements in §§ 53.620(b) and 53.4120(b) that would refer to complying with the ML, including conducting manufacturing processes within facilities for which the license holder can control activities. The essential role of post-manufacturing inspections would also be incorporated into these proposed sections by requiring the holder of the ML to perform inspections and have acceptance processes for manufactured reactors or portions of a manufactured reactor.

Sections 53.620(c) and 53.4120(c) in Frameworks A and B, respectively, would provide proposed requirements for the control of radioactive materials if the holder of an ML plans to possess and use source, byproduct, or SNMload fuel into a manufactured reactor as part of the manufacturing process. Under the proposed requirements in this section, the Commission would find that a manufactured reactor would not be a utilization facility or part of a utilization facility until it is installed at a commercial nuclear plant and all ITAAC are complete. The regulation of the manufactured reactor with fuel loaded in it during transportation would be governed under part 70. By and large, the proposed subparts E and O would refer to NRC regulations in 10 CFR part 30, "Rules of

~~General Applicability to Domestic Licensing of Byproduct Material," 10 CFR part 40, "Domestic Licensing of Source Material," and part 70 for the requirements on controlling radioactive materials.~~ Several specific requirements to address the potential hazards of radioactive materials are proposed in areas such as having a fire protection program, an emergency plan, training programs, and procedures to minimize contamination.

Section 53.620(c~~e~~) ~~in subpart E and § 53.4120(e) in subpart O~~ would propose to limit the transport of a manufactured reactor or major portions of a manufactured reactor to only the site of a licensee with a COL that authorizes the construction of a commercial nuclear plant using a manufactured reactor under the specific ML. This proposed requirement is similar to the limitations in § 52.153, with the difference being that part 53 would propose to allow the installation of a manufactured reactor at the site of a COL but would not propose to support installation at the site of a CP. The NRC does not have information suggesting that potential applicants under part 53 would be interested in a possible combination of a manufactured reactor and the licensing option of CP and OL. Additionally, this combination would introduce complexity into the licensing process by potentially needing to resolve ITAAC identified for the manufactured reactor within the licensing provisions for CP and OL. Additional proposed paragraphs in §§ 53.620(e) ~~and 53.4120(e)~~ would provide requirements for protecting manufactured reactors or major portions thereof during transport to the site of the commercial nuclear plant.

~~Sections 53.620(f) and 53.4120(f) in Frameworks A and B, respectively, would include proposed requirements for the acceptance and installation of a manufactured reactor at the site of a commercial nuclear plant. The proposed requirements would reference the construction requirements in §§ 53.610 and 53.4110 to govern the integration of the manufactured reactor into the construction of a commercial nuclear plant. Other proposed requirements in the sections would address required receipt~~

~~inspections and verification that interface requirements between the manufactured reactor and the balance of the commercial nuclear plant have been met.~~

Subpart F – Requirements for Operation

Proposed subpart F would provide the requirements for the operations phase of a commercial nuclear plant to ensure that the safety criteria in subpart B are satisfied throughout the plant's lifetime and during all modes of normal operation and unplanned events. ~~Section 53.700 would provide the overall objectives and general organization of subpart F, which would be to establish requirements during operations for: (1) plant SSCs; (2) plant personnel; and (3) plant programs.~~

Proposed § 53.710 would provide the requirements for ~~maintaining capabilities, availability, and reliability of SSCs to demonstrate compliance with the safety criteria and design requirements for unplanned events that are described in proposed subparts B and C. The basic structure of this proposed section would be that controls for SR SSCs are provided by~~ technical specifications (TS) and controls for NSRSS SSCs are required to be addressed with licensee-controlled documents and procedures.

The general content and control of TS under ~~the proposed Framework A~~part 53 would be similar to the requirements in part 50. The proposed requirements for TS would include limits on the inventories of radioactive materials, plant operating limits, and specific requirements for each SR SSC, including limiting conditions for operation (LCO) and required surveillances. The proposed requirements for TS would also include a section on important design elements, which is similar to design features in § 50.36, and a section for administrative controls. ~~A provision addressing the development and submittal of TS to address decommissioning activities would also be included in the proposed subpart G.~~

The proposed requirements for TS under part 53~~Framework A~~ would not carry over safety limits or associated limiting safety system settings from § 50.36, which contains TS requirements for operating reactors under parts 50 and 52. As discussed in SECY-18-0096, systematic assessments and more mechanistic approaches to evaluating source terms support an alternative approach to establishing barrier-based safety limits. An example provided in that paper is a comparison of: (1) the traditional specified acceptable fuel design limits (SAFDL) that support protecting a specific barrier from potential failure mechanisms (e.g., departure from nucleate boiling to protect fuel cladding); and (2) the specified acceptable system radionuclide release design limit (SARRDL) concept, which limits the possible increase in circulating radionuclide inventory during normal operations or an AOO as part of an integrated or "functional containment" approach. Additional discussion of the use of SARRDL in the design and licensing of advanced reactors is provided in RG 1.232. The SARRDL could be addressed as an operating limit within this proposed construct of requirements for TS. In cases, such as LWRs, where a SAFDL approach might be used as part of a mechanistic approach to meeting the design and analysis requirements in subpart C, the associated functional design criteria proposed in § 53.410 and TS under the proposed § 53.710(a) would define similar requirements as those provided by the safety limit and limiting safety system setting requirements in § 50.36.

The proposed requirements for TS under ~~Framework A~~part 53 would not include specific criteria for identifying when LCOs must be established (i.e., would not include an equivalent to § 50.36(c)(2)(ii)). Instead, consistent with subparts B and C, the TS requirements in subpart F ~~of Framework A~~ would define TS LCOs as providing limits on SR SSCs. The SR SSCs protect against an immediate threat to public health and safety to demonstrate compliance with the safety criteria in the proposed § 53.210. In the

proposed construct for part 53~~Framework A~~, risk significant SSCs would be addressed through a combination of TS for the SR SSCs and establishment and monitoring of performance standards for NSRSS SSCs.

In addition to addressing TS for SR SSCs, proposed § 53.710 would require appropriate controls be developed and implemented for NSRSS SSCs. Examples include appropriate surveillances and controls established through reliability assurance programs. Configuration management and other special treatments would provide that the capabilities, availabilities, and reliabilities of NSRSS SSCs are maintained consistent with the underlying risk assessments while providing flexibility to licensees through maintaining the management functions within licensee-controlled programs. Controls on NSRSS SSCs are appropriate as part of the overall performance-based approach within proposed part 53~~Framework A~~. Additionally, these controls justify proposed changes in part 53~~Framework A~~ from the traditional or deterministic approaches in parts 50 and 52 in areas such as replacing the single-failure criterion with a probabilistic reliability criterion (s~~S~~ee SRM-SECY-03-0047, "Policy Issues Related to Licensing Non-Light-Water Reactor Designs," dated June 26, 2003). This approach could also support the incorporation of risk insights and analytical margins to gain operational flexibilities in areas such as siting and staffing requirements described in subsequent sections of proposed subpart F.

Proposed § 53.715 would provide the requirements for developing and implementing a program to do the following: (1) control maintenance activities; (2) take appropriate corrective action when performance issues are identified; (3) conduct routine evaluations of effectiveness; and (4) assess and manage risks resulting from maintenance activities. These proposed requirements are similar to those included in § 50.65 (maintenance rule). While, for the maintenance rule, specific criteria must be

developed to capture both SR and non-safety-related but otherwise important SSCs, the proposed § 53.715 would cover SR SSCs and NSRSS consistent with other subparts in part 53~~Framework A~~.

Proposed § 53.720 would provide the requirements for responding to a seismic event during the operating phase of the life cycle of a commercial nuclear plant and would be equivalent to the requirements in paragraph IV(a)(3) of appendix S, "Earthquake Engineering Criteria for Nuclear Power Plants," to part 50.

The proposed part 53 would include provisions to address staffing, training, personnel qualifications, and HFE in a manner that is risk informed, technology inclusive, performance based, and flexible in nature. During the development of part 53, the staff prepared a draft white paper on "Risk Informed and Performance Based Human-System Considerations for Advanced Reactors," to support interactions with stakeholders and the ACRS. Key considerations within both frameworks include the recognition that staffing, operator qualifications, and HFE are interconnected areas that must be approached in an integrated manner and, furthermore, that safety functions, including the means by which they are fulfilled, provide an effective method for informing technology-inclusive requirements. ~~Unlike most requirements in subpart F, these requirements would be structured to be common to both Frameworks A and B, and proposed language that references requirements unique to each framework (e.g., for change control processes) would be used where appropriate.~~

The requirements associated with this approach would be in §§ 53.725 through 53.830. Section 53.725 discusses applicability and defines specific terms. Some definitions draw from those in § 55.4. Several new definitions would be introduced for use within the context of subpart F. ~~These new definitions would be the following:~~

~~*Automation, Auxiliary operator, Generally licensed reactor operator, Interaction-dependent-mitigation facility, Load following, Self-reliant-mitigation facility*~~.

Sections 53.725 to 53.830 would be divided into four portions that would cover general operational requirements, operator and senior operator licensing requirements, generally licensed reactor operator (GLRO) requirements, and general training requirements for plant staff. The NRC intends to provide guidance addressing the review of operator staffing plans; the review of operator, senior operator, and GLRO examination programs; and the implementation of scalable HFE reviews. Licensees would be required to use GLROs upon demonstrating compliance with the criteria in § 53.800.

Certain routine communications are necessary to facilitate the operator licensing process. The NRC is proposing to adapt the requirements of §§ 55.5 and 50.74 to § 53.726 to accomplish this.

~~Specific information must be collected in order to facilitate the initial issuance of operator licenses, as well as to allow for license renewals and required updates thereafter. Such information collection activities must also be approved by the OMB. The NRC is proposing to adapt the requirements of § 55.8, to include any needed updates in OMB approval information, to § 53.727 to accomplish this.~~

~~The information used within the regulatory processes of the NRC must be free from omissions and inaccuracies to facilitate effective regulation. Consistent with this, the NRC is proposing to adapt the requirements of § 55.9 to § 53.728 to require the completeness and accuracy of material information provided by individual applicants and license holders.~~

Section 53.730 would provide performance-based and technology-inclusive requirements for assessing the role of personnel in facility safety, applying

human-system considerations within facility design, and incorporating operational approaches that are consistent with design-specific safety considerations. ~~These provisions would apply to facilities licensed under both Framework A and Framework B (it should be noted that proposed § 53.4220 of Framework B states the rules in §§ 53.725 through 53.830 would apply under Framework B as well).~~ Most of these requirements would be adapted from portions of §§ 50.34(f) and 50.54 and 10 CFR part 55, "~~"~~Operators' Licenses," with considerable modification in order to reflect the introduction of new technologies and possible changes in the roles of personnel in preventing and mitigating events. The NRC is proposing that these technical requirements would, together, serve as a component of the required content of applications for OLs and COLs under part 53. Additionally, the NRC proposes that the specific technical requirements associated with HFE, human-system interface design, concept of operations, functional requirements analysis, and function allocation would serve as a component of the required content of applications for both standard DCs and standard design approvals as well.

~~HFE is essential to facilitate the role of personnel in facility safety in a manner that is both effective and reliable. The NRC proposes to adapt § 53.730(a) from the HFE design requirements of § 50.34(f)(2)(iii). A key difference would be that the requirement would now be focused on settings where personnel fulfill their safety or emergency response roles wherever they may occur. The NRC additionally proposes to include within the scope of this requirement activities for assuring the continued availability of plant equipment that is needed for safety, and envisions that this may encompass relevant maintenance, inspections, and testing as well. The NRC intends that this requirement would be associated with staff guidance for conducting scalable reviews of HFE that is planned to accompany part 53.~~

Human-system interfaces provide vital information to operators across a spectrum of operating conditions that can range from normal operations through severe accident conditions. The specific types of information that must be available to support operations staff during such conditions include, in part, those associated with safety function parameters, safety system status, possible core damage states, barrier integrity, and radioactive leakage. Due to the importance of such information, the NRC proposes under § 53.730(b) to require such human-system interface design features for all facilities, irrespective of other flexibilities proposed under part 53. Therefore, the NRC proposes to adapt specific post-Three Mile Island requirements of § 50.34(f) in a technology-inclusive manner as detailed in the following:

- Paragraph (b)(1) would be adapted from § 50.34(f)(2)(iv).
- Paragraph (b)(2) would be adapted from § 50.34(f)(2)(v).
- Paragraph (b)(3) would be adapted from § 50.34(f)(2)(xi), 50.34(f)(2)(xii), and 50.34(f)(2)(xxi).
- Paragraph (b)(4) would be adapted from § 50.34(f)(2)(xvii), 50.34(f)(2)(xviii), 50.34(f)(2)(xix), and 50.34(f)(2)(xxiv).
- Paragraph (b)(5) would be adapted from § 50.34(f)(2)(xxvi).
- Paragraph (b)(6) would be adapted from § 50.34(f)(2)(xxvii).

In addition to the requirements of § 53.730(b)(1) through (6), a further set of human-system interface design requirements applicable only to those facilities that will be staffed by GLROs would be provided under § 53.730(b)(7). This prescriptive set of design requirements for those facilities which demonstrate compliance with the criteria of § 53.800 would recognize that the application of HFE under § 53.730(a) is anticipated to be significantly reduced at such facilities in the absence of an expected operator role for the fulfillment of safety functions. However, it should be noted that the capability for an

~~immediately initiated, manual reactor shutdown would be conservatively mandated irrespective of any other design considerations.~~

The NRC proposes § 53.730(c) to require the submittal of a concept of operations that is of sufficient scope and detail to appropriately inform the staff. The development of a concept of operations can facilitate a clear understanding on the part of the NRC for potential novel operating concepts. Additionally, such information is likely to reduce the degree of resources and interactions needed for the NRC to obtain the understanding necessary to enable flexible requirements in areas such as staffing, operator qualifications, and HFE.

The NRC proposes § 53.730(d) to require the submittal of both a Functional Requirements Analysis and a Function Allocation. The identification of design-specific safety functions and how they are fulfilled serves as a primary means for achieving technology-inclusive requirements within areas such as staffing, operator qualifications, and HFE. The Functional Requirements Analysis and Function Allocation processes (which are both HFE methods derived from systems engineering principles), provide an effective means to identify both how safety functions will be satisfied and how to characterize any associated operator role in doing so. A Functional Requirements Analysis shows what features, systems, and human actions are relied upon to demonstrate safety (i.e., fulfill safety functions). A Function Allocation then describes how safety functions are assigned to both personnel and automatic systems. However, an important adaptation of the Function Allocation for use under the proposed rule would be the further need to not only describe allocations of safety functions to human action and automation, but also to identify allocations made to active safety features, passive safety features, or inherent safety characteristics as well.

Operating experience provides an important source of information by which to inform various aspects of facility design and operations. Accordingly, the NRC proposes in § 53.730(e) to adapt the requirements of § 50.34(f)(3)(i) for requiring an operating experience program.

New technologies may involve concepts of operations that are more conducive to customizable licensed operator staffing requirements than the prescriptive requirements of § 50.54(m). Analyses and assessments that are based on HFE principles provide a performance-based means of determining licensed operator and senior operator staffing needed to support safe operations. In contrast, for those facilities required to be staffed by GLROs, the NRC anticipates that the operator staffing plans will reflect a simpler approach of showing that a continuity of responsibility will be maintained for facility operations throughout the operating phase, with at least one GLRO providing continuous oversight and remaining immediately available when any units are fueled. Additionally, a revised approach to the traditional position of the shift technical advisor that focuses on the availability of engineering expertise as a means of addressing uncertainties and abnormal circumstances is more suitable within the context of part 53 and is intended to be applicable to all facilities, irrespective of other design and staffing considerations. Consistent with this approach, the NRC proposes under § 53.730(f) to require the submittal of a staffing plan that details operations staffing, how engineering expertise will be provided, and what staffing will be available to provide other needed support functions. The NRC intends that this requirement would be associated with staff guidance for reviewing operations staffing plans that is planned to accompany part 53 and that, following NRC approval of the OL or COL, the staffing plan would become a condition of the facility license. The NRC intends that, at a minimum, the approved licensed operator and senior operator (or, if applicable, GLRO) staffing, positions, and

personnel locations will be incorporated into corresponding requirements within the facility TS and that a license amendment would thus be required for any subsequent changes. Operator training and qualification programs provide an essential component of supporting human performance in implementing tasks with safety implications. Such programs must include components that cover the stages of initial training, examination, and continuing training. Additionally, recognizing the potential for varying concepts of operations to affect traditional, prescriptive approaches to operator proficiency, the NRC proposes under part 53 to allow facilities to develop operator proficiency programs based on facility-specific considerations.

Therefore, the NRC proposes in § 53.730(g)(1) to require approval as part of its approval of the OL or COL, of the programs that will be used for the initial training, initial examination, requalification training and examination, and proficiency of both licensed operators and senior operators. In a corresponding manner, the NRC proposes in § 53.730(g)(2) to require approval of the programs that will be used for the GLRO equivalents of each of these programs for facilities with such staffing. The NRC intends that examination program requirements would be associated with staff guidance for the review of tailored examination processes that are planned to accompany part 53. Following the completion of an initial training program, continuing training programs provide an important means of sustaining the knowledge and abilities of individuals. The NRC is proposing to adapt the requirements of § 50.54(i-1) in § 53.730(g)(3) to require that operator continuing training programs be in effect to support operator performance. Under part 53, the NRC proposes to require these programs to be in effect concurrent with when the initial operator examinations first commence, in effect putting the programs in place only when they are needed. This represents a modification of the

comparable requirement of § 50.54(i-1), which links the commencement of these programs to a timeline driven by the licensing of the facility.

The authorization to manipulate controls of the facility that directly affect reactivity or power level is restricted to individuals who are either licensed operators, licensed senior operators, or GLROs. However, for practical purposes, situations in which an individual is participating in an approved training program or reestablishing proficiency may also call for them to operate the controls of the facility under the cognizance of a licensed individual. The NRC is proposing to adapt the requirements of § 55.13 in § 53.735 to accomplish this, with a notable difference being the incorporation of GLROs.

Section 53.740 would provide requirements for ~~facility licensees (i.e.,~~ OL and COL holders~~)~~ under part 53. Portions of § 53.740 would be adapted from the conditions of ~~facility licenses under~~ § 50.54. In general, the conditions for operations staffing under part 53 would reflect considerations for potential technological differences and varying concepts of operation that are expected among part 53 facility licensees. Additionally, certain requirements would be specific to the operating phase while others would remain in effect following the permanent cessation of facility operations during the decommissioning phase.

~~All commercial nuclear plants licensed under part 53 would require some form of licensed operator staffing, whether it be by specifically or generally licensed operators. Consistent with this, the NRC is proposing under § 53.740(a) to require facility licensees to demonstrate compliance with the programmatic requirements for either specifically licensed operators and senior operators or for GLROs, as applicable to the facility.~~

~~The NRC recognizes that technology-inclusive facility staffing will need to account for a potentially wide range of concepts of operations; for this reason, flexible and performance-based approaches for establishing required facility staffing are~~

~~appropriate. However, once the appropriate facility staffing has been determined and approved by the NRC, such staffing must be maintained to ensure that the appropriately qualified individuals will be available when needed to support the safe operation of the facility. Thus, the NRC is proposing under § 53.740(b) to require that the staffing described within the approved facility staffing plan be maintained as a condition of the facility license as opposed to prescriptive staffing requirements like those of § 50.54(k) and (m).~~

Because operation of facility controls directly affects reactivity or power level, only those individuals who possess appropriate levels of qualification and authorization are permitted to operate those controls. The NRC is proposing to adapt the requirements of § 50.54(i) in § 53.740(c) to require that only specifically licensed operators and senior operators or, alternatively, GLROs, may operate facility controls, with allowance for specified exceptions for the purposes of operator training or proficiency.

Senior operators, by virtue of their license level, are qualified and authorized both to perform certain important responsibilities and to direct the licensed activities of licensed operators. Therefore, facilities that are required to be staffed by specifically licensed operators must also include senior operators within their staffing. In contrast, facilities staffed with GLROs only have a single license level available and, therefore, there is no equivalent provision for such facilities. The NRC is proposing to adapt the requirements of § 50.54(l) in § 53.740(d) to require the licensing and designation of senior operators at facilities staffed by specifically licensed operators.

In contrast with control manipulations that directly affect reactor power and reactivity (e.g., control rod movement, control drum rotation, recirculation pump speed adjustment, reactor coolant system boration or dilution, etc.) and are therefore restricted to performance only by licensed operators, other types of plant operations that may

result in reactor power and reactivity changes via means that are indirect in nature (e.g., electrical generation changes, turbine bypass valve operation, steam usage by process heat applications, etc.) may be implemented by non-licensed personnel. However, due to the potential influence of such operations on reactor power and reactivity, the continuous oversight of reactor parameters by a licensed operator is necessary during these ~~conditions~~operations. The NRC is therefore proposing to adapt the requirements of § 50.54(j) in § 53.740(e) to require appropriate oversight of operations, other than those associated with the controls themselves, that may affect reactivity or power level.

~~Load following where plant output automatically changes in response to externally originated instructions or signals is not permitted under the existing regulations of § 50.54. However, new technological considerations and concepts of operation may justify such an operational approach under appropriate circumstances. The NRC recognizes that, beyond electrical power generation, load following may also affect other applications of plant output, such as hydrogen production, desalination, or district heating. For load following to be permissible, measures must be in place to provide assurance that plant output considerations are not permitted to lead to challenges to safe reactor operations. These measures may consist of automated control systems, automatic protective features, or the continuous oversight and immediate intervention capability of an appropriately qualified and authorized individual. Section 53.740(f) would allow for load following, provided that appropriate measures are in place. In considering the acceptability of the measures associated with load following, the NRC expects that any automatic protection relied upon would be separate from that credited for reactor protection purposes and would employ setpoints that are set so as to prevent actuation of the reactor protection system while accomplishing its functions to the extent practical.~~

Section 53.740(f) would allow for load following, provided that appropriate measures are in place.

Core alterations such as refueling are associated with specific considerations that warrant limiting the oversight of such operations to appropriately qualified and authorized individuals. Unlike other types of fuel handling operations, core alterations occur within the confines of a reactor vessel that is specifically designed to support and sustain nuclear criticality, thereby justifying the imposition of higher qualification levels within such contexts. The NRC is proposing to adapt the requirements of § 50.54(m)(2)(iv) in § 53.740(g) to require the supervision of core alterations by either a specifically licensed senior operator, a specifically licensed senior operator whose license is limited to fuel handling, or by a GLRO, as applicable to the facility. Because certain commercial reactor designs may be capable of refueling while at power and, in any event, overall facility oversight would already be required by either a specifically licensed senior operator or by a GLRO, the NRC proposes to omit this requirement as redundant during periods where core alterations occur while the plant is operating.

~~It is impossible to predict every possible scenario that a commercial nuclear plant might potentially encounter. Therefore, it is prudent to grant the authority for appropriately qualified individuals to depart from facility license conditions when emergency circumstances dictate that doing so is in the interest of public health and safety.~~ The NRC is proposing to adapt the requirements of § 50.54(x) and (y) in § 53.740(h) to permit specific individuals to authorize departures from facility license conditions or technical specifications when emergency conditions warrant doing so for the protection of the public health and safety. Recognizing that certain facilities licensed under part 53 may be staffed by GLROs in lieu of specifically licensed senior operators, the NRC proposes to extend this authority to GLROs. While it is not anticipated that

Commented [A21]: Deleted to reflect the view that the general prudential rule would allow an individual to depart from license conditions or technical specifications even in the absence of such an allowance in the regulations formalizing that allowance. That view had been expressed in the preamble for the rulemaking adopting 50.54(x) and (y) and the Commission did not take a position on which view was correct but agreed it was prudent to place the allowance in the regulations.

GLROs will have a role in the fulfillment of safety functions at self-reliant-mitigation facilities and, furthermore, that operators at such facilities would not be in a position by which to significantly influence radiological safety outcomes, the very nature of the § 50.54(x) and (y) and the proposed § 53.740(h) provisions concerns situations that are unanticipated and, therefore, unforeseeable. Thus, it is appropriate to grant GLROs a comparable authority to that of senior licensed operators and certified fuel handlers as it relates to invoking this provision under emergency conditions as a means of accounting for such possibilities.

Due to the unique authorities and responsibilities of both specifically and generally licensed reactor operators, it is essential that any individual fulfilling such a role demonstrate compliance with the regulatory requirements for operator licensing. Section 107 of the AEA authorizes the Commission to prescribe conditions for the licensing of operators and to issue licenses consistent with those conditions. The NRC is proposing to adapt the requirements of § 55.3 in § 53.745 to require that any person performing the function of an operator, senior operator, or GLRO must be authorized by a license issued by the Commission.

The NRC proposes to license individuals as operators under both specific and general licensing frameworks. Specific licenses would be for licensed operators (i.e., reactor operators) and senior operators (i.e., senior reactor operators) and would be issued to a named person upon approval by the Commission of an application for that named person. In contrast, GLROs would perform duties under the provisions of a general license that would be effective without the filing of an application with the Commission or the issuance of licensing documents to a particular person. The NRC proposes requirements for the use of the specific licensing process in part 55 for

licensed operators and senior operators under §§ 53.760 through 53.78095, with § 53.760 addressing applicability.

~~Medical fitness is an important component of the overall process of specifically licensing operators because it provides assurance that operators will be able to carry out important duties without being precluded from doing so by health-related issues. Medical fitness also provides assurance that such issues will not adversely affect the performance of assigned job duties or cause operational errors that endanger public health and safety. In addition to a requirement for medical fitness, a medical examination by a physician to confirm compliance with this requirement is necessary. The NRC is proposing to adapt the requirements of §§ 55.21, 55.23, and 55.27 under § 53.765 to require medical fitness, examinations by physicians, and medical certification for specifically licensed operators and senior operators. In recognition of the fact that GLROs are not expected to have a role in the fulfillment of safety functions at the facilities at which they are licensed, the NRC proposes to not extend a comparable medical requirement to GLROs.~~

~~The NRC is also proposing to adapt the requirements of §§ 55.25 and 50.74(c) in § 53.770 to require that timely notifications be made to the NRC if a specifically licensed operator or senior operator develops a permanent physical or mental condition that adversely affects the performance of assigned operator job duties or could cause operational errors endangering public health and safety. Notwithstanding this requirement related to permanent medical conditions, the NRC continues to recognize that it is appropriate for facility licenses to impose administrative restrictions and conditions upon specifically licensed operators and senior operators in response to temporary medical conditions.~~

~~The process of specifically licensing individuals as licensed operators or senior operators requires the submittal of applications to the NRC for review. These applications must detail certain elements associated with licensing, including the demonstration of compliance with examination, experience, and medical requirements. The NRC is proposing to adapt the requirements of §§ 55.31 through 55.35 in § 53.775 to include requirements for the applications associated with the specific licensing of licensed operators and senior operators at commercial nuclear plants licensed under part 53. In contrast with the part 55 requirements, the NRC proposes to provide additional flexibility by locating certain details associated with the preparation and submittal of these applications within guidance in lieu of placement within this proposed rule itself.~~

The NRC proposes overall programmatic requirements for specifically licensed operator and senior operator training, examination, and proficiency in § 53.780. In general, the proposed requirements are adapted from those in part 55, with several additional flexibilities being incorporated to better account for potential variations in reactor technologies and concepts of operations. The requirements proposed in § 53.780 cover, in part, the initial training, initial examination, requalification training, requalification examination, and proficiency of specifically licensed operators and senior operators.

The initial training process provides individuals with the knowledge and abilities needed to subsequently fulfill assigned duties as licensed operators or senior operators in a safe and reliable manner. The use of a systems approach to training (SAT) ensures that the training program is based upon job requirements in a manner that can be adapted to account for differences in plant technology, concepts of operations, and operator roles in the fulfillment of design-specific safety functions. The NRC is proposing

under § 53.780(a) to require facility licensees to implement a SAT-based training program for the initial training of licensed operator and senior operator applicants. The program must be adequate to ensure that applicants will be capable of performing the duties necessary both to protect public health and safety and to maintain plant safety functions. The NRC further proposes that such programs be subject to NRC approval and subsequent change control processes of an appropriate nature.

Examinations provide a means of assessing that individuals have achieved a degree of knowledge and ability that is sufficient to carry out assigned duties as licensed operators or senior operators in a manner that is safe and reliable. The NRC is proposing to adapt the requirements of §§ 55.40, 55.41, 55.43, and 55.45 in § 53.780(b) to require that facilities establish and implement an initial examination program. However, a key difference from the comparable requirements of part 55 would be that facilities have the flexibility to propose, subject to NRC approval, the examination methods and criteria to be used in assessing satisfactory applicant performance. Such examination programs (including those used within the scope of requalification training) would need to provide for acceptable levels of both test validity and test reliability in order to be considered acceptable. The NRC intends that staff guidance would be available to facilitate the review of licensing examination programs that are proposed by facility licensees and that, following NRC approval, initial examination programs would be subject to an appropriate change control process. Furthermore, the NRC proposes that ~~facility~~ holders of licensee~~s~~s to operate commercial nuclear plants under part 53 be provided the alternative of administering their own approved licensing examinations. The NRC would continue to exercise appropriate oversight of the program, make operator licensing decisions based upon the examination results, and reserve the right to administer the examinations in lieu of permitting the facility to do so. However,

irrespective of the provided flexibilities in examination format and structure, at a minimum, topics from the following general categories of knowledge and abilities should be sampled in such examinations:

- Reactor Theory, Thermodynamics, and Chemical Interactions
- Plant Systems and Components
- Reactivity Management and Manipulations
- Radiation Control and Safety
- Emergency, Abnormal, and Normal Operations
- Administrative Requirements and Conditions of the Facility License

Requalification training programs provide for the continuing training and examination of specifically licensed operators and senior operators to ensure that they maintain the knowledge and abilities needed to support the safe and reliable performance of job duties following the completion of an initial training and examination program. The NRC is proposing to adapt the requirements of § 55.59 in § 53.780(c) to require that facilities implement both a SAT-based requalification training program and a biennial requalification examination program. However, a notable difference from the biennial requalification examinations required under part 55 would be that distinct annual operating test and biennial written examination components would not be mandated, with the facility licensee instead proposing the examination methods and criteria to be used in assessing satisfactory performance. The NRC intends that guidance would be available to facilitate the review of the requalification examination programs that are proposed by facility licensees and that, following NRC approval, requalification examination programs would be subject to an appropriate change control process.

For examinations to provide for valid assessments of the knowledge and abilities of individuals, the examinations must remain free from compromises that could affect

their underlying integrity. The NRC is proposing to adapt the requirements of § 55.49 in § 53.780(d) to require that examinations and related activities remain free from any compromise that might affect the integrity of the examination process.

Simulators provide a valuable means of training and evaluating plant operators, and the NRC is specifically authorized under the Nuclear Waste Policy Act of 1982, as amended (NWPA), section 306 (42 U.S.C. 10226) to establish regulations for the use of simulators within such context. The NRC is proposing to adapt the requirements of § 55.46 in § 53.780(e) to address the use of simulation facilities for training, examinations, and applicant experience requirements, as well as to address the maintenance of simulator fidelity. However, the proposed requirements of part 53 would not mandate that full scope, plant-referenced simulators be used and would allow the use of alternative simulation facilities consisting of, for example, partial scope simulators or the plant itself, provided that all associated requirements can be demonstrated to be met using alternative approaches and methods. Additionally, in allowing for the possibility that an applicant or licensee might demonstrate compliance with training, examination, or experience requirements using the plant itself, the NRC is not allowing the initiation of transients on the actual plant. Consistent with this, aside from controlled reactivity manipulations that are conducted for the purposes of demonstrating compliance with experience requirements, actual plant components may not be operated for these purposes. Rather, the NRC perspective is that the use of the plant for training and examination purposes should be restricted to techniques such as walkthroughs, job performance measures, simulated tasks, use of augmented reality technology, and similar approaches that provide training and examination value while avoiding the operation of actual plant components.

There may be situations in which applicants for operator or senior operator licenses have previous training and experience that justifies waiving some, or all, of the initial examination requirements. The NRC is proposing to adapt the requirements of § 55.47 in § 53.780(f) to allow for consideration of requests for waivers of examinations requirements. In contrast with the part 55 requirements, the NRC proposes to locate certain details associated with such waiver requests within guidance documentation in lieu of placement within the rule itself.

For licensed operators and senior operators to perform their assigned duties safely and reliably, it is essential that they perform those duties frequently enough so as to maintain a sufficient degree of proficiency. The NRC is proposing to adapt the requirements of § 55.53(e) and (f) in § 53.780(g) to require that specifically licensed operators and senior operators maintain proficiency and, if proficiency is not maintained, regain proficiency prior to resuming licensed duties. However, in recognition of the fact that varying concepts of operations are possible for advanced reactor facilities, the NRC is proposing, in contrast with the requirements of part 55, to allow facility licensees to establish their own programs for operator proficiency, subject to NRC approval.

~~As the holders of specific licenses, licensed operators and senior operators must be subject to license conditions on an individual basis to ensure that the basis upon which the licenses were issued remains valid. The NRC is proposing to adapt the requirements of § 55.53 in § 53.785 to require appropriate conditions of licenses for specifically licensed operators and senior operators. However, in contrast with the requirements of § 55.53(e) and (f), the NRC is proposing to allow certain aspects of operator proficiency to be addressed by an NRC-approved facility proficiency program.~~

~~Licenses for specifically licensed operators and senior operators are issued by the NRC and must remain subject to modification or revocation. The NRC is proposing~~

~~to adapt the requirements of §§ 55.51 and 55.61 in § 53.790 to address the issuance, modification, and revocation of licenses issued to specifically licensed operators and senior operators.~~

The licenses issued to specifically licensed operators and senior operators are valid for a period of six years, after which they expire, unless otherwise renewed. The NRC is proposing to adapt the requirements of §§ 55.55 and 55.57 in § 53.795 to address the expiration and renewal of licenses issued to specifically licensed operators and senior operators.

In developing this proposed rule, the NRC has discussed with stakeholders the considerations that might justify the omission of the specifically licensed operators and senior operators. However, even for an inherently safe reactor with autonomous operation features, certain important administrative functions (e.g., compliance with TS, operability determinations, NRC notifications, emergency declarations, risk assessment, maintenance oversight, and radiological release limit compliance) would still need to be accomplished by appropriately qualified and authorized individuals. Additionally, the NRC ~~further~~ recognized that manual manipulations of facility reactivity controls must only be performed by individuals who have been appropriately licensed by the Commission. The NRC therefore proposes under § 53.800 to establish a new class of facility (defined as a self-reliant-mitigation facility)~~, according to~~and the criteria ~~contained in § 53.800 for Frameworks A and B~~for classification of such a commercial nuclear plant. These facilities would employ GLROs ~~in lieu of~~rather than specifically licensed operators and senior operators. The GLRO regulations offer enhanced flexibilities and targeted relaxations in a manner that is commensurate with the modified role of such operators to ensure the safe operation of the associated facilities. In contrast, those ~~facilities~~ commercial nuclear plants not meeting the criteria of § 53.800 would instead be

considered interaction-dependent-mitigation facilities and would require staffing by specifically licensed operators and senior operators. The terminology used to designate these facility types reflects differences in how operators are anticipated to need to interact with their plant systems in mitigating events and achieving safe outcomes; such systems may either need operators to interact with them in some manner (i.e., be interaction-dependent) or may instead be able to rely fully upon their own capabilities independent of operator interaction (i.e., be self-reliant).

Generally licensed reactor operators would differ from specifically licensed operators because the latter would be directly and independently evaluated by the NRC as part of their licensing process. This direct and independent evaluation remains appropriate when operators may reasonably be expected to exert a significant influence on public health and safety outcomes. Therefore, a key determinant as to whether generally licensed reactor operators can be utilized in facility staffing is the assessment of the operator's role in maintaining and fulfilling safety functions at the facility, such as through the performance of credited actions for the mitigation of plant events.

The criteria proposed in § 53.800 would designate self-reliant-mitigation facilities. These criteria are structured to address facilities under ~~both Framework A and B (including those Framework B facilities employing an AERI approach)~~part 53 and are derived from a common set of considerations:

- no human action needed to satisfy radiological consequence criteria;
- no human action needed to address LBEs;
- safety functions not allocated to human action;
- reliance upon robust and highly reliable safety features; and
- adequate defense in depth achieved without reliance on human action.

It should be noted that those facilities not meeting the criteria proposed in § 53.800 would instead be classified as interaction-dependent-mitigation facilities and would require staffing by specifically licensed operators and senior operators instead.

GLROs would perform duties under the provisions of a general license that would be effective without the filing of an application with the Commission or the issuance of licensing documents to a particular person. The NRC proposes requirements for the general licensing process for GLROs under §§ 53.805 through 53.820. The requirements for GLROs would parallel those for senior operators in regard to their comparable administrative responsibilities. Nonetheless, the requirements for GLROs would be relaxed and incorporate greater flexibilities compared to the requirements for specifically licensed operators in a manner that is consistent with the GLRO's role in safety at self-reliant-mitigation facilities.

~~In order to use GLROs in lieu of specifically licensed operators and senior operators, a OL/COL applicant would need to demonstrate that its proposed facility is a self-reliant-mitigation facility, i.e., that it will comply with the following requirements on an ongoing basis:~~Section 53.785 would require that the holder of a license to operate a commercial nuclear plant that is a self-reliant mitigation facility under part 53 to maintain~~ing~~ GLRO qualifications for the performance of important functions and tasks; ~~incorporating relevant programmatic controls into TS;~~ to administer~~ing~~ the related programs for training, examination, and proficiency; and to ensur~~e~~ing that the relevant provisions of parts 26 and 73 are met. Additionally, to provide for an accurate accounting of what individuals are licensed under the general license, facility licensees would be required to report the identities of all generally licensed reactor operators to the NRC on an annual basis. Furthermore, a facility licensee must ensure that the facility design and performance continue to meet the technological criteria to be classified as a self-reliant-

mitigation facility (i.e., the criteria of § 53.800) on a continual basis during the operating phase, as the relaxations afforded to such facilities in the areas of operator licensing, staffing, and HFE would be predicated on this assumption. ~~The NRC therefore proposes under § 53.805 to establish requirements for facility licensees that address issues such as these. Finally, t~~The failure of a self-reliant-mitigation facility to subsequently meet the criteria of § 53.800 after the issuance of an OL or COL would constitute a reportable event (i.e., an unanalyzed condition that significantly degrades plant safety) under the provisions of § 53.1630~~ or § 53.6330~~.

The NRC proposes the general license for GLROs under § 53.810. GLROs would be licensed as a class of individuals under the provision of § 53.810(a) and would be subject to the conditions specified in § 53.810(b) through (g). Portions of these conditions are adapted from § 55.53 and from those conditions currently included in the licenses issued to specifically licensed operators and senior operators. The NRC would retain the ability to suspend or prohibit individuals from operating under the general license should such action be warranted.

The NRC proposes overall programmatic requirements for GLRO training, examination, and proficiency under § 53.815. In general, these proposed requirements are adapted from those of part 55 and parallel those also proposed for specifically licensed senior operators in § 53.780. These requirements include increased flexibilities and several targeted relaxations that reflect the limited role of GLROs in facility safety. The requirements proposed under § 53.815 cover, in part, the initial training, initial examination, continuing training, requalification examination, and proficiency of GLROs. Section 53.805 would require the facility licensee to develop, implement, and maintain these programs. Section 53.810, in turn, would prescribe that the requirements of § 53.805 would need to be met as a requirement of the general license. The implication

of this structure is that the facility licensee would need to implement these programs for training, examination, and proficiency, and GLROs would need to participate in these programs to demonstrate compliance with the requirements of the general license.

The initial training process provides GLROs with the knowledge and abilities needed to fulfill assigned duties as GLROs. The use of a SAT serves to ensure that the training program is based upon job requirements in a manner that can be adapted to account for differences in plant technology and concepts of operations. The NRC is proposing under § 53.815(b) to require facility licensees to implement a SAT-based training program for the initial training of GLROs that is adequate to ensure that they have the necessary knowledge, skills, and abilities to perform their duties. The NRC further proposes that such programs would be subject to NRC approval, oversight, and appropriate change control processes. The training program must ensure that GLROs maintain the necessary knowledge, skills, and abilities.

Examinations provide a means of assessing that individuals have achieved a degree of knowledge and ability that will be sufficient to enable them to carry out assigned duties as GLROs in a manner that is both safe and reliable. The NRC proposes to adapt the requirements of §§ 55.40, 55.41, 55.43, and 55.45 in § 53.815(b) to require that facility licensees establish and implement an initial examination program. A key difference from the comparable requirements of part 55 would be that facility licensees would be afforded the flexibility to propose, subject to NRC approval, the examination methods and criteria to be used in assessing satisfactory individual performance. Such examination programs (including those used within the scope of continuing training) would need to provide for acceptable levels of both test validity and test reliability in order to be considered acceptable. The NRC intends that staff guidance would be available to facilitate the review of initial examination programs that are

proposed by facility licensees and that approved initial examination programs would be subject to an appropriate change control process. In contrast with both the requirements of part 55 and the proposed requirements of § 53.780, the NRC does not intend to administer or evaluate these initial examinations. However, the examination processes themselves will continue to be subject to ongoing NRC oversight. Irrespective of the provided flexibilities in examination format and structure, topics from the following general categories of knowledge and abilities should be sampled in such examinations:

- Reactor Theory, Thermodynamics, and Chemical Interactions
- Plant Systems and Components
- Reactivity Management and Manipulations
- Radiation Control and Safety
- Emergency, Abnormal, and Normal Operations
- Administrative Requirements and Conditions of the Facility License

Continuing training programs provide the ongoing training and examination of GLROs to ensure that they maintain the knowledge and abilities needed to support the safe and reliable performance of job duties following the completion of an initial training and examination program. The NRC is proposing to adapt the requirements of § 55.59 in § 53.815(b) to require that facility licensees implement both a SAT-based continuing training program and a requalification examination program. However, a notable difference from the examinations required under part 55 would be that distinct annual operating test and biennial written examination components would not be mandated. The facility licensee would instead propose examination methods and criteria to be used in assessing satisfactory performance. Furthermore, unlike the comparable requirements of part 55 and those proposed for specifically licensed operators and senior operators, a biennial periodicity for requalification examinations would not be prescribed. However,

adequate justification for the proposed periodicity of requalification examinations would be required. The NRC intends that staff guidance would be available to facilitate the review of the requalification examination programs that are proposed by facility licensees. Approved requalification examination programs would be subject to an appropriate change control process.

For examinations to provide for valid assessments of the knowledge and abilities of individuals, the examinations must remain free from compromises that could affect their underlying integrity. The NRC is proposing to adapt the requirements of § 55.49 in § 53.815(d) to require that examinations and related activities remain free from any compromise that might affect the integrity of the examination process.

Simulators provide a valuable means of training and evaluating plant operators and the NRC is specifically authorized under the NWPA, section 306 (42 U.S.C. 10226) to establish regulations for the use of simulators within such context. The NRC is proposing to adapt the requirements of § 55.46 in § 53.815(e) to address the use of simulation facilities for training and examinations, and experience requirements, as well as to address the maintenance of simulator fidelity. The use of full scope, plant-referenced simulators would not be mandated. The potential use of alternative simulation facilities consisting of, for example, partial scope simulators or the plant itself, would be allowed provided that all associated requirements could be demonstrated to be met using alternative approaches and methods. Additionally, in allowing for the possibility that an applicant or licensee might demonstrate compliance with training and examination requirements using the plant itself, the NRC is not allowing the initiation of transients on the actual plant. Consistent with this, aside from controlled reactivity manipulations that are conducted for the purposes of demonstrating compliance with experience requirements, actual plant components may not be operated for these

purposes. Rather, the use of the plant for training and examination purposes should be restricted to techniques such as walkthroughs, job performance measures, simulated tasks, use of augmented reality technology, and similar approaches that provide training and examination value while avoiding the operation of actual plant components.

There may be situations in which GLROs have previous training and experience that justifies waiving some, or all, of the initial examination. Therefore, the NRC is proposing under § 53.815(f) to allow facility licensees to waive some, or all, portions of initial examinations provided that such waivers are consistent with a program that has been approved by the NRC.

For GLROs to safely and reliably perform their assigned duties, it is essential that they perform those duties frequently enough so as to maintain a sufficient degree of proficiency. However, the NRC recognizes that facilities that utilize GLROs may have concepts of operation that warrant unique proficiency considerations. Therefore, the NRC is proposing in § 53.815(g) to require that facility licensees develop, implement, and maintain programs to maintain and reestablish, if needed, the proficiency of GLROs. This could occur, for example, if an individual's extended absence from watch standing has rendered proficiency requirements unmet.

The general license should remain in effect for an individual only while that individual remains employed in a position that may call for the individual to manipulate the reactivity controls of the facility. The NRC proposes under § 53.820 to require that the general license would cease to be applicable on an individual basis when an individual's employment status becomes such that this is no longer the case. However, the NRC recognizes that for some types of self-reliant-mitigation facilities, very long periods may elapse between circumstances that necessitate manual manipulation of reactivity controls. Therefore, the general license remains in effect for an individual as

long as the individual's current position could potentially require that individual to manipulate reactivity controls at some point within the course of the individual's assigned job duties.

The NWPA, section 306 (42 U.S.C. 10226) authorizes and directs the NRC to, in part, issue regulations and guidance that address the training and qualifications of civilian nuclear power plant operators, supervisors, technicians, and other appropriate operating personnel. The NRC implements this in part 50 through the requirements of § 50.120, "Training and qualification of nuclear power plant personnel." The NRC is proposing under § 53.830 to adapt, with modifications, the requirements of § 50.120 for use in part 53 to provide more flexible personnel training and qualification requirements than those in § 50.120 [or part 50] and better reflect diverse concepts of operations.

The NRC recognizes that the categories of nuclear power plant personnel in § 50.120 may not be needed for the diverse concepts of operations, staffing models, and non-traditional personnel roles and responsibilities anticipated under proposed part 53; conversely, and for the same reasons, additional categories of plant personnel may need to be covered by part 53. The NRC also recognizes that the timeframe prescribed in § 50.120 for the establishment of training programs may not be aligned with the schedules associated with the startup of certain types of commercial nuclear plant facilities. However, the NRC also recognizes that the SAT-based training required under § 50.120 remains an appropriate means by which training programs should continue to be developed and implemented. Thus, the approach taken by the NRC in addressing the training of certain plant staff under the proposed part 53 reflects greater flexibilities in personnel categories and programmatic timeframes, while still retaining the requirement that such training programs be based on SAT.

The NRC is proposing under § 53.830 to require SAT-based training programs with the timeframe for when such programs are required being based upon when the associated personnel are needed to support facility-specific needs. The training programs would cover the training and qualification of plant personnel in the general categories of supervisors, technicians, and other appropriate operating personnel. The licensee would not be required to seek NRC approval of a training program prior to usage. However, the licensee is required to accommodate NRC inspection of the training program. The NRC intends to develop guidance to facilitate the inspection of these training programs but does not intend for such guidance to preclude the potential for the training programs to be maintained by a separate, NRC-approved accreditation process.

~~While similar, the requirements for programs are provided separately in subpart F for Framework A and in subpart P for Framework B. For Framework A, p~~Proposed § 53.845 would require programs to be developed, implemented, and maintained to help ensure that design features and human actions have the capabilities and reliabilities necessary to demonstrate compliance with the safety criteria in subpart B throughout the operating life of each commercial nuclear plant. The proposed programmatic requirements in subpart F would also address areas such as radiation protection needed to control routine effluents during normal operations. The proposed §§ 53.850 through 53.88~~91~~0 would require programs to support specific activities needed to ensure the prevention or mitigation of unplanned events or to support normal operations for any reactor design. However, each holder of an OL or COL would be required to assess whether additional programs are needed for the specific reactor design and location of the commercial nuclear plant. Licensees would be able to combine, separate, and

otherwise organize programs and related documents as appropriate for the technologies and organizations associated with the commercial nuclear plant.

Proposed § 53.850 would require a radiation protection program associated with the requirements in subparts B and C for public doses resulting from normal operations and the protection of plant workers. The proposed requirements related to doses from normal operations, including routine effluents, would be similar to those specified in § 50.36a, “Technical specifications on effluents from nuclear power reactors,” and related requirements in standard TS for offsite dose calculation manuals. While the proposed section would include requirements that are technically and programmatically similar to part 50, proposed § 53.850 would not include a requirement for effluent-related TS as is required in § 50.36a. A proposed requirement similar to that found in the administrative controls section of TS for operating reactors licensed under parts 50 and 52 would be included for programmatic controls of solid wastes to complement the design requirements in proposed § 53.425.

Proposed § 53.855 would require an emergency response plan that demonstrates compliance with the requirements in appendix E to part 50 and § 50.47. The regulations in § 50.47 state that the NRC will not issue certain licenses unless it finds that there is reasonable assurance that adequate protective measures can and will be taken to protect public health and safety in the event of a radiological emergency. The proposed § 53.855 also relates to an ongoing rulemaking activity that would provide alternatives to certain elements of the existing regulations. The draft final rule is described in SECY-22-0001, “Final Rule: Emergency Preparedness for Small Modular Reactors and Other New Technologies,” dated January 3, 2022. If the NRC proceeds with revising its regulations as described in SECY-22-0001, the same flexibility in

determining appropriate emergency preparedness measures, as directed by the Commission, would be added to part 53.

In its 2008 Advanced Reactor Policy Statement, the Commission stated their expectation that “the safety features of advanced reactor designs will be complemented by the operational program for Emergency Planning (EP). This EP operational program, in turn, must be demonstrated by inspections, tests, analyses, and acceptance criteria to ensure effective implementation of established measures.” Consistent with this policy statement, emergency plans are not used to demonstrate compliance with the safety criteria in subpart B but complement safety features in the design. In SECY-97-020, “Results of Evaluation of Emergency Planning for Evolutionary and Advanced Reactors,” dated January 27, 1997, the staff indicated that the rationale upon which EP for current reactor designs is based, that is, potential consequences from a spectrum of accidents, is appropriate for use as the basis for EP for evolutionary and passive advanced LWR designs and is consistent with the Commission's defense-in-depth safety philosophy. Also, in its Safety Goals Policy Statement the Commission stated that: “A defense-in-depth approach has been mandated in order to prevent accidents from happening and to mitigate their consequences. Siting in less populated areas is emphasized. Furthermore, emergency response capabilities are mandated to provide additional defense-in-depth protection to the surrounding population.” Consistent with this policy statement, proposed § 53.855 contributes an additional independent layer of defense in depth for commercial nuclear plants.

Proposed § 53.860 would identify the applicable regulations for part 53 applicants under ~~Framework A~~part 53 related to the programs for physical security, cyber security, FFD, AA and information security. These programs are discussed in

more detail in section V~~I~~, “Changes to Other Parts of 10 CFR Chapter I,” of this document.

Proposed § 53.860(a) would establish the physical protection program and present a graded approach to physical protection requirements. If a licensee can ~~demonstrate compliance with~~meet the proposed criterion in § 53.860(a)(2)~~(i)~~, then the requirement for a physical protection program to protect against the design-basis threat (DBT) of radiological sabotage would not be applicable because the need for such a program would be addressed by design and engineered safety features under § 53.440(f). The ~~o demonstrate compliance with the~~ criterion in § 53.860(a)(2)~~(i),~~ would require a licensee to~~must~~ show that potential consequences resulting from a DBT initiated event would result in offsite doses below the values in § 53.210 even if licensee mitigation and recovery actions, including any operator action, are unavailable or ineffective. Where the criterion is met, the resulting physical protection requirements would be those for protection of SNM and Category 1 and Category 2 radioactive material, if applicable. This proposal would apply a new regulatory approach for certain commercial nuclear plants in which the DBT of radiological sabotage would not be applicable.

For those licensees able to ~~demonstrate compliance with~~meet the criterion in § 53.860(a)(2)~~(i)~~, the NRC would not conduct Force-On-Force (FOF) exercise inspections. Section 170D.a of the AEA permits the Commission to determine which licensed facilities are part of a class of licensed facilities where NRC-conducted FOF exercises are appropriate to assess the ability of a private security force of a licensed facility to defend against any applicable DBT. For the class of licensees that ~~comply with~~ meet the criterion of § 53.860(a)(2)~~(i)~~, it would not be appropriate to conduct FOF exercises to evaluate performance at commercial nuclear plants where the DBT of

radiological sabotage is not applicable and the facility poses a lower risk to public health and safety from potential radiation exposure. These facilities would still have tailored security requirements and oversight consistent with their relatively low risk.

For those licensees not able to ~~satisfy~~ meet the criterion in § 53.860(a)(2)~~(i)~~, proposed § 53.860(a) would permit the licensee to choose one of two paths to provide physical protection: (1) the current set of requirements in § 73.55, which would include any changes resulting from the ongoing proposed rulemaking on Alternative Physical Security Requirements for Advanced Reactors[2] that provides pre-determined physical security alternatives; or (2) the performance-based requirements in proposed § 73.100. In either case, the licensee would be subject to NRC-conducted FOF inspections.

Proposed § 53.860(b) would require licensees to establish, implement, and maintain an FFD program under~~in accordance with~~ part 26. Section 53.860(c) would require licensees to establish, implement, and maintain an AA program in accordance with either § 73.56 or proposed § 73.120, as appropriate. Section 53.860(d) would require licensees to establish, implement, and maintain a cyber security program in accordance with either § 73.54 or proposed § 73.110. Section 53.860(e) would require licensees to establish, implement, and maintain an information protection system that complies with the requirements of §§ 73.21, 73.22, and 73.23, as applicable.

Proposed § 53.865 would establish requirements for quality assurance ~~and refer to proposed subpart K for the part 53 requirements for SR design features. The proposed requirement for a quality assurance program would be similar to regulations in parts 50 and 52.~~using appendix B to part 50. Proposed requirements related to

[2] SECY-22-0072, "Proposed Rule: Alternative Physical Security Requirements for Advanced Reactors," dated August 2, 2022.

evaluating and reporting changes to the quality assurance program would be included in proposed subpart I and would be equivalent to those found in § 50.54.

~~The proposed § 53.870 would require licensees to actively assess possible degradation of SSCs from the effects of aging, fatigue, and environmental conditions. The proposed inclusion of requirements related to designing and monitoring for possible degradation mechanisms reflects important lessons learned from the history of LWRs and the likely introduction of new design features and materials in future commercial nuclear plants. The allowable combinations of design features, operating experience, testing, and monitoring during operations would support performance-based approaches to the initial licensing of new technologies. The proposed performance-based approach to integrity assessment programs would also allow for the subsequent consideration of operating experience and appropriate corrective actions or allowable relaxations for ensuring that design features comply with the proposed functional design criteria of §§ 53.410 and 53.420. The proposed program would be based upon a comprehensive and integrated evaluation of the aging and other degradation mechanisms applicable to the design; identification of the affected SSCs; the allowances provided in the design of the SSCs for degradation; and schedules and procedures for determining if and at what rate degradation is occurring, as well as its cause. Risk insights could be used to prioritize the monitoring, evaluation, and management of degradation based upon the importance of the SSC to safety and the time frame for when the effects of degradation could be of concern.~~

Proposed § 53.875 would establish requirements for a fire protection program supporting operations similar to § 50.48. The proposed fire protection program during operations would work in concert with specific fire protection requirements proposed in

subpart C for design and analyses and in proposed subpart E for construction and manufacturing.

Proposed § 53.880 would establish requirements for an inservice inspection (ISI) and inservice testing (IST) program, which are historically important activities conducted in accordance with ASME codes and regulations in § 50.55a. While the proposed part 53 would not incorporate specific consensus codes and standards into the regulations, § 53.880 allows for the use of generally accepted codes and standards. The proposed requirement for an ISI and IST program would reinforce the need to develop monitoring programs to be conducted during a plant's operations phase to complement the design process and address inherent uncertainties. The NRC encourages the continued use of consensus codes and standards supporting design, testing, and inspections to support integrated and performance-based approaches in demonstrating compliance with the proposed requirements in part 53.

~~Proposed § 53.890 would establish requirements for facility safety programs (FSPs). FSPs would complement proposed requirements in subpart C that call for using and periodically updating PRAs. FSPs would also complement other requirements within proposed Framework A related to configuration control and maintaining the capabilities and reliabilities of SSCs and programmatic controls consistent with underlying analyses. The proposed use of the PRA as a major part of the design and licensing of commercial nuclear plants under Framework A would also allow for its continued use during operations for evaluating changes, managing risks, and improving the relationship between the NRC's licensing and reactor oversight programs. The proposed requirements to periodically update the PRA and to address the possible differences between the inputs to and modeling reflected in the analyses and the performance history of SSCs would be a significant change from the relatively static analyses and~~

prescriptive compliance verifications that are used in many of the requirements in parts 50 and 52.

The FSP concept is being proposed, in part, to address the ability to periodically assess possible risk reduction measures considering technology changes, economic costs, operating experience, and new or revised hazard information and the associated advantages of such an assessment. Various other sections within proposed Framework A would address the need to manage the risk profile of each commercial nuclear plant in a way that complies with the regulations and ensures consistency with the analyses performed in accordance with proposed subpart C. The proposed requirements for an FSP would supplement licensees' actions to maintain the SSCs, personnel, and programmatic controls consistent with the plant design and environs as understood at the time of initial licensing.

The FSP would contribute to the management of risks posed by commercial nuclear plants by providing periodic assessments of subjects such as potential updated information on external hazards and consideration of whether cost effective risk reduction measures might be warranted. The FSP proposal for Framework A was adapted from similar programs in NRC regulations such as § 70.62, "Safety program and integrated safety analysis," and regulations issued by other Federal agencies such as the DOE, U.S. Department of Transportation (DOT), and EPA. Similar to these existing examples, the proposed FSP requirements for Framework A are intended to provide a flexible, performance-based approach to address possible changes in various factors contributing to the risks posed by commercial nuclear plants. When fully considered as part of an overall regulatory regime, the FSP could enable an optimization of NRC oversight programs and more focused operating experience and hazard assessment

programs and could contribute to addressing uncertainties associated with both design features and site characteristics during initial licensing.

While the FSP may require additional effort from licensees, it would also provide more flexibility in addressing changes to a facility's risk profile than the current process. For example, an FSP could increase flexibility during initial licensing or NRC review of generic issues by providing assurance that new information and, when appropriate, possible risk reduction measures are being routinely assessed throughout the operating life of each commercial nuclear plant. The NRC has posed a question in section VII, "Specific Requests for Comments," of this document that asks about how the FSP could contribute to a more integrated regulatory approach and whether a similar requirement should be included in Framework B.

Proposed § 53.890 would provide criteria for considering risk reduction measures when performing the proposed periodic assessments. The proposal would provide screening criterion for considering risk reduction, below which no cost-benefit-type analysis would be required by the licensee. The actual decision on whether to implement a change will include an assessment of costs and other factors. Guidance would be prepared to define appropriate factors and would consider existing guidance used by the NRC in setting an acceptance criterion based on a dollars per person-rem factor, guidance covering regulatory analysis, and guidance used by applicants and licensees when evaluating severe accident mitigation alternatives as required by 10 CFR part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." The goal for establishing criteria for considering risk reduction measures would be that they would be low enough to initiate the process when appropriate but not so low as to initiate unnecessary analyses. The proposed use of person-rem values as part of the criteria would support these types of cost-benefit assessments and would

also introduce the consideration of broader societal impacts (e.g., population dose) than is provided for by only the calculation of doses to hypothetical individuals as is done in the analyses required by proposed subpart C.

The remaining portions of proposed § 53.890 would provide the requirements to develop, implement, and maintain the FSP by developing an FSP plan. The FSP plan would be used to document the details of how assessments are performed; the licensee's overall safety philosophy and safety culture as discussed in the Commission's policy statement, "Final Safety Culture Policy Statement," dated June 14, 2011; the required participants and training; and the periodic reviews of the effectiveness of the FSP. The NRC would review the FSP plan as part of licensing reviews for OLs or COLs. Updates and revisions to the FSP plan would be required to be submitted at least every 24 months and would be subject to NRC review and approval if a proposed change to the FSP plan could not be implemented without an exemption from the requirements of § 53.890.

Proposed § 53.910 would establish requirements for developing, implementing, and maintaining procedures (e.g., operations and emergency operating procedures) and guidelines (e.g., accident management guidelines). The programmatic requirements for many of the procedures listed in this proposed section would be similar to the requirements found in the administrative controls section of TS for plants licensed under parts 50 and 52. The proposed inclusion, where appropriate, of accident management guidelines in these requirements is intended to ensure that an integrated set of procedures and guidelines would be established by licensees to ensure command and control across the spectrum of possible event sequences. The proposed required procedures would also include those needed to complement the design requirements in

~~proposed § 53.440(m) related to criticality alarms and the equivalent of the procedures required in § 50.54(hh) to address notifications of potential aircraft threats.~~

Subpart G – Decommissioning Requirements

The proposed subpart~~s~~ G ~~and Q in Frameworks A and B, respectively,~~ would provide the regulatory requirements for the decommissioning phase of the life cycle of a commercial nuclear plant. ~~The only variations between proposed subpart G in Framework A and proposed subpart Q in Framework B are the references to various sections throughout part 53 (i.e., inter- and intra-subpart references in proposed subpart Q are made to the analogous sections in Framework B).~~ The requirements being proposed ~~in subparts G and Q for the decommissioning of a commercial nuclear plant~~ are ad~~a~~opted from the current regulations in § 50.75, "Reporting and recordkeeping for decommissioning planning," § 50.82, "Termination of license," and § 50.83, "Release of part of a power reactor facility or site for unrestricted use." Although the requirements from those sections of part 50 have been copied into proposed subpart~~s~~ G ~~and Q~~ with relatively few changes, the requirements are reorganized to fit within the part 53 structure. The few changes made were primarily to make the proposed requirements more technology-~~-~~inclusive by adding alternatives within sections, whereas some requirements in part 50 were developed specifically for LWRs.

As an example, § 50.75 provides minimum amounts of decommissioning funds required to demonstrate reasonable assurance of funds for decommissioning LWRs. Such generic amounts have not been developed for all reactor technologies that may be licensed under part 53. Therefore, the Commission proposes in § 53.1020, "Cost estimates for decommissioning," that site-specific cost estimates for decommissioning must be developed considering costs in such areas as engineering, labor, and waste disposal. The derivation of the generic cost estimates for LWRs in § 50.75 is provided in

NUREG/CR-5884, “Revised Analyses of Decommissioning for the Reference Pressurized Water Reactor Power Station,” and NUREG/CR-6187, “Revised Analyses of Decommissioning for the Reference Boiling Water Reactor Power Station.” Similar to part 50, a provision for an annual adjustment of decommissioning cost estimates would be included in proposed § 53.1030. ~~The equivalent sections in Framework B are proposed §§ 53.4620 and 53.4630~~.

The NRC is currently pursuing another rulemaking, “Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning,” which was published as a proposed rule for public comment on March 3, 2022 (87 FR 12254). As these rulemakings progress, the NRC will consider revisions to part 53 to align the two rulemaking efforts. For example, the proposed §§ 53.1075 ~~and 53.4675 in Frameworks A and B, respectively,~~ could be expanded to include or reference requirements for decommissioning in areas such as EP and security in addition to the proposed decommissioning fire protection plans that would provide an equivalent to § 50.48(f).

Subpart H – Licenses, Certifications, and Approvals

Proposed subpart H would provide requirements related to applications under ~~Framework A~~part 53 for NRC licenses, certifications, or approvals for commercial nuclear plants.

Proposed subpart H would specify requirements applicable to all ~~Framework A~~part 53 applications as well as requirements specific to ~~Framework A~~part 53 applications for LWAs, ESPs, standard design approvals, standard DCs, MLs, CPs, OLs, and COLs. Proposed subpart H would be equivalent to and include all existing licensing, certification, and approval processes currently covered under parts 50 and 52, with the exception of the process for early review of site suitability issues. Interactions with external stakeholders during the development of the proposed rule did not identify

significant interest in or need for including the process for early review of site suitability issues in part 53.

Much of the proposed subpart H regulatory text is identical to the corresponding language in parts 50 and 52, with minor changes to account for cross references in ~~Framework A~~part 53, to make language technology neutral, or to reflect the unique analytical approach ~~in Framework A~~. In these instances, this preamble discussion will describe the language as "equivalent" to the existing corresponding requirement in part 50 or part 52 and will describe any deviations, where applicable.

Because part 53~~Framework A~~ carries over the majority of the licensing options from parts 50 and 52, there are several sections in proposed subpart H that are similar to existing regulations in parts 50 and 52. Some of this text corresponds to requirements that are also being addressed in the proposed rulemaking on "Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing" (Docket ID NRC-2009-0196) for parts 50 and 52, hereafter referred to as the "parts 50/52 rulemaking." To minimize confusion and duplicative efforts between this rulemaking and the parts 50/52 rulemaking, the NRC will reconcile similar requirements between the parts 50/52 rulemaking and the part 53 rulemaking once the parts 50/52 rulemaking is issued as a final rule. Therefore, proposed subpart H largely reflects the current version of parts 50 and 52.

Proposed § 53.1100 would address filing of applications for licenses, certifications, or approvals under oath or affirmation and is equivalent to § 50.30. The proposed § 53.1100 does not include the current requirement in § 50.30(a)(2) that the applicant maintain the capability to generate additional copies, because it is unnecessary in the age of electronic submissions. In addition, the existing requirement on applications for OLs in § 50.30(d) is included in proposed § 53.~~1124(g)(2)~~615,

"~~Relationship between sections~~Application for operating licenses," ~~covering OLs,~~ rather than in proposed § 53.1100. The proposed § 53.1100 includes applicants for standard design certifications within the scope of individuals required to submit applications under oath or affirmation under § 53.1100(b), pay necessary § 170.21 fees under § 53.1100(e), and submit environmental reports under § 53.1100(f). Such applicants are not within the scope of § 50.30 despite the requirements of § 51.55 for submittal of environmental reports by design certification applicants and the requirements of § 170.21 for the reimbursement of the full cost of a design certification review.

Proposed § 53.1101 would lay out activities requiring an NRC license and is equivalent to § 50.10(b). Proposed § 53.1103 would address combining applications and is equivalent to §§ 50.31, 50.52, and 52.8. Proposed § 53.1103(b) would continue the Commission's practice of combining multiple authorizations for a facility under parts 30, 40, 50, 52, and 70 into one license based on the Commission's authority under Section 161h. of the AEA to combine NRC licenses. Proposed § 53.1106 would address elimination of repetition and is equivalent to § 50.32.

Proposed § 53.1109 would provide general information requirements for the content of applications submitted to the NRC under part 53~~Framework A~~ and is equivalent to § 50.33, with the exception of § 50.33(f) on financial qualifications, which is covered in proposed subpart J, and § 50.33(h) on earliest and latest dates for completion of construction, which is covered in § 53.1306 of this subpart. Each application would need to include information to address the items in proposed § 53.1109 as cited in the appropriate section of this subpart for the application type. Proposed § 53.1109(g) and (i) could be updated as needed following the Commission's decision regarding the final rule on "Emergency Preparedness for Small Modular Reactors and Other New Technologies" (Docket ID NRC-2015- 0225). One change from

current requirements can be found in proposed § 53.1109(i), which is not limited to electricity generation as it is currently in part 50. Some prospective NRC applicants are considering development of nuclear plants for other commercial ventures, such as process heat generation or hydrogen production. Additionally, a footnote corresponding to footnote 5 in § 50.33 regarding the incorporation by reference of previously submitted emergency response plans is not provided in § 53.1109 because incorporation by reference would be covered under § 53.1106, “Elimination of repetition.”

Proposed § 53.1112 would address environmental conditions and is equivalent to § 50.36(b~~)~~. Proposed § 53.1115 would address requirements for agreements limiting access to classified information and is equivalent to § 50.37. Proposed § 53.1118 would address ineligibility of certain applicants and is equivalent to § 50.38. ~~Proposed § 53.1120 would address exceptions and exemptions from licensing requirements for Department of Defense and DOE facilities and is equivalent to § 50.11.~~ Proposed § 53.1121 would address public inspection of applications and is equivalent to § 50.39.

Proposed § 53.1124 would address the relationship between the various licenses, certifications, and approvals provided in this subpart, and the requirements are equivalent to a number of similar provisions in parts 50 and 52 including §§ 50.10, 52.13, 52.43, 52.73, 52.133, and 52.153. New provisions are provided in § 53.1124(~~c~~a) ~~and (d),~~ that~~which~~ would allow an application for either a standard design approval or a standard DC under part 53~~Framework A~~ to reference applicable licensing basis information that supported issuance of an OL or COL under part 53~~Framework A~~. These provisions are being proposed to offer additional flexibility beyond what is currently allowed under parts 50 or 52 for an applicant who may wish to license a first-of-a-kind reactor for operation prior to seeking generic approval or certification of the ~~reactor~~ standard design.

Commented [A22]: Edited to cite 50.36b, "Environmental conditions," rather than paragraph (b) of 50.36, "Technical specifications."

Commented [A23]: Edited to use the defined term.

Proposed § 53.1124(be) would address the limitations that a manufactured reactor may only be transported to a site with a COL and is equivalent to § 52.153 with the exception of not allowing transportation to a site under a CP. Proposed § 53.1130 would address LWAs and is equivalent to § 50.10. However, in proposed part 53, the definition of construction from § 50.10 would be included in § 53.0240, "Definitions ~~specific to Framework A~~," rather than in this section on requesting LWAs.

Proposed §§ 53.1140 through 53.1188 would govern the content of ESP applications. Proposed § 53.1140 is equivalent to § 52.12. Proposed § 53.1143 would address filing of applications and is equivalent to § 52.15. Proposed § 53.1144 would address general information requirements for the content of applications and is equivalent to § 52.16.

Proposed § 53.1146 would specify requirements for the technical contents of applications and is equivalent to § 52.17. Note that the proposed requirements in § 53.1146(b)(2) may be affected by issuance of the final rulemaking on "Emergency Preparedness for Small Modular Reactors and Other New Technologies" (Docket ID NRC-2015-0225).

Proposed § 53.1149 would address standards for review of ESP applications and administrative review of applications, including hearings, and is equivalent to §§ 52.18 and 52.21. Proposed § 53.1155 would address referral to the ACRS and is equivalent to § 52.23. Proposed § 53.1158 would address issuance of ESPs and is equivalent to § 52.24. Proposed § 53.1161 would address the extent of activities permitted and is equivalent to § 52.25. Proposed § 53.1164 would address the duration of an ESP and is equivalent to § 52.26. Proposed § 53.1167 would address provisions for requesting a LWA after issuance of an ESP and is equivalent to § 52.27. Proposed § 53.1170 would address transfers of ESPs and is equivalent to § 52.28. Proposed § 53.1173 would

address applications for ESP renewals and is equivalent to § 52.29. Proposed § 53.1176 would address criteria for renewal of an ESP and is equivalent to § 52.31. Proposed § 53.1179 would address the duration of an ESP renewal and is equivalent to § 52.33. Proposed § 53.1182 would address the use of a site for purposes other than those described in the permit and is equivalent to § 52.35. Proposed § 53.1188 would address finality of ESP determinations and is equivalent to § 52.39.

Proposed §§ 53.1200 through 53.1221 would govern the contents of standard design approval applications. Proposed § 53.1200 is equivalent to § 52.131. Proposed § 53.1203 would address filing of applications and is equivalent to § 52.135. Proposed § 53.1206 would address general information requirements for the content of applications and is equivalent to § 52.136.

Proposed § 53.1209 would address requirements for the technical content of applications and is largely equivalent to § 52.137. In proposed § 53.1209(a), the NRC proposes text that expands the discussion of “major portion” standard design approvals. Additional discussion regarding standard design approvals for a major portion of a standard design can be found in the NRC’s "A Regulatory Review Roadmap for Non-Light Water Reactors,” which considers the Nuclear Innovation Alliance (NIA) report “Clarifying ‘Major Portions’ of a Reactor Design in Support of a Standard Design Approval.” Proposed § 53.1209(b) outlines the required content of the Final Safety Analysis Report (FSAR). Proposed requirements in § 53.1209(b)(2) for portions of the application addressing design information state that the application must include design information equivalent to that required for a standard DC. This reference to the pertinent DC requirements (specifically, those in proposed § 53.1239(a)(2) through (27)) is an efficiency that would prevent the need to repeat many of the same requirements for the content of a standard design approval application.

Proposed § 53.1210 would address requirements for the content of a standard design approval application other than the FSAR. Proposed § 53.1210(a) would require the inclusion of a description of availability controls that are not included in the FSAR.

Proposed § 53.1212 would address standards for review of applications and is equivalent to § 52.139. Proposed § 53.1215 would address referral to the ACRS and is equivalent to § 52.141. Proposed § 53.1218 would address staff approval of designs and duration of design approvals and is equivalent to §§ 52.143 and 52.147. Proposed § 53.1221 would address finality of standard design approvals and information requests and is equivalent to § 52.145 with the exception that it extends such finality to a standard approval referenced in a DC application. Standard design approvals issued to date under part 52 have been issued during the NRC's review of the standard DC application and have relied on the same application content. However, a future scenario could arise where the DC application is not submitted until after a design approval has been granted. The NRC would apply the same finality provisions in this situation as in the situation where a standard design approval is referenced in a COL application.

~~There is no equivalent to proposed § 53.1221(d) in part 52 for standard design approvals. This provision would state that the Commission will require, before granting a CP, COL, OL, or ML which references a standard design approval, that engineering documents be completed and available for audit. A similar provision is included in part 52 in relation to a standard DC; and the NRC would require that design and analysis information needed for the Commission to make its safety determination be complete and available for any application the NRC is reviewing. Making this explicit provides increased clarity to future standard design approval applicants under Framework A.~~

Proposed §§ 53.1230 through 53.1263 would address standard DCs. Proposed § 53.1230 would address general provisions for standard DCs and is equivalent to

§ 52.41. Proposed § 53.1233 would address filing of applications and is equivalent to § 52.45. Proposed § 53.1236 would address general information requirements for the content of applications and is equivalent to § 52.46. Proposed § 53.1239 would address requirements for the technical content of applications and is equivalent to § 52.47(a). The requirements in proposed § 53.1239 have been modified from the analogous requirements in § 52.47(a) to align with the technical requirements in proposed part 53~~Framework A~~.

Proposed § 53.1241 would address requirements for the content of a standard DC application other than the FSAR and is equivalent to § 52.47(b) and (d).

Proposed § 53.1242 would address review of applications and is equivalent to §§ 52.48 and 52.51. Proposed § 53.1242(c) would include a provision that would allow a DC applicant to reference applicable licensing basis information for an OL or COL issued under part 53~~Framework A~~. As explained previously, this provision is being proposed to explicitly allow flexibility for an applicant who may wish to license a first-of-a-kind reactor for operation prior to seeking certification of the generic reactor design. For NRC findings on a reactor design in an OL or COL proceeding, this proposal would provide finality in a subsequent DC application that references information on the OL or COL proceeding's docket. This finality accorded to the OL or COL findings would bind the NRC staff and the ACRS but would not bind members of the public or the Commission. (To the extent an Atomic Safety and Licensing Board (ASLB) might have a role in a DC rulemaking, the OL or COL findings would not bind the ASLB either.) Specifically, members of the public would have the opportunity to comment on a proposed DC rule under~~in accordance with~~ well-established NRC practice. The rationale for binding the NRC staff and ACRS is similar to the rationale for a COL applicant referencing a standard design approval under part 52.

Proposed § 53.1245 would address referral to the ACRS and is equivalent to § 52.53. Proposed § 53.1248 would address issuance of standard DCs and is equivalent to § 52.54. Proposed § 53.1251 would address ~~duration of certifications~~referencing standard DC applications in applications for a CP or COL prior to the granting of the DC and is equivalent to § 52.55(c). ~~Proposed § 53.1254 would address application for renewal and is equivalent to § 52.57. Proposed § 53.1257 would address criteria for renewal and is equivalent to § 52.59. Proposed § 53.1260 would address duration of renewals and is equivalent to § 52.61.~~ Proposed § 53.1263 would address finality of standard DCs and is equivalent to § 52.63.

There are no equivalent sections in part 53 corresponding to § 52.55(a)-(b) or §§ 52.57 through 52.61. This reflects the Commission's determination that the imposition of a duration on its finding that the criteria of § 53.1248 have been met would be inappropriate in light of the inefficiency of requiring a further application for renewal of a granted standard DC under the same criteria that were in effect at the initial granting of the standard DC with certain allowances for modifications corresponding to those of § 52.59. Should information come to light following the granting of a standard DC that shows that modification, rescission or the imposition of new requirements on the certification information would be warranted under the finality provisions in § 53.1263, the Commission would take appropriate action based on the totality of the circumstances taking into account the cost of a rulemaking to amend the DC rule, the direct and indirect costs of addressing the circumstances on a facility-specific basis, and the safety implications of the issues. Instances where information shows that action is necessary to provide adequate protection of the public health and safety or the common defense and security at a commercial nuclear plant licensed under part 53 that referenced an effected

standard DC would be required to be addressed by the Commission under proposed §§ 53.1263(a)(4) and 53.1590(a)(5).

Proposed §§ 53.1270 through 53.12954 would address MLs covering manufacturing activities at one or more licensee facilities. Proposed § 53.1270 would address the scope of these sections and is equivalent to § 52.151.

Proposed § 53.1273 would address filing of applications for an ML and is equivalent to § 52.155(a).

Proposed § 53.1276 would address general information requirements for the content of ML applications and is equivalent to § 52.156, with one exception. Proposed § 53.1276 would require each application for an ML to also include the information required by § 53.1109(e). This information includes the type of license applied for, the use to which the facility will be put, the period of time for which the license is sought, and a list of other licenses, except operator's licenses, issued or applied for in connection with the proposed facility to address the potential variations in how MLs might be formulated under the proposed part 53.

Proposed § 53.1279 would address requirements for the technical content of applications for MLs to be included in the FSAR, and is equivalent to § 52.157. In addition, the requirements in proposed § 53.1279(a) and (b) have been modified from the analogous requirements in § 52.157 to align with the technical requirements in proposed part 53Framework A. Proposed § 53.1279(a)(2) outlines the required content of the application addressing design information and states that the application must include design information equivalent to that required for a standard DC. This reference to the pertinent DC requirements is an efficiency that would prevent the need to repeat the same requirements for the content of an ML application.

Proposed § 53.1279(c) would provide application requirements related to the deployment of the completed manufactured reactor. Proposed § 53.1279(c)(1) would require inclusion of information related to the procedures governing the preparation of the manufactured reactor for shipping to the site where it is to be operated, the conduct of shipping, and the verification of the condition of the shipped items upon receipt at the site. Proposed § 53.1279(c)(2) would require that the application include information on the interaction of the design, manufacture, and installation of a manufactured reactor within the applicant's organization and the manner by which the applicant will ensure close integration between the designer, contractors, and any licensee of a facility in which the manufactured reactor is to be installed. Finally, proposed § 53.1279(c)(3) would require that the application include a description of the measures used for the control of interfaces between the holder of the ML and the holder of the COL for the commercial nuclear plant at which the manufactured reactor is to be installed. This information is necessary for the NRC to determine whether the applicant would have appropriate controls in place to ensure coordination between parties involved in the design, manufacture, and eventual operation of any reactor manufactured under an ML.

Proposed § 53.1279(d) would provide additional considerations to allow for fueling of a manufactured reactor at the factory and its use as transportation container under part 70 prior to its installation at a site as part of a commercial nuclear plant.

Proposed § 53.1282 would provide requirements for other application content for MLs and is equivalent to § 52.158. Proposed § 53.1282(a)(1) would provide requirements to include in the ML application the ITAAC within the scope of the ML that the COL holder referencing the manufactured reactor~~ML~~ must satisfy. Proposed § 53.1282(a)(2) would require that the ITAAC from a referenced standard design apply to the portions of the ML design within the scope of the referenced standard design.

Proposed § 53.1282(a)(3) would state that the COL application may include a notification that required referenced standard DC ITAAC have been satisfied at the manufacturing facility.

Proposed § 53.1282(b)(1) would require an ML application to include an environmental report and, consistent with existing requirements, proposed § 53.1282(b)(2) would note that if the ML application references a standard DC, the environmental report need not contain a discussion of severe accident mitigation design alternatives for the manufactured reactor as used in a commercial nuclear plant.

Proposed § 53.1285 would provide standards for review of applications and administrative review of applications for MLs, including hearings, and is equivalent to §§ 52.159 and 52.163.

Proposed § 53.1286 would address referral of applications to the ACRS and is equivalent to § 52.165. Proposed § 53.1287 would address issuance of an ML and is equivalent to § 52.167.

Proposed § 53.1288 would address finality of MLs and is equivalent to § 52.171. Proposed § 53.1291 would address the duration of MLs and is equivalent to § 52.173. Proposed § 53.1293 would address the transfer of MLs and is equivalent to § 52.175. Proposed § 53.1295 would address the renewal of MLs and is equivalent to §§ 52.177, 52.179 and 52.181, with a minor exception. Proposed § 53.1295(a)(3) would state that an ML for which a timely application for renewal has been filed remains in effect until the Commission has made a final determination on the renewal application~~, provided, however, that the holder of an ML may not begin manufacture of a manufactured reactor less than six months before the expiration of the license~~ but would not include a prohibition of initiation of manufacture 3 years before the expiration of the license. Any safety concerns related to the duration of the manufacturing license are addressed by

the requirement in § 53.1291 to cease the manufacture of uncompleted reactors upon expiration of the manufacturing license. ~~The proposed 6-month time frame for this provision is changed from the 3-year period in the equivalent provision in part 52 because future reactor applicants may present smaller, simpler designs, to include microreactor designs, in ML applications than those that were envisioned when the existing requirements were written. A 6-month time frame for this provision would provide greater flexibility for ML holders related to manufactured reactors being produced when the ML expires.~~

Proposed §§ 53.1300 through 53.1348 would address licensing requirements for CPs. Proposed § 53.1300 would set out general requirements for CPs and is equivalent to § 50.23. Proposed § 53.1306 would address the general information requirements for the content of applications for CPs and is equivalent to § 50.33~~(f) and (h)~~.

Proposed § 53.1309 would address requirements for the technical content of applications for CPs and includes the requirement to submit a Preliminary Safety Analysis Report (PSAR) that describes the facility and presents a preliminary safety analysis of the facility as a whole. This is in contrast to an OL application which is required to include an FSAR that describes the facility and presents a final safety analysis of the facility as a whole. Proposed § 53.1309 is equivalent to § 52.17(a)(1)(iv) through (x) and 52.17(b), with two exceptions. First, proposed § 53.1309 would replace the analysis of the dose criteria required by § 52.17(a)(1)(ix) with analysis to demonstrate compliance with the safety criteria defined in §§ 53.210 and 53.220. Second, proposed § 53.1309(a)(2) would add a requirement for a CP application to include several categories of detailed design information, although § 53.1309(a)(2)(ii) would allow certain relaxations of this requirement in view of aspects of a design that may not yet be fully developed. Section 53.1309 would reference the requirements for

the content of an ESP application to address application requirements related to siting and would reference the requirements for the content of a DC application to address application requirements related to design of the commercial nuclear plant. Proposed § 53.1309(a)(2)(ii) would address the treatment of preliminary design information and notes that information provided in the application may include some aspects of the design that are not fully developed. This provision would require that the completed design, including any changes during construction, be described in the FSAR in an application for an OL. This would include the requirement for a description of the ~~PRA~~ risk evaluation required by § 53.450(a) and its results. ~~PRAs~~ Risk evaluations developed for commercial nuclear plants prior to construction would be based on the design and other information available at the time of the CP application. ~~PRAs~~ Risk evaluations performed in early design stages or prior to construction may be inherently less detailed and may include projected information that will be subsequently verified or revised when the plant is built. Proposed § 53.1309(a)(4) would address preliminary description of the plans for coping with emergencies.

Proposed § 53.1312 would address other application content for CPs. Proposed § 53.1312(a)(1) is equivalent to § 52.80(b) but is adapted for a CP application. Proposed § 53.1312(a)(2) is equivalent to § 52.80(c) but is adapted for a CP application. Proposed § 53.1312(b)(1) is equivalent to § 52.79(b), (c), and (d) but is adapted for a CP application. Section 53.1312(b)(2) is equivalent to portions of §§ 52.63(b)(1), 52.79(b)(1) though (3), (c), and (d)(1) and (3), 52.80, and 52.93(b), but is adapted for a CP application. Guidance for equivalent requirements in parts 50 and 52 is also addressed in RG 1.206, “Applications for Nuclear Power Plants,” Revision 1, section C.1.7.

Proposed § 53.1315 would address standards for review of applications and administrative review of applications, including hearings, and is equivalent to §§ 52.81 and 52.85, but is adapted for a CP application.

Proposed § 53.1318 would address finality of NRC approvals, licenses, and certifications referenced in a CP application and is equivalent to § 52.83(a) but is adapted for a CP application.

Proposed § 53.1324 would address referral to the ACRS and is equivalent to § 50.58(a) and to § 52.87 but is adapted for a CP application.

Proposed § 53.1327 would address authorization to conduct LWA activities and is equivalent to § 52.91 but is adapted for a CP application. Proposed § 53.1327(a) is equivalent to § 52.91(a) but is adapted for a CP application. Proposed § 53.1327(b) is equivalent to § 52.91(b) but is adapted for a CP application. Proposed § 53.1330 would address exemptions, departures, and variances for CP applicants.

Proposed § 53.1333 would address issuance of CPs. Proposed § 53.1333(a) is equivalent to § 50.35(a). Proposed § 53.1333(b) is equivalent to § 50.35(b) and to § 52.97(c) but is adapted for a CP application. Proposed § 53.1336 would address the effect of CPs and is equivalent to § 50.35(b). Proposed § 53.1342 would address the duration of CPs. Proposed § 53.1342(a) is equivalent to § 50.55(a). Proposed § 53.1342(b) is equivalent to § 50.55(b). Proposed § 53.1345 would address the transfer, assignment, and disposal of CPs and is equivalent to § 50.80. Proposed § 53.1348 would address the termination of CPs and is equivalent to §§ 52.3(b)(8) and 52.110(a)(1) but is adapted for a CP application.

Proposed §§ 53.1360 through 53.1405 address requirements for OLs.

Proposed § 53.1366 would address requirements for the general content of applications for OLs. It would refer to general content requirements in proposed

§ 53.1109 and would require supplemental information. Proposed § 53.1366(a) is equivalent to § 50.33(f). Proposed § 53.1366(b) is equivalent to § 50.33(k).

Proposed § 53.1369(a) would provide requirements for the technical content of applications for OLs to be included in the FSAR and is equivalent to § 50.34(b) but has been modified to align with the technical requirements in proposed part 53~~Framework A~~. It would require that the FSAR include and, as needed, update information provided in the PSAR that was submitted and reviewed to support the associated CP application.

Similar to the proposed requirements for the content of CP applications, proposed § 53.1369(a)(1) would reference the requirements for the content of an ESP application to address application requirements related to the site. Section 53.1369(~~b~~a)(2) would reference the requirements for the content of a DC application to address some of the application requirements related to design of the commercial nuclear plant.

Proposed § 53.1369(a~~c~~)(3) is equivalent to § 50.34(b)(7). ~~Proposed § 53.1369(d) would require a description of the Integrity Assessment Program that would be required by proposed § 53.870.~~ Proposed § 53.1369(a~~e~~)(4) is equivalent to § 50.34(e). Proposed § 53.1369(a~~g~~)(5) would provide requirements for OL application content to support proposed § 53.730 related to the role of personnel in the operation of the commercial nuclear plant and is adapted from requirements in part 55 and § 50.34(f). Likewise, proposed § 53.1369(~~h~~a)(6) would provide requirements for OL application content related to training programs to support proposed §§ 53.730(g) and 53.830 and includes requirements equivalent to § 50.34(b)(8), § 52.79(a)(33), and ~~requirements in~~ part 55. Proposed § 53.1369(a~~i~~)(7) would provide requirements for OL application content related to emergency plans to support proposed § 53.855 and is equivalent to § 50.34(b)(6)(v). If the NRC proceeds with revising its regulations as described in SECY-22-0001, the

same flexibility in determining appropriate emergency preparedness measures, as directed by the Commission, would be added to part 53.

Proposed § 53.1369(aj)(8) would provide requirements for OL application content related to the applicant's organizational structure and is equivalent to § 50.34(b)(6)(i). Proposed § 53.1369(ak)(9) would provide requirements for OL application content related to the applicant's proposed maintenance program to support proposed § 53.715 and is equivalent to § 50.34(b)(6)(iv). Proposed § 53.1369(al)(10) would provide requirements for OL application content related to the applicant's quality assurance program to support proposed § 53.865 and Subpart Kappendix B to part 50 and is equivalent to § 50.34(b)(6)(ii). Proposed § 53.1369(am)(11) would provide requirements for OL application content related to the applicant's proposed radiation protection program to support proposed § 53.850 and is equivalent to § 50.34(b)(3).

Proposed § 53.1369(an)(12) through (pa)(14) would provide requirements for OL application content related to the applicant's proposed physical security program to support proposed § 53.860(a) and are equivalent to § 50.34(c) and (d). Proposed § 53.1369(aq)(15) would provide requirements for OL application content related to the applicant's proposed cyber security plan to support proposed § 53.860(d) and is equivalent to §§ 52.79(a)(36)(iv) and 73.54. Proposed § 53.1369(ar)(16) would provide requirements for OL application content related to the implementation of proposed security, safeguards, and cyber security plans to support proposed § 53.860 and is equivalent to § 52.79(a)(35)(ii) and 52.79(a)(36)(iv) and (v).

Proposed § 53.1369(as)(17) would provide requirements for OL application content related to the applicant's proposed fire protection program to support proposed § 53.875 and is equivalent to § 52.79(a)(40). Proposed § 53.1369(at)(18) would provide requirements for OL application content related to the applicant's proposed ISI and IST

program to support proposed § 53.880 and is equivalent to part of § 52.79(a)(11). ~~Proposed § 53.1369(v) would provide requirements for OL application content related to the applicant's FSP to support proposed § 53.890. Section 53.1369(v) has no analog in parts 50 and 52 since the FSP is a new proposal in part 53. Proposed § 53.1369(w) would provide requirements for OL application content related to the applicant's general employee training program to support proposed § 53.830 and is equivalent to § 52.79(a)(33).~~ Proposed § 53.1369(a~~x~~)(19) would provide requirements for OL application content related to the applicant's FFD program to support part 26 and is equivalent to § 52.79(a)(44). Proposed § 53.1369(a~~y~~)(20) would provide requirements for OL applicant's programs to demonstrate that any safety questions identified at the CP stage have been resolved and is equivalent to § 50.34(b)(5). Proposed § 53.1369(a~~z~~)(21) would provide requirements for OL applicants to describe how the performance of each safety design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof to support proposed § 53.~~44~~0990(d~~a~~). It is largely equivalent to §§ 50.34(b)(5) and 50.43(e). ~~Proposed § 53.1369(aa) would provide requirements for OL application content related to the applicant's proposed TS to support proposed § 53.710(a) and is equivalent to § 50.34(b)(6)(vi).~~

Proposed § 53.1369(b) through (d) would address content of applications; technical information requirements for OL applications referencing early site permits, design approvals, or design certifications modeled on the provisions of § 52.79(b) through (d) and § 53.1416(d) through (f) for COL applications under parts 52 and 53 similarly referencing early site permits, design approvals, or design certifications.

Proposed § 53.1372 would address requirements for the content of OL applications other than the FSAR. Proposed § 53.1372(a) would require submission of an environmental report and is equivalent to § 50.30(f) and § 51.53(b). Proposed § 53.1372(b) does not have a direct parallel in parts 50 and 52 and would require the inclusion of a description of availability controls that are not included in the FSAR to support proposed § 53.710(b).

Proposed § 53.1375 would address standards for review of OL applications and the administrative review of applications, including hearings, and is equivalent to ~~§ 50.43 and to~~ §§ 52.81~~, 50.43(a),~~ and 52.85, except that the NRC has omitted 10 CFR part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants," from the list of standards in the proposed § 53.1375(a). Proposed part 53 does not include detailed requirements related to renewal of licenses, although a general provision and possible placeholder for future requirements has been included as proposed § 53.1595. The NRC will decide after the part 53 final rule is published whether this future section will be retained in part 53 to address license renewal or whether the agency will take another approach to address license renewal for part 53 licensees, such as amending part 54 to address part 53 licensees.

Proposed § 53.1381 would address referral to the ACRS and is equivalent to §§ 50.58 and 52.87. Proposed § 53.1384 would address exemptions, departures, and variances for OL applicants. Section 53.1384(a) is equivalent to § 52.93 but is adapted for OLs. Proposed § 53.1384(b) is equivalent to §§ 52.39(d) (with respect to ESPs) and 52.93 but is adapted for OLs.

Proposed § 53.1387 would address issuance of OLs. Proposed § 53.1387(a)(1)(i) is equivalent to §§ 50.50 and 50.57(a)(1). Proposed § 53.1387(a)(1)(ii) ~~is equivalent~~addresses the requirement for notifications to have been duly made under

§ 50.50. Proposed § 53.1387(a)(1)(iii) is equivalent to § 50.57(a)(2). Section 53.1387(a)(1)(iv) is equivalent to § 50.57(a)(3). Proposed § 53.1387(a)(1)(v) is equivalent to § 50.57(a)(4). Proposed § 53.1387(a)(1)(vi) is equivalent to § 50.57(a)(6). Proposed § 53.1387(a)(1)(vii) is equivalent to § 50.57(a)(5). Proposed § 53.1387(a)(1)(viii) is equivalent to § 52.97(a)(1)(vi) but is adapted for OLs. Proposed § 53.1387(c) is equivalent to § 50.57(b). Proposed § 53.1387(d) is equivalent to §§ 50.36(b) and 50.50.

Proposed § 53.1390 would address ~~backfitting~~ finality of OLs and is equivalent to § 52.98(a) but adapted for an OL application. Proposed § 53.1396 would address duration of an OL and is equivalent to § 50.51(a)~~ and § 52.104~~. Proposed § 53.1399 would address transfer, assignment, and other disposition of an OL by invoking § 53.1570, which~~and~~ is equivalent to § 50.80. Proposed § 53.1402 would address applications for renewal of an OL and refers to the placeholder proposed in § 53.1595. Proposed § 53.1405 would address continuation of an OL and is equivalent to § 50.51(b)~~52.109 but is adapted to address an OL~~.

Commented [A24]: Edited to reflect that the provisions of 53.1390 cover the modification, addition, or deletion of terms and conditions of the license (i.e., finality of Commission decisions) rather than the effects of those actions on the facility (backfitting), which are controlled under 53.1590.

Commented [A25]: Deleted as unnecessary and in order to avoid the need to explain the start date for the 40 years.

Proposed §§ 53.1410 through 53.1461 would address requirements for COLs. Proposed § 53.1410 is equivalent to § 52.71. Proposed § 53.1413 would address general information requirements for the content of applications for COLs and is equivalent to § 52.77, which references § 50.33. Most of the provisions from § 50.33 are restated in proposed § 53.1109. Some requirements in § 50.33 related to financial qualifications and construction timelines are addressed in other sections of ~~Framework A~~part 53.

Proposed § 53.1416 would address the technical content to be included in an FSAR for an application for a COL and is equivalent to § 52.79 except as modified to reflect the technical requirements in part 53~~Framework A and~~ with one addition.

Proposed § 53.1416 includes the statement that the Commission will require, before issuance of a COL, that engineering documents, such as analyses, drawings, procurement specifications, or construction and installation specifications, be completed and available for audit if the more detailed information is necessary for the Commission to verify the information in the application and make its safety determination. This statement is equivalent to DC application requirements in § 52.47 and is included in proposed § 53.1416 for clarity.

Similar to the proposed requirements for the content of OL applications, proposed § 53.1416(a)(1) would reference the requirements for the content of an ESP application to address application requirements related to siting. Section 53.1416(a)(2) would reference the requirements for the content of a DC application to address some of the application requirements related to design of the commercial nuclear plant. The remaining items under proposed § 53.1416(a) are likewise similar to the required content for OL applications under proposed § 53.1369(a). Proposed § 53.1416(b) would require COL applicants to provide a report documenting the resolution of any safety questions for SSCs for which research and development was necessary to confirm the adequacy of their design and is equivalent to § 50.34(b)(5). Proposed § 53.1416(c) would provide requirements for COL applicants to describe how the performance of each safety design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof to support proposed § 53.440(a). It is largely equivalent to §§ 52.79(a)(24) and 50.43(e). Proposed § 53.1416(d) would address the content of COL applications referencing an ESP. Proposed § 53.1416(e) would address the content of COL applications referencing a standard design approval. Proposed § 53.1416(f) would address the content of COL applications referencing a

standard DC. Proposed § 53.1416(g) would address the content of COL applications referencing an ML.

Proposed § 53.1419 would address other application content for COLs and is equivalent to § 52.80. Proposed § 53.1419(a)(2) is new and would require the inclusion of a description of availability controls that are not required to be included in the FSAR.

Proposed § 53.1422 would address standards for review of applications and the administrative review of applications, including hearings, and is equivalent to §§ 52.81 and 52.85. The NRC has removed part 54 from the list of standards in proposed § 53.1422(a). ~~Proposed part 53 does not include requirements related to renewal of licenses, in relation to proposed §§ 53.1422 and 53.1595.~~

Proposed § 53.1425 would address the finality of NRC approvals referenced in a COL application and is equivalent to § 52.83(a). Proposed § 53.1431 would address the referral of COL applications to the ACRS for review and is equivalent to § 52.87. Proposed § 53.1434 would address the authorization to conduct LWA activities and is equivalent to § 52.91. Proposed § 53.1437 would address exemptions, departures, and variances and is equivalent to § 52.93. Proposed § 53.1440 would address issuance of COLs and is equivalent to § 52.97. Proposed § 53.1443 would address finality of COLs and is equivalent to § 52.98.

Proposed § 53.1449 would address inspection during construction and is equivalent to § 52.99. Proposed § 53.1452 would address operation under a COL and is equivalent to § 52.103. Proposed § 53.1455 would address duration of COL and is equivalent to § 52.104. Proposed § 53.1456 would address the transfer of a COL and is equivalent to § 52.105. Proposed § 53.1458 would address application for renewal by reference to the placeholder provision in § 53.1595 and is equivalent to § 52.107. Proposed § 53.1461 would address continuation of COL and is equivalent to § 52.109.

Proposed § 53.1470 would address standardization of commercial nuclear plant designs and licenses to construct and operate commercial power reactors of identical design at multiple sites and is equivalent to appendix N of part 50 and appendix N of part 52. This section would set out the particular requirements and provisions applicable to situations in which applications for CPs and subsequent OLs, or COLs, under this part are filed by one or more applicants for licenses to construct and operate nuclear power reactors of identical design ("common design") to be located at multiple sites. Additional information related to this proposed section is provided in the final rule to revise part 52 (72 FR 49352; August 28, 2007).

Subpart I – Maintaining and Revising Licensing Basis Information

Part 53 would establish requirements for the maintenance of licensing basis information in subpart I ~~for Framework A and in subpart S for Framework B~~. ~~The two subparts would be in most respects similar, except as described in the following paragraphs, and included separately within the frameworks to support clarity and ease of use due to the differences in the internal references between Framework A and Framework B.~~

Section~~s~~ 53.1500 ~~and 53.6000~~ would describe the purpose of the subpart~~s~~ in terms of the common definition of licensing basis information in subpart A. Subpart~~s~~ I ~~and S~~ would be closely tied to the requirements in subpart~~s~~ H ~~and R~~, which would provide the requirements for contents of applications for the various types of licenses issued under part 53~~Framework A or Framework B~~. Subpart~~s~~ I ~~and S~~ would generally be organized into sections dealing with: (1) licensing basis information that licensees are not authorized to change without NRC approval (e.g., licenses, regulations); and (2) licensing basis documents that licensees may change provided specified criteria are satisfied (e.g., FSAR, program descriptions). The subpart~~s~~ would also capture certain

general conditions on licenses and changes to the licenses related to the transfer and termination of licenses.

Section~~s~~ 53.1502 ~~and 53.6002 within Frameworks A and B, respectively,~~ would define specific terms and conditions of licenses. These terms and conditions would be equivalent to the regulations in: (1) § 50.54(h) stating that each license is subject to the provisions of the Act and requirements issued by the Commission; (2) § 50.54(~~sq~~)(2)(ii) and (s)(3) stating th~~eat actionseach licensee, after~~ the Commission would take if it makes ~~its~~ a finding that there is not reasonable assurance ~~finding~~that adequate protective measures can and will be taken in the event of a radiological emergency~~, shall follow and maintain the effectiveness of an emergency plan that meets the requirements in appendix E to part 50 and the planning standards of § 50.47(b)~~; (3) § 50.54(aa) stating that each license is subject to the specified sections of the Federal Water Pollution Control Act; and (4) § 50.54(dd) stating that a holder of an OL or COL may take reasonable actions that depart from the license in a national security emergency.

Commented [A26]: The provisions of 50.54(q) are not addressed in 53.1502. The change provisions of 50.54(q) are addressed in 53.1565(d)(3) and the need to follow and maintain an emergency plan is addressed in 53.855.

Instead, 53.1502(d) addresses provisions equivalent to 50.54(s)(2)(ii) and (s)(3) using nearly identical wording.

Section~~s~~ 53.1505(a) ~~and 53.6005(a) in Frameworks A and B, respectively,~~ would serve as an introduction to and overview of the sections that follow on changes to licensing basis information requiring prior NRC approval, namely the elements of licensing basis information defined by licenses, orders, and regulations. The related sections within ~~these~~ subpart~~s~~ I would primarily deal with the process of how a licensee requests and the NRC issues an amendment to a license or issues an order that modifies a license. Another important element of licensing basis information that a part 53 licensee would not be able to change or deviate from without NRC approval would be the NRC regulations themselves. Section~~s~~ 53.1505(b) ~~and 53.6005(b)~~ would refer to ~~the common~~ § 53.080 in subpart A that would provide the criteria ~~for a licensee or other~~

party to satisfy when requestingto be used by the Commission when granting an exemption from NRC regulations when requested by an applicant or on its own initiative.

Sections 53.1510 and 53.6010 would be equivalent to § 50.90 and would require that a licensee submit an application to request an amendment to a license. The required assessments that would be included within an application to amend a license under part 53Framework A would need to address the safety criteria and analysis requirements of subparts B and C. As with parts 50 and 52, licensees under part 53in both frameworks would be required to include in their applications to amend a license an analysis of whether the amendment involves no significant hazards consideration using the standards in §§ 53.1520 and 53.6020, which would be equivalent to the standards in § 50.92. Although this rulemaking provided an opportunity to revise the terminology related to no significant hazards consideration determinations, which dates to the early 1960s when applications were supported by final hazard summary reports, the NRC is proposing to maintain the same terminology used in part 50 to minimize the need for associated changes in other regulations, guidance, and public notices.

Sections 53.1515 and 53.6015 would establish requirements for public notices and state consultations associated with the NRC's processing of a license amendment request and is. These sections would be equivalent to § 50.91 for the NRC's processes related to applications to amend an OL or COL. Section 50.91(b) stipulates that the Commission will make available to the licensee the name of the appropriate State official designated to receive such amendments. While the Commission fully intends to continue following this practice, the Commission has not included this administrative matter in proposed part 53. Proposed §§ 53.1515(b)(3) and 53.6015(b)(3) contains some modifications compared to § 50.91(b)(3) for clarity; these revisions are not intended to revise the substance of the provisions in part 53 compared to part 50.

Section~~s~~ 53.1520 ~~and 53.6020~~ would be based on § 50.92~~.~~ and~~Both sections~~ would continue to use the criteria in § 50.92 for determining that a proposed amendment involves no significant hazards consideration. Although more specific terms such as event sequence are used throughout ~~Framework A~~part 53, § 53.1520 would use the term "accident" to maintain consistency ~~between the two frameworks in part 53 and~~ with the long history of making no significant hazards consideration determinations under part 50.

Section~~s~~ 53.1525 ~~and 53.6025~~ would provide requirements for holders of an OL or COL requesting to revise information from a DC rule that was referenced in the initial license application and included in or incorporated by reference into the facility FSAR. In keeping with the current requirements in part 52, the portion of the part 53 facility licensing basis information obtained from the certified design would be divided into two categories. The most significant design information and the ITAAC would be certified by rule and designated as "certification information." The remaining information, which makes up the majority of the design information approved as part of the DC, would not be certified by rule and is not considered "certification information." Part 52 refers to these categories of information as Tier 1 and Tier 2 information, respectively, and refers to a change made to that information on a plant-specific basis as a departure. Under part 52, a departure from Tier 1 information requires an exemption and, for information incorporated into the license, a license amendment.

~~Both Framework A and Framework B~~ Part 53 would dispense with the Tier 1 and Tier 2 terminology. Rather, ~~§~~§§ 53.1525 ~~and 53.6025~~ would use the term "certification information" in place of Tier 1, and a plant-specific departure from the certification information would require both a request for an exemption from the associated DC rule and, for information such as ITAAC incorporated into the license, a license amendment.

However, as would be provided in §§ 53.1525(c) and 53.6025(c), a plant-specific departure from the information approved by the NRC as part of the DC rule but which is not certification information (i.e., Tier 2 information under part 52) would be assessed using the process and criteria defined in §§ 53.1550 and 53.6050 for changes to a FSAR. An applicant or licensee would need to identify such a change as a departure from the referenced standard design in the updated FSAR. The process for making a generic change to a certified design would be described in the associated sections in subparts H and R of Framework A and Framework B, respectively.

Sections 53.1530 and 53.6030 would not allow the holder of an ML or the holder of a COL using a manufactured reactor to make changes to the design of the manufactured reactor without requesting a license amendment from the NRC. Thisese sections would provide the equivalent requirements as those in §§ 52.98 and 52.171.

Sections 53.1535 and 53.6035 would establish requirements for license amendments during construction. Thise sections would provide the equivalent options and requirements for the holders of a CP as those in § 50.35(b). The regulations would allow but do not require the holder of a CP or LWA to request an amendment under §§ 53.1510 and 53.6010 if the licensee desires to obtain NRC approval of a specific design feature or specification. The requirements for obtaining an amendment to a COL to address changes during construction would also be provided in §§ 53.1535 and 53.6035. The proposed process would differ from the current requirements in part 52 by adopting a requirement similar to that included in SECY-22-0052, “Proposed Rule: Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150-AI66).” The proposed regulation would allow the holder of a COL to proceed at its own risk in making a change during the construction process and would require

that licensee to submit a license amendment request no later than 45 days from the date the licensee begins to implement the change or departure requiring NRC approval.

Section~~s~~ 53.1540 ~~and 53.6040 in Frameworks A and B, respectively,~~ would serve as an introduction to the sections that follow on changes to licensing basis information that are primarily under the control of a licensee but for which evaluations are made to determine if a submittal to the NRC requesting approval would be required. ~~The sections would also include definitions that would be applicable when using the processes in §§ 53.1545 through 53.1565 and §§ 53.6045 through 53.6065 of Frameworks A and B, respectively. The definitions would be largely equivalent to those in § 50.59(a) but include some revision to reflect the structure and terminology in other subparts in part 53. For example, the definition of "change" in § 53.1540(b) would address a "safety function" rather than a "design function," because the former is a defined term in Framework A. In contrast, the corresponding text in § 53.6040(b) would use the definition in § 50.59(a)(1) without modification. Similarly, in § 53.1540(b), the phrase "design basis" from § 50.59(a)(2) would be replaced with "functional design criteria" for SR SSCs."~~

Section~~s~~ 53.1545 ~~and 53.6045~~ would provide the proposed requirements for updating of FSARs. ~~The proposed requirements in Framework B under § 53.6045 would be equivalent to the current requirements in § 50.71.~~ While the process-related requirements proposed ~~for Framework A~~ under § 53.1545 would be largely the same as those in ~~Framework B and~~ § 50.71, the specifics of information to be updated would differ due to the role of risk evaluation~~PRA~~ in satisfying the requirements in subparts B and C. Additionally, the use of the risk-informed approach in subpart C would result in some but not all risk~~PRA~~ information being in the FSAR or another licensing basis

document and therefore a separate ~~PRA~~ update requirement similar to § 50.71(h) is not included in proposed subpart I.

Proposed § 53.1239(a)(18) in subpart H and the related references to this proposed requirement for the holders of OLs and COLs would require a description of the risk evaluation~~PRA~~ required by § 53.450(a) and its results to be included in FSARs. However, guidance documents are planned to clarify the division of risk~~PRA~~-related information that would need to be in the FSAR, in other possible licensing basis documents, and controlled as plant records subject to inspections and audits. At a minimum, the information from the risk evaluation~~PRA~~ that would be needed to show compliance with subpart C would be included in the FSAR (e.g., ~~PRA~~ summary and analytical results for LBEs). The submittal of voluminous PRA information was initially required under part 52, but that proved to be impractical and was revised in the 2007 revision of part 52. Guidance is being developed to ensure sufficient information is submitted to the NRC to support the licensing process and the NRC's regulatory findings under part 53~~Framework A~~ or similar applications using the LMP under parts 50 or 52.

The NRC has posed a question in section VII, "Specific Requests for Comments," of this document that asks about the appropriate level of detail for risk~~PRA~~-related information in an FSAR and whether other licensing basis documents might be more appropriate to both provide information to the NRC and ensure the ~~PRA~~ risk evaluation is maintained and updated as proposed in subpart C. The program document would provide more detail than the summaries in the FSAR but still be a much-condensed source of information in comparison to the documentation of a~~the~~ PRA, for example.

Section 53.1545(a)(3) and (4) would be based on the inclusion of at least a summary of ~~PRA~~ risk evaluation results and the related margins to safety criteria in the

FSAR and would require updates to that information. ~~The routine reporting of these margins would also inform application of the criteria for allowing changes without an amendment in the following section (§ 53.1550) in subpart I.~~

Section~~s~~ 53.1550 ~~and 53.6050~~ would establish requirements for evaluating changes to a facility as described in its FSAR. Th~~ese proposed sections~~is would provide the equivalent of the requirements in § 50.59 for evaluating changes to an Updated Final Safety Analysis Report (UFSAR) and determining if a license amendment is required to implement a change to a facility or procedures. ~~The differences between the frameworks would relate to how safety analyses are performed and used to derive or confirm design requirements and related programmatic controls to determine if an amendment is required. Because Framework B would be similar to parts 50 and 52 in its structure and terminology, § 53.6050~~ Given that the options provided for an applicant or licensee under part 53 allow the use of certain deterministic approaches to items such as fire protection, the protection of SR SSCs from external hazards, and the control of reactivity after a DBA, § 53.1550 would propose to use the same evaluation criteria as provided in § 50.59. ~~The evaluation criteria proposed~~Guidance would be provided on the application of the criteria in § 53.1550 that would reflect the role of the ~~PRA~~ risk evaluation in the safety analyses under part 53~~Framework A~~ that~~and~~ would include several measures related to the changes in plant risk resulting from a change in the plant design or plant procedures. Examples would include criteria that rely on the identification of risk-significant event sequences in accordance with the analysis requirements of § 53.450; exceeding the LBE evaluation criteria as defined in § 53.450; the consideration of potential reductions in margin between the estimated plant risks and the cumulative risk measures ~~in the safety criteria in § 53.220~~; changes to the safety classification of SSCs; and consideration of reductions in defense in depth.

Both §§Section 53.1550 and 53.6050 would include a criterion related to a departure in a method of evaluation used in the safety analyses and. Specifically, § 53.6050 would use the same wording as all eight criteria in § 50.59, including criterion (viii) on departing from methods of evaluation. Therefore, licensees could consider technically relevant information in existing guidance documents related to § 50.59 to support such evaluations for § 53.6050. The NRC has not yet developed draft guidance for use in applying proposed § 53.1550 but anticipates that the NRC staff and stakeholders will assess the potential need for such guidance and that such guidance would, if needed, be developed as part of ongoing or future activities.

Section 53.1550 in Framework A would include certain concepts taken from existing guidance for § 50.59 in the proposed criteria related to DBAs. Specifically, criterion (iv) for changes made to a method of evaluation of DBAs under § 53.450(f) would be equivalent to a change in a method of evaluation under § 50.59, and criterion (viii) on assessing if a change creates a possibility for an accident of a different type than previously analyzed in the FSAR would be similar to the § 50.59 criterion (v). Guidance documents will be prepared to address the content of applications for PRA-related information under proposed Framework A, and this guidance will also influence how potential changes in the evaluation of LBEs other than DBAs analyzed under § 53.450(e) are evaluated and reported under the proposed criterion (iv).

Section 53.1550(a)(2)(x) would require evaluating plant changes to ensure they would not prevent satisfying the design requirements in § 53.440(j) related to the impact of a large commercial aircraft. The inclusion of a proposed requirement under § 53.1550 related to design features for protecting against aircraft impact would reflect the proposed design requirement in subpart C and related proposed requirements in subpart H to address the proposed design requirement in FSARs submitted under part

53Framework A. Framework B would include an assessment that would be equivalent to § 50.150 under proposed § 53.6054.

Section 53.6052 would provide requirements for maintaining the risk evaluation required by § 53.4730(a)(34). This requirement would be equivalent to existing requirements under § 50.71(h) with changes that reflect the different ways in which risk is assessed in Framework B (i.e., through a PRA or an AERI). Guidance for maintenance of risk evaluations that are based on a PRA is provided in RG 1.200, "Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities," (for LWRs) and trial RG 1.247 (for non-LWRs), which endorse industry consensus PRA standards. Additional detail on addressing maintenance of a risk evaluation that is based on the AERI approach will be provided in the guidance that is being developed.

Proposed § 53.6054 would help ensure that pertinent elements of § 50.150 would be appropriately captured in Framework B. While the technical requirements in § 50.150(a) and (b) would be included subpart R, the change control provisions in § 50.150(c), with minor differences for cross-references, would be included in subpart S. Since Framework A would include design and analyses requirements related to aircraft impact assessments in proposed subpart C and the content of FSARs in proposed subpart H, criterion (x) was added to the proposed § 53.1550 to require licensees to evaluate plant changes to ensure the protections against aircraft impacts would be maintained.

Sections 53.1560 through 53.1565 in subpart I and §§ 53.6060 through 53.6065 in subpart S would define the processes for a licensee to evaluate changes to the program documents included in the licensing basis information submitted to the NRC and to modify such programs without NRC prior approval.

Section~~s~~ 53.1560 ~~and 53.6060~~ would include the proposed requirements for updating program documents included in licensing basis information and would provide the equivalent of UFSAR updates for key program documents. The proposed requirements ~~in these sections~~ would provide a uniform approach for updating program documents, which correspond to the programs required under subpart~~s~~ F ~~and P~~.

The proposed ~~§~~§ 53.1565 ~~and 53.6065, in Framework A and B, respectively,~~ would provide a process for licensees to make changes to program documents included in licensing basis information without obtaining prior NRC approval. The proposed requirements would include several generic criteria that, if not satisfied, would prompt the need for NRC approval of a change to a program document. These generic criteria would include whether a change would comply with TS and NRC regulations. Another proposed criterion for evaluating changes to program documents would be conforming with program-specific requirements, including NRC-approved program documents with more specific criteria for a particular program, regulations, administrative controls sections of TS, and NRC-approved program documents.

Proposed ~~§~~§ 53.1565(d) ~~and 53.6065(d)~~ would include specific criteria for evaluating changes to several program documents that have well established change processes and guidance for licensees under parts 50 and 52. The program documents specifically addressed in the proposed section~~s in both Framework A and B~~ would include quality assurance programs that would be equivalent to § 50.54(a), an emergency preparedness program that would be equivalent to § 50.54(q), and the security program documents which would be equivalent to § 50.54(p).

The proposed ~~§~~§ 53.1570 ~~and 53.6070~~ would establish requirements for the transfer of commercial nuclear plant licenses by providing the equivalent requirements of § 50.80 for the possible transfer of an ESP, CP, OL, or COL. ~~Likewise, the proposed~~

§§ 53.1575 and 53.6075 would establish requirements for the termination of an OL or COL under Framework A or B by providing the equivalent requirements of § 50.82. Other proposed requirements related to decommissioning and license termination would be included in subparts G and Q.

Sections 53.1580 and 53.6080 would establish requirements for information requests the NRC could send to the various types of licensees under part 53proposed Frameworks A and B and would provide requirements that would be equivalent to requirements in § 50.54(f). The proposed §§ 53.1585 and 53.6085 would provide the requirements that would be equivalent to requirements in § 50.100 to address revocation, suspension, modification of licenses, and approvals for cause under part 53within either Framework A or B. Sections 53.1590 and 53.6090 would propose to address backfitting requirements by providing requirements that would be equivalent to those in § 50.109 within Framework A and B.

Proposed §§ 53.1595 and 53.6095 would provide a placeholder to address license renewals under part 53 Frameworks A and B with simple statements that licenses may be renewed. Thisese section wouldsare likely to be expanded through future rulemakings to more fully describe or reference the processes related to requesting and processing applications to renew ESPs, OLs, and COLs issued under part 53 (if finalized).

Subpart J – Reporting and Other Administrative Requirements

Part 53 would address various reporting and administrative requirements in subpart J for Framework A and in subpart T for Framework B. The two subparts would be essentially the same and would be included separately within the frameworks to support clarity and ease of use due to the differences in the internal references and terminology between Framework A and Framework B.

Section~~s~~ 53.1600 ~~and 53.6300~~ would explain the organization of the various sections within the subpart~~s~~ related to providing unfettered access to NRC inspectors; maintaining certain records and reporting specified events or conditions; demonstrating compliance with financial qualification requirements and providing specified financial reports; and maintaining financial protections to address potential accidents.

Section~~s~~ 53.1610 ~~and 53.6310~~ would establish requirements for the provision of facilities and unfettered access for inspections. These requirements would be equivalent to § 50.70 with only minor changes proposed to provide additional flexibilities and address possible differences related to reactors licensed under part 53 and the possibility that some commercial nuclear plants may not be assigned resident inspectors.

Section~~s~~ 53.1620 ~~and 53.6320~~ would provide for maintenance of records and the making of various reports to the NRC. These requirements would be largely equivalent to § 50.71. This section is not intended to reflect all provisions in § 50.71; several important requirements in § 50.71 would be captured in other sections of part 53. For example, § 53.1545 within subpart I ~~and § 53.6045 within subpart S~~ would provide requirements that would be equivalent to § 50.71(e), updating FSARs, and ~~§~~§ 53.1680 ~~and 53.6380~~, “Annual financial reports,” would provide the equivalent of § 50.71(b), which covers financial reports. A reporting requirement related to completion of power ascension testing would be added to ~~§~~§ 53.1620 ~~and 53.6320~~ to support the assessment of annual fees under 10 CFR part 171, “Annual Fees for Reactor Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC,” which normally commence upon completion of those testing activities.

Sections 53.1630 and 53.6330 would establish requirements for immediate notification requirements for operating commercial nuclear plants. These requirements would be equivalent to § 50.72 with minor changes proposed to make the reporting criteria technology inclusive. The slight differences between these requirements and those of § 50.72 sections in Frameworks A and B would reflect the differences in terminology and approaches to topics such as safety functions. Whereas Section 53.1630Framework A would refer to the derivation of safety functions underin accordance with § 53.230, Framework B would referas compared to a standard set of safety functions used in defining SR SSCs and organizing PDCs. In addition, a new version of NRC Form 361 (NRC Form 361S) would be created for use by part 53 licensees (including Framework A and Framework B), but without LWR-specific terminology to ensure technology-inclusiveness. A separate rulemaking activity, "Reporting Requirements for Nonemergency Events at Nuclear Power Plants," has been initiated to consider possible changes to the requirements in § 50.72. At a future date, the NRC may consider reconciling future changes to § 50.72 with the requirements proposed in part 53, which have been taken or derived from the current reporting requirements.

Sections 53.1640 and 53.6340 would address the licensee event report system. These requirements would be equivalent to § 50.73 with minor changes proposed to make the requirements inclusive of various reactor technologies and to reflect appropriate internal references to other sections in Framework A and Framework Bpart 53 and framework-specific terminology. In addition, NRC Forms 366, 366A, and 366B would be revised to include corresponding check boxes for part 53 licensees.

Sections 53.1645 and 53.6345 would require periodic reporting of the quantity of radionuclides released to unrestricted areas in liquid and gaseous effluents. These

reporting requirements ~~in Framework A and Framework B~~ would be largely equivalent to the reporting requirements in § 50.36a, "Technical specifications on effluents from nuclear power reactors." The only difference would be that a § 50.36a requirement to specifically address conditions where the dose to the maximally exposed individual could be significantly above design objectives would refer to a design objective of 10 mrem/year instead of referring to the design objectives in appendix I to part 50. The proposed section~~s~~ would also include an equivalent to the reporting requirement in section IV of appendix I to part 50 if the radiation exposure to a member of the public in any calendar quarter exceeds one-half of the annual ~~ALARA~~ design objective.

Section~~s~~ 53.1650 ~~and 53.6350~~ would include a reporting requirement to support safeguards agreements between the United States and IAEA and would be equivalent to § 50.78.

Sections 53.1660 through 53.1700 ~~in Framework A and §§ 53.6360 through 53.6400 in Framework B~~ would address financial requirements and would be largely similar to existing regulations in parts 50 and 52. Section~~s~~ 53.1670 ~~and 53.6370~~ would be entitled "Financial qualifications" and would require applicants other than electric utilities to possess or have reasonable assurance of obtaining funds for the activities for which the license is being sought. The NRC is seeking feedback on these sections and their ramifications for merchant plants[3] in section VII, "Specific Requests for Comments," of this document. The remaining financial reports in ~~both Frameworks A and B~~part 53 would be equivalent to § 50.71(b) for annual financial reports, § 50.76 for a change of status, § 50.54(cc) for the filing of a petition for bankruptcy, and § 50.81 for creditor regulations.

[3] A "merchant plant" is a plant licensed to a non-rate-regulated entity (e.g., a nonutility) that engages in the business of production, manufacturing, generating, buying, aggregating, marketing, or brokering electricity for sale at wholesale or for retail sale to the public.

~~Sections 53.1710 through 53.1730 in Framework A and §§ 53.6410 through 53.6430 in Framework B would address financial protection requirements.~~ Section~~s~~ 53.1720 ~~and 53.6420~~ would require insurance to stabilize and decontaminate a plant following an accident. These requirements would be taken from § 50.54(w) with the only notable change being the addition of a provision allowing plant-specific estimates of costs to stabilize and decontaminate a plant as an alternative to the $1.06 billion minimum coverage in § 50.54(w). ~~Sections 53.1730 and 53.6430 are equivalent to § 50.57(a)(5) and would refer to the requirements in 10 CFR part 140, "Financial Protection Requirements and Indemnity," related to financial protection requirements and indemnity agreements, including the financial protection requirements of the Price-Anderson Act.~~

Commented [A27]: Deleted as unnecessary because the equivalent to 50.57(a)(5) is actually 53.1387(a)(1)(vii).

Subpart X – Enforcement

Subpart X would contain two provisions, § 53.9000 and § 53.9010, which are analogous to provisions contained in other parts of 10 CFR Chapter I imposing requirements on regulated entities. Section 53.9000 would provide notice of the Commission's authority under the AEA to obtain injunctions or other court orders for the enumerated violations. Paragraph (a) of § 53.9010 would provide notice to all persons and entities subject to part 53 that they are subject to criminal sanctions for willful violations, attempted violations, or conspiracy to violate certain regulations under part 53. Criminal sanctions would not apply to the regulations listed in paragraph (b). The regulations for which criminal penalties would apply are limited to those that establish either a regulatory obligation or prohibition.

Subpart K – Quality Assurance Criteria for Commercial Nuclear Plants

The proposed subparts K and U would provide a consolidated set of quality assurance requirements for applicants and licensees implementing either framework in proposed part 53. The two subparts would essentially be the same, with some differences resulting from framework-specific approaches and terminology related to safety classification schemes and supporting safety analyses. Both proposed subparts K and U would be equivalent to appendix B to part 50, with the only differences being those needed to reflect part 53 terminology and safety classifications. For example, the term "commercial nuclear plant" is used throughout the proposed part 53 to distinguish it from parts 50 and 52, which use terms such as "nuclear power plant," and that difference would be reflected in the proposed subparts K and U. An example relative to only Framework A is that subpart K would not use the term "design bases," as defined in part 50 and used in appendix B to that part. Instead, in subpart K of part 53, the staff is proposing to use the term "functional design criteria," defined in subpart A of part 53, in place of the term "design bases." See section IV, "Framework A," of this document, where subpart C of part 53 is discussed, for a discussion of "functional design criteria." Most of the proposed sections within subparts K and U would align directly with the associated criteria in appendix B to part 50. Proposed changes in terminology or context in subparts K and U from appendix B to part 50 are highlighted in the following discussions of specific sections.

The requirements in § 53.1800 in Framework A would be equivalent to the introduction to appendix B in part 50 and the proposed § 53.6600 in Framework B, except for the proposed use of "licensing-basis events, including DBAs, as described in § 53.240," in lieu of "postulated accidents." The reason for this language in proposed subpart K is to align it with the event classification terminology used in subpart C. In

defining the scope of the quality assurance requirements, both proposed subparts K and U would specify that they would apply to SR SSCs as defined within the respective frameworks. This change is proposed to clarify the scope of the requirements considering the differences in the safety analyses and related terminology between part 50, Framework A, and Framework B. Although there might be some differences between the SSCs that would be classified as SR, the quality assurance requirements on those SSCs designated as SR would be the same in part 50, Framework A, and Framework B.

Unlike criterion II, "Quality assurance program," in appendix B to part 50 and the proposed equivalent in § 53.6610 in subpart U, the phrase "importance to safety" is not used in the proposed § 53.1810 in subpart K or elsewhere in Framework A. However, the effect of this quality assurance program requirement would be the same in both frameworks because SSCs traditionally characterized as important to safety would be captured within Framework A by the performance-based controls and special treatments developed and implemented for NSRSS SSCs within the design and analyses requirements in the proposed subpart C and the operational requirements proposed for subpart F. This proposed construct within Framework A would provide a clear distinction between SR SSCs and NSRSS SSCs and their relationship to the quality assurance requirements in subpart K.

Section 53.1815 in the proposed subpart K would address design control and would be equivalent to criterion III, "Design control," in appendix B to part 50 and § 53.6615 in the proposed subpart U. However, this is an instance where subpart K would use the term "functional design criteria" instead of "design basis" to describe how design requirements for SSCs are translated into specifications, drawings, procedures, and instructions. This proposed change in terminology reflects that "design basis" is not used in Framework A in large part to avoid confusion relative to current requirements in

part 50. Nonetheless, "functional design criteria" in this section would serve the same purpose as "design basis" in subpart U and appendix B to part 50 because it will ensure that the needed information for specific SSCs is translated to other engineering documents and that the appropriate quality assurance measures are applied.

V. Framework B

Subpart N – Siting Requirements

Subpart N would provide the siting requirements for Framework B. The scope of subpart N would be outlined in § 53.3505.

Section 53.3510 would provide definitions applicable to subpart N. This section would include definitions from § 100.3 and appendix S to part 50. Other definitions from the current siting requirements in § 100.3 would be included as definitions common to the entirety of part 53 in § 50.020 (e.g., "Exclusion Area," "Low Population Zone"). Section 53.3510 would also include two terms that are not currently defined in the existing regulatory framework: "Ground Motion Response Spectra" and "Probabilistic Seismic Hazard Analysis." These terms would be defined in a manner that is largely equivalent to their use in Framework A (subpart D) and would support the use of the alternative, risk-informed, performance-based, graded approach to seismic design provided in § 53.4733.

The proposed siting requirements are based largely on the existing requirements for siting in part 100. Section 53.3515 would provide siting requirements that would be equivalent to the existing requirements in § 100.20 with proposed changes to support the use of these requirements in Framework B. Section 53.3520 would provide siting requirements that would be equivalent to the existing requirements in § 100.21 with proposed changes to support the use of these requirements in Framework B.

Section 53.3525 would provide siting requirements that would be equivalent to the existing requirements in § 100.23, with certain changes to support the alternative use of multiple DBGMs in lieu of the single Safe Shutdown Earthquake Ground Motion when developing the Ground Motion Response Spectra for seismic design purposes.

Section 53.3525 would rely on the development and use of site-specific Ground Motion Response Spectra, as defined in § 53.3510. Ground Motion Response Spectra are based on geologic, seismic, and geotechnical investigations of the site in question. Applicants using appendix S to part 50 would use the Ground Motion Response Spectra to derive the Safe Shutdown Earthquake Ground Motion for use in the design of SSCs important to safety, consistent with the approach taken in the existing regulatory frameworks in part 50 and part 52. Under the alternatives in § 53.4733, applicants would use the Ground Motion Response Spectra to derive the DBGMs for use in the design of SSCs important to safety.

The phrase "site subsurface material properties" would be used in § 53.3525 instead of the phrase "site foundation material" that is currently in § 100.23. This difference reflects that the material properties of the subsurface layers above and below the foundation level must be accounted for when assessing soil-structure interactions.

Subpart O – Construction and Manufacturing Requirements

Proposed subpart O would provide the requirements for construction and manufacturing activities for a commercial nuclear plant for applicants and licensees under Framework B. See the discussion for subpart E in section IV, "Framework A," of this document for a detailed description of the regulatory requirements for construction and manufacturing under Frameworks A and B of part 53.

Subpart P – Requirements for Operation

The proposed subpart P would provide the requirements for the operations phase of a commercial nuclear plant in Framework B. Section 53.4200 would provide a general overview of the objectives in subpart P and would draw a connection between plant safety, personnel, and programmatic controls, including those associated with maintenance effectiveness. This section would be equivalent to § 53.700 in Framework A with the exception of language specific to the safety functions in § 53.230 and other high-level performance requirements that are specific to Framework A. Framework B is more closely aligned with existing regulatory requirements (e.g., part 52) in that overarching safety goals and design requirements would be met by adherence to design criteria and other specific programmatic and technical requirements. To accommodate this difference in structure compared to Framework A, the language in § 53.4200 would not include references to specific, overarching safety functions. A definition of safety functions is included in § 53.020, which describes how safety functions are addressed in each framework.

Section 53.4210 would address maintenance, repair, and inspection programs. The proposed requirements in this section were derived from the requirements in § 50.65 with changes proposed to adapt these requirements for Framework B. These modifications include changes to the language in § 53.4210(a)(3) to reflect that certain commercial nuclear plants may not have refueling schedules or cycles structured similarly to those in the current LWR fleet that were used to develop the existing requirements in § 50.65(a)(3). The modified language in § 53.4210(a)(3) would still limit the maximum time between program evaluations to 24 months.

The scope of SSCs that would be covered by the maintenance, repair, and inspection programs described in § 53.4210 would be modified to ensure technology

inclusiveness when compared to § 50.65(b). These modifications would be reflected in § 53.4210(b)(1), which would use the definition of SR SSCs from § 53.028 to assist in defining the scope of SSCs that would need to be considered, as opposed to the prescriptive list of SR SSCs outlined in § 50.65(b)(1). One additional modification made in § 53.4210(a)(2), as compared to § 50.65(a)(2), would be the requirement that documentation be maintained to demonstrate that monitoring is not required for certain SSCs when the licensee is able to demonstrate that they are being appropriately maintained. This modification would provide clarity and traceability that a particular SSC demonstrates compliance with the requirements in § 53.4210(a)(2).

The proposed requirements for TS in § 53.4213 would be largely equivalent to the requirements in § 50.36 for plants licensed under the existing requirements in part 50 or part 52. Unlike proposed subpart F, which did not carry over into Framework A certain specific requirements from § 50.36 such as the safety limits, limiting safety system settings, and limiting control settings, as explained in the discussion of subpart F, Framework B is carrying over most of the requirements from § 50.36 because Framework B aligns more closely with the traditional licensing approach in part 50 and part 52. Modifications to the requirements taken from § 50.36 would support technology inclusiveness. Modifications to the language taken from existing requirements are also proposed to limit the applicability of these requirements to licenses issued under part 53, which are limited to utilization facilities under AEA section 103.

Further, in Framework B, the NRC is proposing to include the requirements for establishing LCOs in § 50.36, with modifications to the § 50.36 criteria 1, 3, and 4 requirements, for the reasons explained below.

Proposed modifications to criterion 1 in § 53.4213(b)(2)(ii)(A) would add flexibility for designs in which fission product retention would be provided by functional

containment rather than a reactor coolant pressure boundary. Modifications to criterion 3 in § 53.4213(b)(2)(ii)(C) would acknowledge that there are aspects of the functional containment that are not part of the "primary success path" but are still expected to be available. Modifications to criterion 4 in § 53.4213(b)(2)(ii)(D) would provide flexibility for a risk evaluation to be used to inform the establishment of an LCO. This is broader than the current language in § 50.36(c)(2)(ii)(D), which only focuses on establishment of an LCO based on operating experience or a PRA. Risk evaluations in Framework B refer to either a PRA or an AERI, the latter of which could be used to determine whether an LCO is warranted for applicants satisfying the entry criteria for AERI in § 53.4730(a)(34)(ii).

The proposed requirements in § 53.4215 relative to shutting down and restarting a commercial nuclear plant following vibratory ground motion that exceeds the operating-basis earthquake (OBE) ground motion or causes significant damage to the plant are derived from § 50.54(ff). Proposed requirements in § 53.4733 would provide, and appendix S to part 50 would be amended to also provide related requirements for the OBE ground motion for Framework B licensees and applicants.

The requirements for staffing, training, personnel qualifications, and HFE in Framework B would be collocated with those in Framework A. Section 53.4220 would reflect this collocation and would note that the requirements for these areas in proposed §§ 53.725 through 53.830 would be applicable to Framework B.

Section 53.4300 would address programs and would provide equivalent requirements to those proposed in § 53.845, including the flexibilities to combine, separate, and otherwise organize programs and related documents as appropriate for the technologies and organizations associated with the commercial nuclear plant.

Section 53.4310 would address the programmatic requirements for radiation protection. The programmatic requirements for radiation protection in Framework B

would be equivalent to those under Framework A in § 53.850. The proposed rule language in § 53.4310 would only vary from § 53.850 due to different internal references for the two frameworks.

Section 53.4320 would address emergency preparedness program requirements. These requirements would be collocated with those under Framework A in proposed § 53.855. A reference to the requirements in § 53.855 would be provided.

Section 53.4330 would address requirements for security programs. The programmatic requirements for security in Framework B would be equivalent to those under Framework A in proposed § 53.860.

Section 53.4340 would address requirements for quality assurance programs. The programmatic requirements for quality assurance in Framework B would be largely equivalent to those under Framework A in proposed § 53.865. The proposed rule language in § 53.4340 would only vary from § 53.865 due to the difference in internal references for the two frameworks (i.e., proposed subpart K for Framework A and proposed subpart U for Framework B).

Section 53.4350 would provide requirements for fire protection under Framework B. Section 53.4350(a) would describe the requirements for the fire protection plan. It would be equivalent to § 53.875(a) in Framework A and to § 50.48(a). Section 53.4350(a)(3) would describe the fire protection plan requirements for DCs and standard designs. Section 53.4350(b) would establish the general requirements for the fire protection program and would be equivalent to section II.A of appendix R to part 50. Section 53.4350(b)(3) would be equivalent to § 53.250 of Framework A. Section 53.4350(b)(4) would establish that there are performance requirements for the fire protection program and that a fire hazards analysis must be part of the fire protection program.

Section 53.4350(c) would establish general performance requirements for the fire protection program established in § 53.4350(b). It would be equivalent to § 53.440(e) in Framework A and General Design Criterion 3 of appendix A to part 50.

Section 53.4350(d) would establish the general requirements for performing the fire hazards analysis. It would be equivalent to § 53.450(g)(1) of Framework A and section II.B of appendix R to part 50.

Section 53.4360 would provide requirements for ISI and IST for applicants and licensees under Framework B. The proposed requirements would be bifurcated for technology inclusiveness. Boiling or pressurized water-cooled commercial nuclear plant licensees would be required to demonstrate compliance with the existing requirements under § 50.55a. The applicability of § 50.55a is limited to LWRs under Framework B to ensure that Framework B provides an equivalent level of safety as an LWR licensed under part 50 or part 52. Non-LWR licensees would be required to demonstrate compliance with the same requirements for ISI and IST in Framework A in § 53.880.

Section 53.4380 would provide the requirements for environmental qualification (EQ) of electric equipment important to safety for commercial nuclear plants licensed under Framework B. This section would provide requirements that would be equivalent to those currently in § 50.49, with minor exceptions. Notably, in § 53.4380(e)(3), combustion would be added as a new chemical effect to consider as part of the EQ program due to the wide spectrum of fluids and materials that may be employed in certain non-LWR designs. Sodium combustion and the resulting combustion products (e.g., NaOH) provides one example of a chemical effect specific to a particular type of reactor design. Additional examples include combustion products from sodium-concrete reactions that lead to hydrogen release, burning, and non-sodium fires. Other

modifications to the proposed requirements, as compared to the existing requirements in § 50.49, would conform to the requirements to Framework B.

Section 53.4390 would provide requirements for the development, implementation, and maintenance of procedures and guidelines. This section would provide the equivalent of the requirements in § 53.910 with conforming changes proposed to accommodate the use of these proposed requirements in Framework B. Section 53.4390(b)(5) would provide the equivalent requirements to § 50.54(hh) regarding potential aircraft threats that are applicable to licensees under the existing regulatory frameworks in part 50 and part 52.

Section 53.4400 would address the requirements for integrity assessment programs. The language in proposed § 53.4400 was developed to mirror the requirements in proposed § 53.870 to ensure that licensees under Framework B adequately address the effects of aging, cyclic and transient loads, and other degradation mechanisms on certain SSCs. The primary difference between the integrity assessment program requirements in Framework B, as compared to Framework A, would be the scope of SSCs that would be included in the program. This difference would result from the fundamental variation in how SSCs are classified and categorized between the two frameworks. The scope of SSCs within the integrity assessment program under proposed Framework B was developed to be equivalent to the scope of SSCs for which maintenance effectiveness would be assessed under § 53.4210(b).

Section 53.4410 would establish regulatory requirements for primary containment leakage rate testing programs for water-cooled commercial nuclear plants. This section would provide the equivalent of § 50.54(o) with conforming changes proposed to support the use of these provisions in Framework B. This requirement is being proposed to accommodate the potential for new water-cooled commercial nuclear plants licensed

under Framework B. Inclusion of this proposed requirement would provide assurance that essentially leak-tight containments used in water-cooled commercial nuclear plant designs are designed, operated, and maintained consistent with the requirements under the existing regulatory framework. This would ensure that LWR designs licensed under Framework B will provide an equivalent level of protection of public health and safety as LWR designs licensed under parts 50 or part 52.

Section 53.4420 would establish the regulatory requirements for commercial nuclear plant applicants and licensees to mitigate beyond-design-basis events. The proposed requirements would be largely equivalent to the existing, analogous requirements under § 50.155, with certain modifications to ensure technology inclusiveness. Examples of modifications proposed include the replacement of LWR-specific damage states (e.g., loss of normal access to the normal heat sink for passive reactor designs) with a more generic focus on damage states that would immediately challenge the safety functions of the commercial nuclear plant. An analogous set of requirements is not provided and is not necessary in Framework A because the requirements for identifying and analyzing LBEs under subpart C would inherently address these requirements.

Subpart Q – Decommissioning

Proposed subpart Q would provide the requirements for decommissioning of a commercial nuclear plant for applicants and licensees implementing Framework B (subparts N through U). The requirements for decommissioning in this subpart would be equivalent to those provided in proposed subpart G for Framework A, except for minor reference changes. Specifically, the only variations between proposed subpart G in Framework A and proposed subpart Q in Framework B would be the references to various sections throughout part 53 (i.e., inter- and intra-subpart references in proposed

subpart Q are made to the analogous sections in Framework B). See the discussion for Framework A, subpart G, in section IV, "Framework A," of this document for a more detailed description of the regulatory requirements for decommissioning.

Subpart R – Licenses, Certifications, and Approvals

Subpart R would provide requirements for applications under Framework B for NRC licenses, certifications, or approvals for commercial nuclear plants. The proposed requirements in subpart R would govern general application requirements applicable to all Framework B applications as well as specific application requirements for Framework B applicants for LWAs, ESPs, standard design approvals, standard DCs, MLs, CPs, OLs, and COLs. Accordingly, the proposed requirements in subpart R would cover all of the licensing, certification, and approval processes currently covered under parts 50 and 52, with the exception of the process for early review of site suitability issues. As with the proposed rules in Framework A, interactions with external stakeholders during the development of the proposed rule did not identify significant interest in or need for including the process for early review of site suitability issues in part 53. Consequently, much of the proposed subpart R regulatory text is identical to the corresponding language in parts 50 and 52, as described in the following paragraphs, with minor changes to account for cross references in Framework B, to make language technology inclusive, or to reflect the unique analytical approach in Framework B. In these instances, this preamble discussion will describe the language as "equivalent" to the existing corresponding requirement in part 50 or part 52 and will describe any deviations, where applicable.

The proposed structure and requirements in subpart R also closely align with the proposed structure and requirements in subpart H. All of the proposed sections that would provide administrative and process (i.e., non-technical) requirements are identical.

Examples of these requirements include issue finality, referrals to the ACRS, and the duration of a given license. The explanation of those sections in section IV, "Framework A," of this document discussing subpart H of Framework A also apply to the corresponding section in subpart R and are not repeated here. For example, the explanation of § 53.1143, "Filing of applications," for ESPs in Framework A covers § 53.4753, "Filing of applications," for ESPs in Framework B. Therefore, the subsequent discussion regarding the proposed requirements in subpart R focuses only on those sections and paragraphs that differ between subpart H and subpart R.

Section 53.4730 would provide general technical requirements. Subsequent technical contents of application sections for the individual application types would specify which general technical requirements in § 53.4730 apply. For example, § 53.5016 would denote which requirements in § 53.4730 are applicable to a COL application. Consolidation of the technical requirements into one section would minimize the length of the rule and limit the potential that future modifications to these requirements would be implemented inconsistently across the application types.

The majority of the requirements proposed in § 53.4730 would be derived from comparable requirements in § 52.79, which governs contents of applications for COL applications in part 52. Detailed discussion of requirements that would differ from those in existing part 50 or 52 requirements is provided in the following paragraphs. Additional information regarding the source reference for these requirements is also discussed, as applicable.

Section 53.4730(a)(1) would contain site safety analysis requirements, derived from § 52.79(a)(1), which provides content of application requirements for a part 52 COL, and would provide similar requirements for other Framework B license application types as described in § 53.4730(a). Modifications have been made to accommodate

different licensing applications apart from a COL, such as an ESP, OL, CP, DC Rule, Standard Design Approval, or an ML, and to provide for a sufficiently technology-inclusive set of requirements related to radiological releases in § 53.4730(a)(1). To maintain technology inclusivity, § 53.4730(a)(1)(vi) includes the language "fuel or core damage or potential for large radiological releases from sources other than the reactor system" to address all radiological accident sources, including those that are not inside the traditional reactor coolant boundary but directly support reactor operation. Examples could include fuel/coolant cleanup systems in molten fuel designs or online continuous fueling systems.

Due to the broad range of technologies currently being considered, and in order to provide rule text that can accommodate further unanticipated technology types, the requirement in § 53.4730(a)(1) would be written to accommodate multiple approaches. The siting requirements in § 53.4730(a)(1)(i) through 53.4730(a)(1)(v) would be equivalent to the requirements in § 52.79(a)(1)(i) through 52.79(a)(1)(v).

The requirement in § 53.4730(a)(1)(vi) to analyze a "postulated fission product release, using the expected demonstrable barrier leak rate(s) and any fission product cleanup systems intended to mitigate the consequences of the accidents" does not require consideration of a postulated fission product release that would result in potential hazards exceeded by those from any accident considered credible, as required in the corresponding provision in § 52.79(a)(1)(vi). Instead, two options would be provided in § 53.4730(a)(1)(vi) to provide flexibility: use of a mechanistic source term derived from physically representative models of the facility response, or use of a bounding assessment assuming severe plant conditions, such as those evaluated when considering severe accident vulnerabilities as would be required in § 53.4730(a)(5)(v). In both cases, the assessment must be based on conditions more severe than those

analyzed for DBAs in proposed § 53.4730(a)(5)(ii), and must serve to effectively demonstrate defense-in-depth, consistent with Commission policy.

Similar to the existing requirements in § 52.79(a)(1)(vi), the fission product release assumed for this evaluation in § 53.4730(a)(1)(vi) must be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of credible accidental events. Realistic best-estimate assessments (that include considerations for uncertainty) of the scenario, whether directly analyzed as part of a physical sequence used in a mechanistic source term or created to provide a demonstrably bounding event, would be appropriate for use in performing the assessments under this section.

Section 53.4730(a)(1)(vi) would also explicitly require that the application contain information related to the barriers credited in the assessment. This information is intended to in part address how the design provides defense-in-depth through multiple barriers. Due to the variety of potential radionuclide release mitigation options, this section would not presume a fuel-coolant boundary and integral essentially leak-tight containment barrier arrangement like the requirements in parts 50 and 52 that were developed for LWRs. Accordingly, the purpose of proposed § 53.4730(a)(1)(vi) is to ensure that doses to the public remain below specified levels in the event of a major accident. Acceptance criteria in § 53.4730(a)(1)(vi)(A) and (B) for these analyses would be the same as the comparable requirements in each application type in parts 50 and 52, with the addition of a supplemental requirement in § 53.4730(a)(1)(vi)(C) that the design satisfy acceptable dose consequence criteria. This supplemental requirement would be added for applications where the applicant elects to use a more restrictive set of dose consequence criteria (e.g., 1 rem TEDE over 96 hours) to demonstrate

~~compliance with other alternative requirements (e.g., emergency preparedness for small modular reactors [SMRs] and other nuclear technologies).~~

~~Section 53.4730(a)(2) would provide requirements related to the facility description to be provided in the FSAR and is derived from and similar to requirements in § 52.79(a)(2), which applies to a part 52 COL. This section would require that information on SSCs and facility design features be discussed insofar as they are pertinent to the safety of the facility; examples of SSCs the NRC expect would be pertinent to safety are included in the regulation. These examples are not exclusive or limiting, and what SSCs fall within this category will be dependent on the design. Safety impacts of SSCs would need to consider interfaces with other aspects of the facility. Details of the design or function of many secondary system components may not be pertinent to the safety of a given facility, but the characteristics and boundary conditions associated with the secondary system interface may be pertinent to the response of the facility and therefore should be provided.~~

~~Section 53.4730(a)(3) would provide requirements related to the kinds and quantities of radioactive materials to be discussed in the FSAR and is derived from § 52.79(a)(3) for a COL and similar requirements for other license application types. Section 53.4730(a)(3) would include additional language beyond that currently in § 52.79(a)(3) to clarify the role of a combination of programmatic controls and design features to satisfy ALARA principles. The proposed rules relative to ALARA principles are equivalent to those proposed in § 53.260(b) under Framework A.~~

~~Section 53.4730(a)(4) would require applicants to provide PDCs~~. ~~Use of design criteria is foundational in providing regulatory evaluation standards for a deterministic approach. Existing section 52.79(a)(4) provides a comparable requirement, but § 53.4730(a)(4) would more clearly delineate the requirements for PDCs~~. ~~For LWRs, the~~

PDCs would be required to be based on the general design criteria (GDCs) in appendix A to part 50. For non-LWRs, the PDCs would be required to establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs important to safety, consistent with existing requirements in Appendix A to part 50 for the role of the PDCs. Non-LWR applicants could use the GDCs or other generally accepted methods (such as RG 1.232) to inform the development of the provided PDCs.

Section 53.4730(a)(5) would contain requirements for analysis and evaluation of initiating events and is derived from § 50.34(a)(4) (similar requirements exist for part 52 applications). The proposed section would provide an additional level of detail with respect to the categorization of events and the associated acceptance criteria and analysis requirements. These requirements would be generally consistent with existing regulations, historical practice, and international standards for these classes of events. The phrase "to include the cumulative risk from all radionuclide sources on site licensed under Framework B of part 53" would be included in § 53.4730(a)(5)(i)(B) to make clear that the analysis must consider all radionuclide sources licensed as part of the commercial nuclear reactor license, but not those addressed by a separate NRC licensing action (such as the subsequent installation of an independent spent fuel storage installation (ISFSI)). This clarification would help provide for consistent regulation of radionuclide sources while providing a technology-inclusive pathway to do so, as some reactor designs may not confine all the radionuclide sources within a single component (the fuel plus any coolant activity, in the case of traditional LWRs).

Section 53.4730(a)(5)(ii) would set forth requirements for DBAs. It would require applicants to define acceptance criteria for DBAs, similar to the existing part 50 and 52 requirements for LWR fuel acceptance criteria. SSCs used to mitigate the effects of DBAs would be required to be SR, consistent with existing regulations and practices for

this class of events. The requirements in § 53.4730(a)(5)(ii)(D) would provide an avenue for an applicant to provide bounding analyses (potentially involving conservative assumptions with margin beyond the maximum expected values to adequately bound events) for some or all of the analytical requirements for this part. This is largely consistent with existing practice—a single analysis to cover a category of event (e.g., overcooling) is often provided as part of a safety analysis. Section 53.4730(a)(5)(ii)(D) would go a step further and also allow for bounding analyses to be provided to cover larger portions of the DBA analytical space, provided the analysis envelopes the full range of conditions it is stated to bound.

Section 53.4730(a)(5)(ii)(E) and (F) would include requirements, for reporting, largely equivalent to § 50.46, which addresses emergency core cooling systems, for all reactor designs. Applicants would be required to identify surrogate safety acceptance criteria, akin to peak cladding temperature for LWRs, and track and report errors in the analysis for these acceptance criteria. These acceptance criteria would offer the flexibility to use either: (1) the traditional SAFDL (e.g., departure from nucleate boiling to protect fuel cladding); (2) the specified acceptable SARRDL concept, discussed in RG 1.232; or (3) other acceptance criteria of the applicant's choosing that serve a similar role in their analysis.

Section 53.4730(a)(5)(iii) would provide requirements for normal operation and AOOs. For AOOs in particular, applicants would be required to provide analyses that demonstrate the consequences of AOOs comply with part 20 acceptance criteria, consistent with the existing regulatory framework. Sections 53.4730(a)(5)(iii)(B) and (C) would require that applicants analytically demonstrate that AOOs can be precluded from escalating to more severe events and do not impair the capability of SR SSCs to perform

safety functions to mitigate DBEs, consistent with current requirements for this class of events in parts 50 and 52.

Section 53.4730(a)(5)(iv) would establish requirements for a subset of events with consequences potentially greater than DBAs, referred to as "additional licensing-basis events" (ALBEs). The deterministic process for analyzing DBEs included in Framework B, is derived from part 50 and dates back more than 50 years in the nuclear industry; this process is a well-established means to provide a reasonably comprehensive assessment of challenges to a design. However, decades of operating experience and research have shown there are limitations associated with this process. In particular, this process may not adequately address challenges that occur due to overreliance on a single analysis, design function or feature within the analysis, or considerations resulting from common cause failure from a single initiating event.

Consistent with the reasoning outlined in SECY-83-293, "Amendments to 10 CFR 50 Related to Anticipated Transients Without Scram (ATWS) Events," and the June 21, 1988, rulemaking entitled "Station Blackout," (53 FR 23203), the NRC has imposed requirements for reducing risk associated with credible events that have the potential to lead to plant conditions that exceed design parameters and potential unacceptable consequences. Section 53.4730(a)(5)(iv)(A) would require that applicants perform assessments for events that are unlikely but credible that could lead to situations not considered for DBAs. Although not subject to the full panoply of requirements that apply to the analysis of DBAs and the inclusion of design features and other measures to prevent or mitigate DBAs, ALBEs would be subject to the requirements in § 53.4730(a)(5)(iv)(A).

Section 53.4730(a)(5)(iv)(B) would require mitigation of additional licensing basis events that involve recognized initiators or complex accident sequences that may have

substantial uncertainty associated with their frequencies and outcomes. Given the reduced role of PRA in Framework B, which is a central tenet of this framework, it is difficult to directly establish a threshold for these additional licensing basis events. The provisions in § 53.4730(a)(5)(iv)(B) would include requirements for events of comparable frequency to DBEs (considering uncertainty) with the potential for unacceptable consequences that are not captured within the scope of the requirements associated with those DBEs. For existing LWRs, operating experience justified regulatory actions for ATWS and SBO events (as examples) because those events were credible and had the potential to result in core damage, challenges to containment, and the release of radioactivity to the public and environment. The conceptual phenomena associated with these events could also apply to other reactor technology types; the requirement in § 53.4730(a)(5)(iv)(B) is intended to ensure these types of event sequences are appropriately considered in the design and analysis under Framework B.

Under the proposed approach in § 53.4730(a)(5)(iv), a designer or applicant would have numerous alternatives beyond adding systems to address such events: (1) credit an already existing (non-safety-related) system or procedural action with mitigating the event in question and either augment the quality or availability of the system or identify how or why the alternative would be expected to be available to mitigate the event; (2) provide additional analysis or testing to demonstrate the frequency of the event is not similar to DBEs, considering the efficacy of systems that already exist and are credited to mitigate similar DBEs; or (3) identify how defense-in-depth measures (e.g., additional barriers, programmatic controls) for the design prevent consequences from reaching unacceptable levels by providing sufficient safety margin. SSCs identified to perform this mitigation could, but need not be, SR, in accordance with § 53.4730(a)(5)(iv)(B)*(1)*.

Section 53.4730(a)(5)(iv)(A) would identify events for which § 53.4730(a)(5)(iv)(C) would establish performance, reliability, and availability targets for safety functions. This requirement would be akin to the regulatory treatment of non-safety systems under part 52.

Section 53.4730(a)(5)(v) would require a description and analysis of design features for the prevention and mitigation of severe accidents. This requirement is intended to provide a technology-inclusive requirement filling the same role as § 52.79(a)(38). This paragraph would require applicants to provide information regarding safety features and barriers used in the analysis and identify severe accident vulnerabilities that could result in fission product releases. Notably, the proposed requirements would not contain dose or analytical acceptance criteria—only analysis and evaluation requirements, consistent with part 52.

Section 53.4730(a)(5)(vi) would provide a new technical requirement for applicants to consider chemical hazards of licensed material. The broad spectrum of reactor technologies that could be licensed under part 53 includes those using coolants and other materials that pose unique chemical hazards in addition to radionuclide source terms. The language in this section would be based on the requirement proposed in § 53.440(k) with conforming changes made for Framework B.

Section 53.4730(a)(6) would provide requirements for fire protection and would be equivalent to the existing requirements under § 52.79(a)(6) and 52.79(a)(40), with conforming changes to reference equivalent requirements for operation under subpart P.

Section 53.4730(a)(7) would provide requirements for combustible gas control and would be equivalent to the existing requirements under § 52.79(a)(8). The requirements from § 50.44 that would be referenced in this paragraph are considered

~~sufficiently technology-inclusive such that § 50.44 could be met by any future design without the need for an exemption.~~

~~Section 53.4730(a)(8) would provide application requirements for the EQ of electric equipment important to safety and would be equivalent to the existing requirements under §§ 52.79(a)(10) and 50.49, by extension. Modifications from the source requirements in parts 50 and 52 have been proposed to reflect equivalent program requirements for EQ in subpart P (§ 53.4380). The requirements in § 53.4730(a)(8) would be reorganized when compared to § 52.79(a)(10). This reorganization reflects that the level of detail provided for EQ of electric equipment important to safety varies depending on the application type.~~

~~Section 53.4730(a)(9) would provide requirements for the role of personnel and would be equivalent to the existing requirements under § 52.79(a)(14) and § 52.79(a)(34). Modifications from the source requirements in part 52 have been proposed to reflect references to the relevant requirements for operation (e.g., operator licensing) that have been proposed in subpart F.~~

~~Section 53.4730(a)(10) would provide application requirements for maintenance effectiveness programs and would be equivalent to the existing requirements under §§ 52.79(a)(15) and 50.65, by extension. Proposed modifications reflect conforming changes made to cross-reference the equivalent requirements for operation under subpart P.~~

~~Section 53.4730(a)(11) would require applicants to identify ALARA design objectives for limiting radiation dose to members of the public. It would also require that the Safety Analysis Report include information to demonstrate that the design is adequate to demonstrate compliance with the ALARA design objectives during normal reactor operations, including expected operational occurrences (not accidents). The~~

Safety Analysis Report would be required to include an estimate the quantities of radionuclides to be released during normal reactor operation and the dose to the maximally exposed member of the public from the planned licensed operation.

The requirement in § 53.4730(a)(11) would be similar to the existing requirements under § 50.34a, which require that ALARA design objectives be developed for normal effluents and that applicants describe the means for keeping doses ALARA for part 50 and part 52 reactor licensees. However, instead of referencing appendix I to part 50 for the design objectives (as is done in § 50.34a), a criterion of 10 mrem/year TEDE for planned licensed operation is proposed. The design objectives in appendix I to part 50 and as proposed in part 53 provide objective performance criteria that constitute a demonstration that doses to the public are ALARA and no additional efforts are required to further reduce radioactive effluent releases or other contributors to public dose from normal operations. Reasons for the change include the following. First, appendix I to part 50, is based on International Commission on Radiological Protection (ICRP) Publication 2 dose methodology, which is inconsistent with most of the other regulatory dose criteria used by the NRC, such as the dose criteria in part 20, which use TEDE criteria (ICRP 26 and 30). The use of TEDE criteria would allow the same dose methodology to be used for part 20 and the ALARA design objectives in Framework B. In addition, TEDE criteria include organ dose weighting factors, which allows for simplified dose criteria, instead of including separate criteria for organ doses. Second, the proposed part 53 TEDE criteria for the ALARA design objectives would also include consideration of direct radiation (non-effluent) exposure. This is appropriate because while the quantities of radioactive material released from the facility are expected to be low and the total dose to the public is expected to be low, many new reactors may have a smaller site footprint and members of the public could be located nearer to radiation

sources. For current licensees, direct radiation is normally included in the offsite dose calculation manual and included in annual radioactive effluent reports. Last, the 10 mrem/year TEDE dose criterion is consistent with § 20.1101(d), which is used for non-power reactor air emissions.

As stated in the proposed requirements under § 53.4730(a)(11) and consistent with § 50.34a and appendix I to part 50, the 10 mrem/year ALARA design objective for the planned licensed operation is not a dose limit and different criteria for design objectives may be allowed with justification, based on a specific applicant or licensees circumstances. While the part 53 ALARA design requirements do not include a cost-benefit population dose criterion, as is used in section II.D of appendix I to part 50, a cost-benefit analysis may be used to justify an alternative design objective value. NUREG-1530, Revision 1, "Reassessment of NRC's Dollar Per Person-Rem Conversion Factor Policy, Final Report," and RG 1.110, "Cost-Benefit Analysis for Radwaste Systems for Light-Water-Cooled Nuclear Power Reactors," provide guidance that may be useful in evaluating the cost-benefit of adding additional features to reduce the radiation exposure to members of the public.

The design objective is not a limit for operation. Licensees would be permitted flexibility of operation to generally maintain the release of radioactive material effluents and the dose to members of the public in unrestricted areas at small percentages of the dose limits specified in § 20.1301 and within design objectives for the licensed operations. Section 53.4730(a)(11) would require a licensee using this flexibility to keep levels of radioactive material in effluents and doses to members of the public as low as is reasonably achievable.

Section 53.4730(a)(12) would provide three requirements for post-accident radiation monitoring and protection that would be equivalent to the existing requirements

under §§ 50.34(f)(2)(vii), 50.34(f)(2)(viii), and 50.34(f)(2)(xv). Consistent with the existing requirements under § 50.34(f), these would only be required if they are technically relevant to an applicant's proposed design.

Section 53.4730(a)(14) would provide requirements for the seismic design of certain SSCs for applicants under Framework B that are equivalent to the existing requirements under § 52.79(a)(19) and appendix S to part 50, by extension, with modifications to conform the existing language to Framework B. These conforming changes include language acknowledging that the GDCs in appendix A to part 50 provide guidance for establishing the PDCs for other designs even though the GDCs may not be directly applicable to all designs under Framework B. This is specifically reflected in the proposed requirements, which would require that applicants provide information on earthquake engineering criteria, in part to demonstrate compliance with a PDC addressing natural external hazards (corresponding to GDC 2). This paragraph would also provide flexibility for applicants, with an option to use alternative, risk-informed and performance-based seismic design requirements under § 53.4733 if sufficient risk insights are available.

Section 53.4730(a)(15) would provide application requirements for emergency plans and would be equivalent to the existing requirements under § 52.79(a)(21) with conforming changes made to reference specific program requirements under subpart P.

Section 53.4730(a)(16) would provide requirements for State, participating Tribal, and local government cooperation in EP and would be equivalent to the existing requirements under § 52.79(a)(22) with modifications to include participating Tribal organizations. This change aligns with the Commission's policy statement "Tribal Policy Statement" dated January 9, 2017, and the 2019 issuance of NUREG-0654/Federal Emergency Management Agency (FEMA) REP-1, Revision 2, "Criteria for Preparation

and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," which encourages the involvement of Tribal Governments in NRC activities.

Section 53.4730(a)(17) would provide requirements for safety feature testing, analyses, operating experience, and prototypes and would be equivalent to the existing requirements under §§ 52.79(a)(24) and 50.43(e) with conforming changes made to reference requirements equivalent to § 50.43(e) that are proposed in § 53.090(c).

Section 53.4730(a)(18) would provide application requirements for quality assurance. Section 53.4730(a)(18)(i) would be equivalent to the existing requirements under § 50.34(f)(3)(iii), with modifications made for conforming changes. Section 53.4730(a)(18)(ii) would be equivalent to the existing requirements under § 52.79(a)(25), with modifications made for conforming changes.

Section 53.4730(a)(19) would provide requirements for organizational structures and would be equivalent to the existing requirements under § 52.79(a)(26).

Section 53.4730(a)(20) would provide requirements for managerial and administrative controls and would be equivalent to the requirements under § 52.79(a)(27), with conforming changes, and § 50.34(f)(3)(vii), with modifications made to limit the applicability of this requirement based on its relevance to a given applicant consistent with the existing applicability of requirements under § 50.34(f). Specifically, the phrase "as applicable" would serve the same purpose as the phrase "technically relevant" in § 50.34(f) and applicants would only have to address this requirement if it were applicable. Additional changes would include changing "nuclear steam supply vendor" to "commercial nuclear reactor vendor" to ensure that the requirement is technology-inclusive.

~~Section 53.4730(a)(21) would provide requirements for preoperational testing and initial startup and would be equivalent to the existing requirements under § 52.79(a)(28).~~

~~Section 53.4730(a)(22) would provide requirements for normal operations and maintenance and would be equivalent to the existing requirements under § 52.79(a)(29), with conforming changes made to reference specific program requirements under subpart P.~~

~~Section 53.4730(a)(23) would provide application requirements for TS and would be equivalent to the existing requirements under § 52.79(a)(30), with conforming changes made to reference specific requirements under subpart P and modifications to differentiate the requirements applicable to different application types. Specifically, these modifications would acknowledge the difference in level of detail for TS required for each application type and would be consistent with the existing requirements under parts 50 and 52.~~

~~Section 53.4730(a)(24) would provide application requirements for FFD programs and would be equivalent to the existing requirements under § 52.79(a)(44) and part 26, by extension. Changes that are proposed for part 26 as part of this rulemaking would also be applicable to Framework B.~~

~~Section 53.4730(a)(25) would provide requirements for assessing the risks associated with multi-unit sites (construction-related impacts on operating reactors) and would be equivalent to the existing requirements under § 52.79(a)(31).~~

~~Section 53.4730(a)(26) would provide requirements for the technical qualifications of an applicant and would be equivalent to the existing requirements under § 52.79(a)(32).~~

Section 53.4730(a)(27) would provide application requirements for training programs and would be equivalent to the existing requirements under § 52.79(a)(33), with conforming changes made to reference specific program requirements under subpart F (subpart P points to subpart F for these requirements).

Section 53.4730(a)(28) would provide application requirements for physical security programs and would be equivalent to the existing requirements under § 52.79(a)(35) with conforming changes made to reference specific program requirements under subpart P.

Section 53.4730(a)(29) would provide application requirements for safeguards, security, and related training and qualifications and would be equivalent to the existing requirements under § 52.79(a)(36) with a modification that would include an additional reference to § 73.22.

Section 53.4730(a)(30) would provide requirements for assessing operating experience and would be equivalent to the existing requirements under § 52.79(a)(37) with modifications that acknowledge that newer designs may have limited operating experience.

Section 53.4730(a)(31) would provide application requirements for radiation protection programs by requiring a description of the radiation protection program required by § 53.4310, which in turn requires compliance with the requirements of part 20. This section would be equivalent to the existing requirements under § 52.79(a)(39) with conforming changes made to reference specific program requirements under subpart P.

Section 53.4730(a)(32) would provide requirements for preventing criticality accidents and would be equivalent to the existing requirements under § 52.79(a)(43)

with modifications that reference the proposed requirements in § 53.440(m) in lieu of the existing requirements under § 50.68.

Section 53.4730(a)(33) would provide requirements for minimization of contamination to facilitate decommissioning and would be equivalent to the existing requirements under §§ 52.79(a)(45) and 20.1406, by extension.

Section 53.4730(a)(34) would require a description of a risk evaluation and its results in the Safety Analysis Report. Framework B would maintain the traditional role of specific design rules (including use of the single failure criterion as a tool in the reactor safety review process and deterministic approaches to define LBEs and performance requirements for SSCs) and the establishment of PDCs to ensure that safety criteria are met. The risk evaluation would be used to help confirm that a commercial nuclear plant can be constructed and operated without undue risk to the public health and safety. The risk evaluation would be based on a PRA or an AERI provided that specified entry conditions are met.

The proposed use of risk evaluation in Framework B would implement existing Commission policy. In its Advanced Reactor Policy Statement, the Commission stated its expectation that advanced reactor designs will comply with the Commission's Safety Goals Policy Statement, the Commission's PRA Policy Statement, and the Commission's policy statement "Severe Reactor Accidents Regarding Future Designs and Existing Plants," dated August 8, 1985. The proposed use of PRA as one approach to develop a risk evaluation would be equivalent to existing requirements in part 52 and to proposed requirements for part 50 CPs and OLs as discussed in SECY-22-0052, "Proposed Rule: Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150-AI66)." The proposed use of AERI in lieu of a PRA, provided that specified entry conditions are met, would be consistent with the

Commission's PRA Policy Statement. There, the Commission noted that "… not all of the Commission's regulatory activities lend themselves to a risk analysis approach that utilizes fault tree methods. In general, a fault tree method is best suited for power reactor events that typically involve complex systems. Given the dissimilarities in the nature and consequences of the use of nuclear materials in reactors, industrial situations, waste disposal facilities, and medical applications, the Commission recognizes that a single approach for incorporating risk analyses into the regulatory process is not appropriate." With respect to using risk evaluation in a confirmatory role during initial licensing processes, an AERI approach would be expected to provide results that are equivalent to the results provided by a PRA if the AERI entry conditions are satisfied. Specifically, AERI would yield the following insights: (1) a demonstrably conservative risk estimate for comparison to the Commission's QHOs; (2) a search for severe accident vulnerabilities; (3) a qualitative identification of risk insights; and (4) an assessment of defense-in-depth adequacy.

The proposed AERI entry conditions in § 53.4730(a)(34) would allow applicants for approvals, certifications, licenses, and permits under Framework B to develop an AERI in lieu of a PRA when the consequences of a postulated bounding event are below specified criteria, which would ensure that the use of AERI is consistent with the Commission's expectations described above. If the postulated bounding event demonstrates compliance with the proposed consequence and distance criteria in § 50.4730(a)(34)(ii)(A), then the proposed commercial nuclear plant would reasonably be expected to comply with the Commission's safety goals without the need to estimate the likelihood of individual event sequences. The proposed AERI entry conditions would also include a requirement in § 53.4730(a)(34)(ii)(B) to inform the identification of the postulated bounding by conducting a systematic and comprehensive search for severe

accident scenarios that considers various aspects of the proposed commercial nuclear plant's design and operation. Accordingly, the proposed AERI entry conditions were selected such that if they are met, they would limit use of the proposed AERI approach to commercial nuclear plants with relatively small fission product inventories and straightforward designs that do not involve overly complex systems (such as some microreactors or other small power reactors) such that the development of a PRA to provide quantitative risk insights would not be warranted. The proposed AERI entry conditions would not be safety or siting criteria. Rather, they would be used to determine which applicants could develop an AERI in lieu of a PRA to demonstrate compliance with the proposed risk evaluation requirement in § 53.4730(a)(34), when the requirements to address the mitigation of beyond-design-basis events in § 53.4420 must be met, and when the requirements to address combustible gas control in § 53.4730(a)(7) must be met. In addition, the proposed AERI entry conditions would be used in combination with other conditions to determine when a commercial nuclear plant is a self-reliant mitigation facility, as provided in § 53.800(a)(2).

Section § 53.4730(a)(35) would provide requirements for applicants to assess the potential effects of aircraft impacts. These proposed requirements would be equivalent to the aircraft impact requirements in the existing regulatory frameworks in § 50.150. The proposed requirements in this section have been modified from § 50.150 to be technology-inclusive.

Section 53.4730(a)(36) would include requirements for retaining radionuclides in a containment. The proposed rules would be split into two sets of requirements. Water-cooled reactors would be required to have an essentially leak-tight containment structure, subject to the same requirements in place for a part 50 or 52 application. This is consistent with the existing requirements and Commission policy, and therefore would

provide a similar level of protection of public health and safety as provided by parts 50 and 52. For non-LWRs, the proposed functional containment requirements would be provided in lieu of existing containment-related regulatory requirements developed for LWRs. However, non-LWR applicants could choose to provide a containment structure consistent with the LWR containment requirements as an essential part of their functional containment. These requirements are intended to be high-level, technology-inclusive requirements for non-LWRs, consistent with the Commission policy stated in SECY-18-0096, "Functional Containment Performance Criteria for Non-Light-Water Reactors," and the associated SRM. These requirements would establish what constitutes a functional containment and makes functional containment SSC qualification commensurate with the purpose of the component (SR if used to mitigate against DBAs).

Section 53.4730(a)(37) would provide requirements that would be applicable only to water-cooled reactor designs. These requirements would provide an equivalent level of safety to the requirements set forth in parts 50 and 52 using a deterministic approach while also maintaining technology-inclusive requirements overall. The rules in this section would apply certain technology-specific requirements from parts 50 and 52 to applicants for water-cooled reactor designs under Framework B. The applicability of the individual paragraphs in this section would be refined further in some instances to maintain alignment with the existing requirements under parts 50 and 52 (e.g., SBO requirements under § 50.63 are only applicable to light-water cooled commercial nuclear plants and not all water-cooled designs).

Section 53.4731 would describe risk-informed classification of SSCs and would provide an alternative in Framework B that is equivalent to that provided in § 50.69. The proposed alternatives in § 53.4731 would not be available for applicants and licensees

that elect to perform an AERI approach in lieu of a PRA to demonstrate compliance with the requirements for a risk evaluation in accordance with § 53.4730(a)(34). This limitation is proposed because an AERI may not provide the quantitative risk information that has historically been required to implement the risk-informed SSC classification scheme permitted by § 50.69.

Section 53.4733 would provide alternative rules for the seismic design of certain SSCs. These rules would provide an alternative to appendix S to part 50. Section 53.4733 could be used by applicants and licensees that have risk insights sufficient to grade the assumptions and inputs necessary for the seismic analyses and qualification of SSCs important to safety. This would be accomplished through the use of DBGMs in lieu of the single safe shutdown earthquake ground motion; either would be determined in accordance with the requirements of subpart N.

Each DBGM set would have horizontal and vertical components that could be applied to the dynamic analysis and qualification of a particular SSC commensurate with the risk significance of the SSC (e.g., less severe design assumptions for a low risk-significant SSC with a correspondingly low SDC). Guidance would be developed to provide additional clarity on the implementation of this graded approach to seismic design.

The proposed alternatives in § 53.4733 would largely be equivalent to those proposed in Framework A (§ 53.480), with some exceptions. The primary difference between § 53.480 and § 53.4733 is the SSCs to which the rules would apply. The scope of SSCs to which the alternatives in § 53.4733 would apply are those that are important to safety; in contrast, these rules would apply to SR and NSRSS SSCs in Framework A. The existing regulations in part 50 and part 52 use this concept for determining the scope of SSCs that must be designed to withstand the effects of earthquakes.

~~Framework B has largely adopted the same approach as that used in the existing regulations.~~

~~The alternatives in § 53.4733 would also focus on the use of PDCs instead of functional design criteria, which are used in Framework A. This difference would be reflected in § 53.4733(c) and 53.4733(d) (as compared to § 53.480(c) and 53.480(d)). The use of PDCs instead of functional design criteria would be a fundamental difference between the frameworks where the former is consistent with the existing regulatory philosophy in part 50 and part 52 that aligns closely with the approach taken in Framework B. Subpart U would provide quality assurance requirements for certain design activities performed to demonstrate compliance with the alternatives under § 53.4733.~~

~~Section 53.4756 would provide the technical content of application requirements for ESPs under Framework B. This section would provide the equivalent of § 52.17 with modifications made for technology-inclusiveness and conforming changes necessary for Framework B. Most conforming changes would reference paragraphs in § 53.4730 that would be equivalent to the existing paragraph requirements and references in § 52.17.~~

~~Section 53.4809 would provide the technical content of application requirements for standard design approvals under Framework B. This section would provide the equivalent of § 52.137 with modifications made for technology-inclusiveness and conforming changes necessary for Framework B. Most conforming changes would reference paragraphs in § 53.4730 that would be equivalent to the existing paragraph requirements and references in § 52.137.~~

~~Section 53.4839 would provide the technical content of application requirements for DCs under Framework B. This section would provide the equivalent of § 52.47(a) with modifications made for technology-inclusiveness and conforming changes~~

~~necessary for Framework B. Most conforming changes would reference paragraphs in § 53.4730 that would be equivalent to the existing paragraph requirements and references in § 52.47(a).~~

~~Section 53.4841 would provide requirements for other DC application content (ITAAC, an environmental report, and safeguards information protection) and provides the equivalent of § 53.1241 with some modifications that align this section closer to the content of application requirements for a DC under part 52 (i.e., § 52.47). These modifications would reflect that the application requirements under Framework B are generally more aligned with those currently used under the existing regulatory framework. Specific modifications to this section, as compared to § 53.1241, would reflect the differences in the SSC classification schemes used in each framework and also reflect the use of similar, but different, requirements in some portions of each framework (e.g., § 53.440(a) versus the equivalent provisions in § 53.090(c)).~~

~~Section 53.4879 would provide the technical content of application requirements for MLs under Framework B. This section would provide the equivalent of § 52.157 with modifications made for technology-inclusiveness and conforming changes necessary for Framework B. Most conforming changes would reference paragraphs in § 53.4730 that would be equivalent to the existing paragraph requirements and references in § 52.157.~~

~~Section 53.4882 would provide requirements for other ML application content (ITAAC, an environmental report, and safeguards information protection) and provides the equivalent of § 53.1282 with some modifications that align this section closer to the content of application requirements for an ML under part 52 (i.e., § 52.158). These modifications reflect that the application requirements under Framework B would generally be more aligned with those used under the existing regulatory framework. Specific modifications would reflect the use of similar, but different, requirements in~~

some portions of each framework (e.g., § 53.440(a) versus the equivalent provisions in § 53.090(c)).

Section 53.4909 would provide the technical content of application requirements for CPs under Framework B. This section would provide the equivalent of § 50.34(a) with modifications made for technology-inclusiveness and conforming changes necessary for Framework B. For CP applications, the information provided in the application may include some aspects of the design that are not fully developed, and the information is therefore preliminary. Most conforming changes would reference paragraphs in § 53.4730 that would be equivalent to the existing requirements and references in § 50.34(a).

Section 53.4969 would provide the technical content of application requirements for OLs under Framework B. This section would provide the equivalent of § 50.34(b) with modifications made for technology-inclusiveness and conforming changes necessary for Framework B. Most conforming changes would reference paragraphs in § 53.4730 that would be equivalent to the existing requirements and references in § 50.34(b).

Section 53.4972 would provide requirements for other OL application content (environmental report and the mitigation of beyond-design basis events) and provides the equivalent of § 53.1372 with some modifications that would align this section closer to the content of application requirements for an OL under part 50 (i.e., § 50.34(b)). These modifications would reflect that the application requirements under Framework B are generally more aligned with those currently used under the existing regulatory framework. Specific modifications to this section, as compared to § 53.1372, would reflect fundamental differences between the frameworks when considering SSC classification schemes and related requirements for operation (e.g., availability controls). This section would also include a requirement for OL applicants to address requirements

for mitigation of beyond-design-basis events through a reference to subpart P (§ 53.4420) if these applicants do not satisfy the AERI entry criteria. This proposed requirement would be aligned with requirements in the existing regulatory framework that require OL applicants to demonstrate compliance with the equivalent requirements in § 50.155.

Section 53.5016 would provide the technical content of application requirements for COLs under Framework B. This section would provide the equivalent of § 52.79 with modifications made for technology-inclusiveness and conforming changes necessary for Framework B. Most conforming changes would reference paragraphs in § 53.4730 that would be equivalent to the existing paragraph requirements and references in § 52.79.

Section 53.5019 would provide requirements for other COL application content (ITAAC and an environmental report) and provides the equivalent of § 53.1419 with some modifications that align this section closer to the content of application requirements for a COL under part 52 (i.e., § 52.80). These modifications reflect that the application requirements under Framework B would generally be more aligned with those currently used under the existing regulatory framework. Specific modifications to this section, as compared to § 53.1419, would reflect fundamental differences between the frameworks when considering SSC classification schemes and related requirements for operation (e.g., availability controls). This section would also include a requirement for COL applicants to address requirements for mitigation of beyond-design-basis events through a reference to subpart P (§ 53.4420) if these applicants do not satisfy the AERI entry criteria. This proposed requirement would be aligned with requirements in the existing regulatory framework that would require COL applicants to demonstrate compliance with the equivalent requirements in § 50.155.

Subpart S – Maintaining and Revising Licensing Basis Information

~~Proposed subpart S would address the maintenance of licensing basis information for Framework B. Refer to the discussion for subpart I in section IV, "Framework A," of this document for a more detailed description of the regulatory requirements for maintaining and revising licensing basis information for licensees under Frameworks A and B.~~

~~**Subpart T – Reporting and Other Administrative Requirements**~~

~~Proposed subpart T would address reporting and other administrative requirements for Framework B. Refer to the discussion for subpart J in section IV, "Framework A," of this document for a more detailed description of the regulatory requirements for reporting and other administrative requirements under Frameworks A and B.~~

~~**Subpart U – Quality Assurance Criteria for Commercial Nuclear Plants**~~

~~Proposed subpart U would address quality assurance requirements for Framework B. Refer to the discussion for subpart K in section IV, "Framework A," of this document for a more detailed description of the regulatory requirements for quality assurance under Frameworks A and B.~~

~~VI.~~V. Changes to Other Parts of 10 CFR Chapter I

10 CFR Part 26

Introduction

The NRC is proposing a technology-inclusive, risk-informed, and performance--based approach for the application of drug and alcohol testing and fatigue management requirements for facilities licensed under part 53. The proposed requirements applicable to these applicants, licensees, and other entities would be commensurate with the radiological consequences presented by the applicants' facilities

and the operation of these facilities.[4] The proposed FFD framework would consist of a two-tiered graded approach similar to that currently in part 26 and an optional third tier for part 53 commercial nuclear plants that perform an analysis that demonstrates the facility and its operation would satisfy the criterion in proposed § 26.6043(ac), which matches the criterion of refers to either § 53.860(a)(2) or § 53.4330(a), depending on the part 53 framework under which the part 53 entity is licensed. This proposed FFD framework would be established in subpart M, "Fitness for Duty Programs for Facilities Licensed Under Part 53," of part 26.

The NRC used operating experience to provide regulatory flexibility in the proposed subpart M of part 26 framework to help support a licensee's or other entity's response to changes in societal drug use, drug testing technologies and processes, and FFD program performance. The flexibility would also help in FFD program implementation because of the wide variety of staff sizes anticipated at commercial nuclear plants licensed under part 53 and the geographically remote locations in which commercial nuclear plants may be sited.

The proposed first-tier FFD program requirements would apply to part 53 licensees and other entities of commercial nuclear plants under construction who satisfy the criterion in § 26.6043(ac) but elect not to implement proposed § 26.604, "FFD program requirements for low consequence facilities that satisfy the § 26.603(c) criterion," or who do not satisfy the criterion in § 26.6043(ac), and to holders of MLs who are assembling or fuelingtesting manufactured reactors. These requirements would be provided in proposed § 26.605(a) and would be essentially equivalent to those requirements in subpart K, "FFD Program for Construction," of part 26 as supplemented

[4] The NRC uses the term "operation" in its part 26 discussion to focus on human performance, namely the necessity of individuals to operate, maintain, surveil, and protect the facility and respond to operational transients and DBEs.

by select requirements from subparts E, “Collecting Specimens for Test,” and I, “Managing Fatigue,” of part 26, and the requirements in subparts A, “Administrative Provisions,” and O, “Inspection, Violations, and Penalties,” of part 26. The first-tier requirements would involve policies, procedures, behavioral observation, fatigue management, drug and alcohol testing, determinations of fitness, appeals, training, sanctions, auditing, change control, performance monitoring, recordkeeping, and reporting. These requirements would help deter individuals subject to this section from illicit drug and/or alcohol use and from being impaired from any cause including fatigue. These proposed requirements would also help licensees and other entities identify individuals as users of impairing substances and demonstrate compliance with § 26.23, “Performance objectives.”

The proposed second tier would include all the proposed first-tier requirements, plus the more comprehensive set of FFD program requirements in current subparts C, “Granting and Maintaining Authorization,” D, “Management Actions and Sanctions to be Imposed,” H, “Determining Fitness-for-Duty Policy Violations,” and N, “Recordkeeping and Reporting Requirements,” of part 26. These requirements would be provided in proposed § 26.605(b) and would be applicable to licensees and other entities satisfying the § 26.60~~4~~3(a~~c~~) criterion, at their discretion. These requirements would also apply to licensees or other entities not satisfying the § 26.60~~4~~3(a~~c~~) criterion that implement an FFD program under subpart M of part 26, before the loading of fuel onsite into a reactor vessel; before receiving a manufactured reactor; or before operating, testing, performing maintenance of, or directing the maintenance or surveillance of security-related equipment or equipment that a risk informed evaluation process or alternative method for evaluating safety significance has shown to be significant to public health and safety.

The second-tier requirements are based on the additional risk presented by nuclear reactor assembly, testing, fueling, and operation and the necessity for human actions in certain event sequences. The inclusion of the current part 26 requirements would align proposed part 53 FFD and AA program requirements with the current FFD and AA programs required for facilities licensed under parts 50 and 52. This approach would ensure effective and consistent AA and FFD program implementation across the commercial nuclear power industry, thereby ensuring uniform requirements for individuals who may perform roles and responsibilities for multiple facilities regardless of facility licensure.

Proposed § 26.604 would offer an alternate option for an applicant implementing an FFD program under subpart M of part 26. If the applicant demonstrates that the criterion in proposed § 26.60~~4~~3(a~~c~~) is met, then the applicant (and the subsequent licensee or other entity) must still implement an FFD program described in subpart M of part 26; however, drug and alcohol testing would not be required unless FFD performance declines or the applicant, licensee, or other entity elects to implement drug and alcohol testing. The proposed § 26.604 requirements are equivalent to those proposed in § 26.605(a) except for required drug and alcohol testing. This proposed framework would focus on the human performance of individuals while they are performing those duties and responsibilities that make them subject to the FFD program. This performance would be verified through behavioral observation, evaluation of any FFD concerns, performance monitoring, fatigue management, and determinations of fitness. Applicants that do not satisfy the criterion in proposed § 26.60~~4~~3(a~~c~~), or elect not to perform the analysis required to demonstrate that the criterion in § 26.60~~4~~3(a~~c~~) is met, would be subject to an FFD program described in § 26.605, “FFD program requirements

for facilities that do not implement § 26.604," or an FFD program that implements all part 26 requirements, except for those requirements in subparts K and M of part 26.

In establishing the minimum FFD program requirements in § 26.604, the NRC reviewed current advanced reactor designs against that of a non-power production or utilization facility (NPUF) that is not required to implement an FFD program for those individuals who have unescorted access to the controlled access area (and vital area for some facilities), including NRC-licensed operators.[5] This review was performed because commercial nuclear plants licensed under part 53 could be designed with similar power levels and radiological consequences as the currently licensed NPUFs. From this review, three principal considerations supported the minimum set of requirements for the § 26.604 FFD program.

First, the radiological consequences presented by a part 53 licensed facility and its operation that satisfies the criterion in § 26.604~~3~~(a~~c~~) may present a greater potential radiological consequence to workers and the public in the vicinity of the facility than does an NPUF. Second, the operating characteristics of a part 53 licensed facility are unlike that of an NPUF because there may be a higher reliance on individuals at the part 53 site to safely and competently operate, maintain, surveil, and secure SSCs that may not be required at an NPUF, such as systems that provide secondary heat transfer, reactor coolant flow, pressure control, and at-power core refueling. Differences in operating characteristics could include, for example: long-term, full power operation with automated reactivity control systems for load-following; active and passive safety and security systems; innovative non-light water heat transfer systems; and energy storage and hazardous chemical systems. The individuals at part 53 facilities may also be required to communicate to individuals both onsite and offsite any conditions adverse to

[5] Controlled access area and vital area are defined in § 73.2, "Definitions."

safety, security, or quality, such as electrical load dispatchers. Third, part 53 licensed facilities may be sited in geographically remote locations that may not have a physically available administrative or corporate support team to provide face-to-face oversight, engineering expertise, and maintenance support like that at NPUFs. This places a higher reliance on those individuals required at a part 53 facility being fit for duty and trustworthy and reliable because a replacement individual may not be readily available.

The NRC proposes to exclude drug and alcohol testing from the proposed § 26.604 framework for five reasons: (1) the § 26.23 performance objectives can be met through effective implementation of the defense-in-depth regulatory framework established by behavioral observation, reporting of legal actions, the proposed performance monitoring and review program (PMRP), FFD training, and requirements from the physical protection, AA, cyber protection, and licensed operator programs; (2) the PMRP would require the licensee or other entity to monitor its FFD program performance (both qualitatively and quantitatively) against its historical site performance, fleet-level performance, if applicable, and industry performance. The licensee or other entity would be required to implement corrective actions if site FFD performance meets a licensee- or other entity-established threshold or to resolve a finding resulting from a qualitative review or audit in a manner that restores performance and corrects root causes, contributing causes, or both; (3) the requirements in proposed § 26.609, "Behavioral observation," are more robust than those in § 26.407, "Behavioral observation," of subpart K of part 26 and are proposed to synchronize with and reinforce the AA behavioral observation requirements in § 73.56, "Personnel access authorization requirements for nuclear power plants," or the proposed requirements under § 73.120, "Access authorization program for commercial nuclear plants"; (4) a part 53 commercial nuclear plant that satisfies the § 26.60~~4~~43(a~~c~~) criterion will be designed, operated, and

secured with a radiological risk profile that is lower than that described in § 53.860(a)(2) ~~or § 53.4330(a)(2), as applicable~~, and perhaps will approach the radiological risk profile of an NPUF (which does not implement an FFD program); and (5) the NRC is aware that a part 53 commercial nuclear plant could be designed and constructed in such a manner to reduce reliance on an onsite security force to protect SSCs, NRC-licensed materials, and sensitive information, with enhanced capabilities for the detection, assessment, and delay of a DBT adversary.

Regarding fatigue management requirements, work hour controls would be required for personnel at utilization and manufacturing facilities in accordance with the existing scoping criteria in § 26.4, "FFD program applicability to categories of individuals," as revised in this proposed rule. The amended § 26.4 also would be used to determine whether an individual would be subject to drug and alcohol testing. The applicability of these scoping criteria for certain individuals (such as operators and maintenance personnel) would be determined by the licensee or other entity through its risk-informed evaluation process (or alternative method for evaluating the safety significance) performed to assess the risk significance of the SSC upon which work is being performed or directed by the individual. These requirements also would be scaled based on the potential radiological consequences presented by the facility. However, fatigue management would be applied to all individuals subject to the FFD program, similar to FFD program implementation by the current fleet of commercial nuclear plants because fatigue management is a proactive requirement designed to help prevent on-shift impairment through work hour scheduling and time off. The behavioral observation program (BOP) would be the principal requirement to provide reasonable assurance that individuals on shift are not mentally or physically impaired due to fatigue, which in any way could adversely affect their ability to safely and competently perform their duties.

The NRC is proposing subpart M of part 26 for facilities licensed under part 53, in lieu of subjecting all part 53 licensees to the same part 26 requirements that apply to facilities licensed under part 50 or 52, for four principal reasons. First, subpart M of part 26 would apply FFD requirements in a risk-informed manner commensurate with the radiological consequences presented by facilities licensed under part 53. This regulatory strategy is consistent with the current part 26, which provides a comprehensive set of deterministic requirements for licensees and other entities at facilities that are operating. This approach is also consistent with the current subpart K of part 26, which provides a more flexible framework for nuclear power reactors under construction, where the probabilities of serious radiological accidents are lower and consequences from such accidents are less severe than at operating plants.

Second, subpart M of part 26 would enable a part 53 licensee or other entity to implement innovative drug testing technologies and behavior observation techniques while continuing to demonstrate compliance with the part 26 performance objective in § 26.23(b) of providing reasonable assurance that individuals are not under the influence of any substance or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform assigned duties. These technologies include drug and alcohol testing using oral fluid, urine, and hair specimens; screening using point of collection testing and assessment (POCTA) devices; and monitoring using passive drug and alcohol detection instrumentation. Part of the basis to enable the use of innovative drug and alcohol testing technologies is to maintain FFD program effectiveness should the staff size at a part 53 commercial nuclear plant be small and challenge the effective implementation of the behavioral observation and drug and alcohol testing programs. Also, a commercial nuclear plant that is sited at a geographically remote location may present additional challenges to behavioral

observation and drug and alcohol testing that are not presented by traditional LWR facilities licensed under part 50 or 52, such as: efficiency of postal services for shipping and controlling biological specimens; proximity to drug and alcohol collection facilities that are reasonably equivalent to that described in subpart E of part 26; availability of internet and cellular services to enable same-time discussions among the Medical Review Officer (MRO), donor, and laboratory; accessibility to substance abuse treatment services described in subpart H, "Determining Fitness-for-Duty Violations and Determining Fitness," of part 26; and proximity to an MRO (or management and clinical staff) to evaluate potential impairment caused by fatigue and/or substance use or abuse, for-cause and post-accident occurrences, and the individual's potential to return to duty.

A part 53 commercial nuclear plant that is sited in a geographically remote location and has a small staff size may present implementation challenges and the potential for small group dynamics to impact FFD program effectiveness. Particularly in isolated environments, psychological phenomena known as "groupthink" may take effect and could impact the effectiveness of BOPs and the ability to effectively manage safety culture. For example, in circumstances where small staffs are drawn from the same small town and thereby have a potentially narrow experience base, it could be challenging to maintain a safety conscious work environment in which personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination, and organizations may resultingly experience groupthink-like effects. Groupthink is particularly prevalent among cohesive and insulated groups that experience high levels of decisional stress.[6] Small staffs at part 53 commercial nuclear

[6] See e.g., Irene Wærø, Ragnar Rosness, and Stine Skaufel Kilska, "Human performance and safety in Arctic environments," SINTEF (2018).

plants may therefore be more susceptible to groupthink if they are working in an isolated environment where decision-making pressures may be high.

Groupthink could have adverse effects on workplace safety culture, as studies show that individuals will be more hesitant to speak out against practices they deem unsafe for fear of deviating from group norms.[7] Individuals may also be unaware of systematic biases in the group decision-making process and may then be less likely to scrutinize the potential risks of the group's decision or sufficiently contemplate alternative paths of action.[8] Furthermore, the literature indicates that groups make riskier decisions than individuals acting alone due to the diffusion of responsibility among group members.[9] This phenomenon, known as "the risky shift," also runs counter to a safety culture. Accordingly, "groupthink" and "the risky shift" may lead to group behaviors that render behavioral observation less effective. As such, alternative approaches to behavior observation programs, such as the utilization of video-based surveillance by individuals separate from the onsite work unit, could serve to mitigate potential issues associated with groupthink. The incorporation of remote observation, performed by individuals physically separate from the site, could help to bring in independent and objective perspectives and help to break patterns of thought and communication that may result in groupthink.

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[7] See e.g., Russell Mannion and Carl Thompson, "Systematic biases in group decision-making: implications for patient safety," *International Journal for Quality I Health Care*, Vol. 26, No. 6 (2014): 606-612 (arguing that small group dynamics in healthcare teams produce systematic biases in group decision-making because healthcare professionals may be reticent to vocalize concerns they have about quality of care).

[8] See e.g., Wærø, Rosness, and Kilska (arguing that groupthink leads teams to "develop shared rationalizations that bolster a proposed choice, rather than examining alternative options and identifying the risks associated with the proposed choice"). See also David Hofmann and Adam Stetzer, "A Cross-Level Investigation of Factors Influencing Unsafe Behaviors and Accidents," *Personnel Psychology*, Vol. 49 (1996) (finding that in a study of fatal accidents involving offshore oil rigs, in the absence of standard operating procedures, workers "equated normal work methods (i.e. what everyone else does) with safe and/or ideal work methods," revealing that the groupthink phenomena will further cement modes of work that do not reflect safety protocols in small groups that lack strong norms around workplace safety and tacitly reward short-cuts that prioritize efficiency over safety).

[9] Mannion and Thompson, "Systematic biases in group decision-making: implications for patient safety," *International Journal for Quality I Health Care*, Vol. 26, No. 6 (2014): 606-612.

Even without the influence of small group dynamics, there are other practical constraints to implementing FFD requirements, such as random drug and alcohol testing, among small staffs. Random testing is less effective when applied to small staff sizes because it may be easier for staff to communicate and predict when individuals will be subject to drug and alcohol testing. Furthermore, if a facility is sited in a remote location, program implementation could be challenged by the following factors: limited mail services to laboratories certified by the U.S. Department of Health and Human Services (HHS), availability of local clinical or medical options for treatment and determinations of fitness by an MRO or Substance Abuse Expert, and use of offsite drug and alcohol collection facilities.

The increased potential for small staff sizes to impact FFD policy compliance warrants an approach to FFD that emphasizes performance over prescriptive requirements that may be ineffective or infeasible at these facilities. Therefore, the NRC proposes the subpart M of part 26 framework to provide a performance-based approach to FFD. For example, proposed § 26.603(c~~d~~) would use existing part 26 auditing requirements and the reporting requirement in § 26.717, “Fitness-for-duty program performance data,” and clarify how FFD performance data would be used to maintain or improve, if necessary, FFD program effectiveness. Specifically, § 26.603(c~~d~~) would require each licensee and other entity that elects to implement subpart M of part 26 to monitor and assess their site-specific performance against the preceding year’s site performance, the licensee’s most recent fleet-level performance, and the most recent industry performance. Licensees and other entities would use these datapoints to develop performance measures, which would be qualitative descriptions of the specific FFD program elements, and threshold values for each performance measure that, if exceeded, would indicate a performance deficiency. Each licensee and other entity

would compare its site's current performance data against the performance measures and, if a threshold is exceeded, the licensee or other entity would be required to take corrective actions to restore performance. Also, the NRC proposes a change control requirement to allow a licensee or other entity to change its subpart M of part 26 FFD program while ensuring that FFD program effectiveness is maintained.

Lastly, subpart M of part 26 would consolidate the applicable FFD requirements by placing in one subpart all proposed part 26 requirements (either new requirements or cross-references to existing part 26 requirements) for part 53 licensees and other entities. This should help licensees and other entities implement the requirements because it would enable easy cross-reference to similar requirements in other subparts that are being implemented by non-part 53 licensees and entities subject to part 26. Understanding how other licensees or other entities implement similar FFD requirements may facilitate the sharing of operating experience in program implementation.

The use of innovative technologies and a risk-informed performance-based framework parallels the considerations presented in the Advanced Reactor Policy Statement. As stated in the policy statement, "~~[S]~~simplified systems should facilitate operator comprehension, reliable system function, and more straightforward engineering analysis." Furthermore, these same attributes may reduce potential radiation exposures, help prevent the theft of nuclear materials, and use technology and design innovations. Should these components and systems be designed, implemented, and maintained to minimize reliance on human actions and leverage technology and innovation, then the robust and prescriptive FFD requirements in, for example, subparts B, "Program Elements," and E of part 26 could be scaled to the part 53-licensed facility and its operation. This strategy would be implemented in the subpart M of part 26 framework.

Even though current subpart K of part 26, provides for FFD requirements commensurate with the radiological consequences presented by a nuclear power plant construction site, proposed subpart M of part 26 would not allow part 53 licensees and other entities to implement the requirements in subpart K. The principal reasons are that (without significant changes to subpart K that would be outside the scope of this rulemaking): (1) subpart K does not apply to holders of MLs who assemble or test a reactor; (2) subpart K only applies during construction, whereas subpart M would apply during construction, operation, and decommissioning through implementation of the insider mitigation program (IMP) required by § 73.55 or proposed § 73.100; (3) subpart K does not address training, authorization as defined in § 26.5, and MRO performance; (4) subpart K does not expressly authorize the use of innovative drug and alcohol testing technologies; (5) subpart K does not describe the use of time-dependent alcohol limits or special analysis testing of dilute urine specimens; and (6) subpart K has less rigor in the protection of worker rights and sensitive information than that proposed in subpart M.

Despite the differences between subparts K and M of part 26, the requirements in subpart M would bearе essentially equivalent to many in subpart K that were implemented by the licensees of Vogtle Nuclear Station and V.C. Summer Nuclear Station when they were constructing four commercial nuclear power reactors and NRC inspection and operating experience evaluation determined that the use of subpart K contributed to adequately protecting the public health and safety and the common defense and security. Further, given the risk profile posed by facilities licensed under part 53 and the proposed additional requirements in subpart M of part 26 that were developed from operating experience and other part 26 subparts (but are not included in subpart K of part 26), the NRC concludes that if licensees and other entities effectively

implement the proposed requirements in subpart M of part 26, then individuals subject to the rule should be fit for duty and trustworthy and reliable.

Proposed Changes to Part 26, Subparts A through E and I

Section 26.3(d) is the applicability paragraph for contractor/vendors (C/Vs) who implement FFD programs or program elements, to the extent that the licensees and other entities specified in § 26.3(a) through (c) rely on those C/V FFD programs or program elements to meet the requirements of part 26. Section 26.3(d) would be amended to address part 53 licensees and other entities in proposed § 26.3(f).

Proposed § 26.3(f) would place part 53 licensees or other entities within the scope of part 26. For licensees and other entities of a part 53 commercial nuclear plant, except a holder of an ML, the FFD program would be required to be implemented no later than the start of construction activities. The holder of an ML would need to implement its FFD program before commencing activities that assemble a reactor.

Current § 26.4 describes FFD program applicability to categories of individuals. These categories are based on the duties, responsibilities, and the types of access an individual may possess. The NRC proposes to amend § 26.4 to include licensees and other entities described in § 26.3(f). The NRC expects that not all categories of individuals described in current § 26.4 would be applicable to all part 53 facilities. The NRC is proposing regulatory guidance in DG-5073, "Fitness-of-Duty Programs for Commercial Nuclear Plants and Manufacturing Facilities Licensed Under 10 CFR Part 53," and DG-5078, "Fatigue Management for Nuclear Power Plant Personnel at Commercial Nuclear Plants Licensed Under 10 CFR Part 53," to help address program applicability to certain individuals.

Section 26.4(a)(1) and (a)(4) would be amended to account for the possibility that certain individuals may perform or direct the performance of operational and

maintenance activities from a remote facility (for example, a remote-control station) for licensees or other entities licensed under part 53.

The framework of the current part 26 does not account for individuals who perform operating and maintenance duties at remote facilities. Although current § 26.4(a)(1) does not limit the operating of applicable SSCs to onsite operating, § 26.5 limits the definition of “maintenance,” for the purposes of § 26.4(a)(4), to include only “onsite maintenance activities.” In the 2008 part 26 final rule preamble, the NRC explained that the work hour requirements apply to those individuals who perform maintenance activities within the licensee’s owner-controlled area. Furthermore, regarding the direction of applicable operations and maintenance activities, current § 26.4(a)(1) and (4) address only individuals who perform “onsite direction.”

Under the proposed amendments to part 26, the limitation of “onsite” activities to those performed within the owner-controlled area would still apply to facilities licensed under part 50 or 52. However, for licensees and other entities described in § 26.3(f), the NRC would remove the “onsite” limitation to include activities performed both within the owner-controlled area as well as operations and maintenance duties performed at remote facilities where safety-significant systems and components are expected to be operated within the design basis of the commercial nuclear plant.

In the 2008 part 26 final rule, the purpose of limiting "directing" activities to those "directing" activities that are conducted onsite was to avoid requiring work hour controls for individuals performing incidental duties, consistent with § 26.205(b)(5), from an offsite location in instances where those duties might be considered to be “directive” in nature. Under the proposed amendments to part 26, the exclusion of incidental duties while calculating work hours would still be applicable for licensees and other entities licensed under part 53. However, for these licensees and other entities, beyond instances of

incidental duties, the direction of operations and maintenance activities associated with safety-significant SSCs, when performed at remote facilities, would be considered in an equivalent fashion as direction performed at non-remote facilities, for the purposes of administering work hour controls.

Section 26.4(a)(1) and (4) would also be amended to include a provision for using an alternative method of evaluating the safety significance of SSCs. ~~This additional language would account for certain entities, licensed under Framework B within part 53, that may not use a risk-informed evaluation process as required in current § 26.4(a)(1) and (4).~~

Proposed § 26.4(b) would include in an FFD program individuals who are granted unescorted access to the protected area of a facility licensed under part 53 and do not perform or direct the performance of the duties described in § 26.4(a). This requirement would contribute to the defense-in-depth regulatory framework that helps provide that individuals who have unescorted access are fit for duty, trustworthy, and reliable. For example, the NRC is proposing amendments to part 73 to require a part 53 licensee to subject individuals to a series of reviews to help determine whether those individuals are trustworthy and reliable before granting them unescorted access to the facility's protected area.

The NRC would amend § 26.4(c) to include in an FFD program individuals who are assigned to physically report to the part 53 licensee's emergency response facility (or facilities) or participate remotely in emergency response activities, and individuals without unescorted access to the part 53 facility who, remotely or otherwise, make decisions and/or direct actions regarding plant safety or security. Part 53 commercial nuclear plants may be licensed for and rely upon offsite facilities to fulfill the role of a Technical Support Center (TSC) or Emergency Operations Facility (EOF). Therefore, the

proposed rule would account for such offsite facilities or remotely performed activities. Further, the use of personnel to operate systems and components, maintain and surveil SSCs, and respond to plant conditions and security events may be different than those included in the TSC or EOF team for power reactors currently licensed under part 50 or part 52.

For the individuals whose duties for the licensees and other entities in § 26.3(c) require the individuals to have the types of access or perform the activities listed in § 26.4(e)(1) through (6) at the location where the commercial nuclear plant will be constructed and operated, current § 26.4(e) requires them to be subject to an FFD program that satisfies all the requirements of part 26 except subparts I and K. The NRC would amend § 26.4(e) to except subpart M as well as subparts I and K. The NRC would also amend § 26.4(e) to include in an FFD program the individuals whose duties for the licensees and other entities in § 26.3(f) require the individuals to have the types of access or perform the activities listed in § 26.4(e)(1) through (6) or perform construction activities as defined in § 26.5.

Section 26.4(e)(4) would be revised to include in an FFD program individuals who witness or determine inspections, tests, and analyses certifications required under part 53 because current § 26.4(e)(4) includes the individuals who perform the same duties under part 52.

The proposed rule would amend § 26.4(f) to require individuals who construct, manufacture, or direct the construction or manufacture of safety- or security-related SSCs at facilities licensed under part 53 to be subject to an FFD program under subpart M of part 26 or an FFD program that demonstrates compliance with all of the requirements of part 26 except for subparts I, K, and M of part 26.

Section 26.4(g) is the applicability paragraph for FFD program personnel (e.g., the FFD manager, MRO, and technicians) and persons who perform AA determinations (e.g., the licensee- or other entity-designated Reviewing Official). This section would be amended to address part 53 licensed facilities. Specifically, a part 53 licensee or other entity would use FFD program personnel to implement its FFD program as well as other assigned individuals who are not involved in the day-to-day operations of the program to implement specific elements of its FFD program, such as the collection of a specimen for drug or alcohol testing. These individuals would be held accountable for program implementation, including consistent implementation of protections afforded to all individuals subject to the FFD program.

Section 26.4(h) would be amended to include subpart M of part 26.

The NRC proposes to include several new definitions in § 26.5, “Definitions,” and amend some existing definitions. The NRC is proposing to add a definition for “biological marker.” The proposed definition would be consistent with “biomarker” defined by the HHS in its Mandatory Guidelines for Federal Workplace Drug Testing (HHS Guidelines) using oral fluid as the biological specimen to be tested (84 FR 57554; October 25, 2019). However, the proposed definition for § 26.5 would add that the endogenous substance used to validate that the biological specimen “was produced by the donor” because subpart M of part 26 proposes to have the MRO evaluate any discrepant biological marker identified in a biological specimen collected from a donor.

The NRC is proposing a definition for the word “change” as used in the proposed § 26.603(e), “FFD program change control,” process. The proposed definition would be consistent with the definition of “change” for a part 50 or 52 licensee’s emergency plans in § 50.54(q)(1)(i).

The NRC proposes to revise the definition of “constructing or construction activities” to clarify that for licensees or other entities in § 26.3(f), the definition of “construction” would be that as proposed in § 53.024 or § 53.028.

The definitions of “contractor/vendor” (C/V) and “other entity” would be revised to make them applicable to part 53 licensees. A holder of an ML under part 53 could be a C/V under the proposed C/V definition.

The NRC is proposing a definition for “illicit substance” because this phrase is used in subpart M of part 26 and would address substances that cause impairment and possible addiction but are not an “illegal drug” as defined in § 26.5. This proposal is based on operating experience where individuals have admitted to using common household, non-drug substances to achieve a high or satisfy an addiction. These common household items include, but are not limited to nitrous oxide, butane, propane, glue, paint vapors, lighter fluid, nail polish remover, degreasers, permanent markers, and methyl alcohol (which is found in hand sanitizer and mouthwash).

The definition of “questionable validity” would be revised to make it applicable to an FFD program implemented under subpart M of part 26, which would include all biological specimens.

The NRC is proposing a definition for “reduction in FFD program effectiveness” because this phrase, similar to the proposed definition for “change,” is used in proposed § 26.603(e). The proposed definition is generally consistent with the definition of “reduction in effectiveness” provided for emergency plans in § 50.54(q)(1)(iv).

The proposed rule would make the current definition of “reviewing official” applicable to those licenses and other entities in § 26.3(f).

The current part 26 definition of “safety-related structures, systems, and components” would be amended to use the NRC’s proposed definition~~s~~ in ~~§~~§§ 53.02~~04~~ ~~and 53.028~~ for the part 53 licensees and other entities described in § 26.3(d) and (f).

The NRC would amend the definition of “security-related SSCs” in § 26.5 to make it applicable to a licensee or other entity described in § 26.3(d) and (f).

The NRC proposes a definition for “Special Nuclear Material” that would refer to the definition in § 70.4, “Definitions,” of part 70 to ensure consistency.

The NRC is proposing a revision of the definition of “unit outage” to account for the potential use of commercial nuclear plants for purposes other than electricity generation.

Section 26.21, an applicability statement for part 26 FFD programs, would be amended to include licensees and other entities described in § 26.3(f) that choose to implement an FFD program that implements all part 26 requirements, except those in subparts K and M of part 26.

Section 26.51, “Applicability,” would be amended to apply to licensees and other entities described § 26.3(f) that elect not to implement the requirements in subpart M of part 26 for the categories of individuals in § 26.4 and those licensees and other entities that elect to implement the requirements in § 26.605.

Section 26.53(e), (e)(1) and (3), and (g) through (i), which are general provisions for granting and maintaining authorization, would be amended to apply to licensees and other entities described § 26.3(f).

Section 26.63(d), a suitable inquiry requirement, would be amended to apply to licensees and other entities described § 26.3(f).

Section 26.73, the applicability statement for subpart D of part 26, would be amended to apply to licensees and other entities described § 26.3(f) that elect not to

implement the requirements in subpart M of part 26 for the categories of individuals in § 26.4 and those licensees and other entities that elect to implement the requirements in § 26.605(b).

Section 26.81, the purpose and applicability statement for subpart E of part 26, would be amended to apply to licensees and other entities described in § 26.3(f) that elect not to implement the requirements in subpart M of part 26 for the categories of individuals in § 26.4 and those licensees and other entities that implement proposed § 26.605(a) or (b). The subpart E requirements to be implemented are listed in proposed § 26.607(c)(2)(i) and (ii) and (3).

Section 26.201, the applicability statement for subpart I of part 26 would be amended to apply to licensees and other entities described in § 26.3(f). Also, the applicability statement would be divided into two paragraphs for clarity.

The NRC proposes to add § 26.202, "General provisions for facilities ~~licensed under~~implementing subpart M of this part ~~53~~," for licensees or other entities described in proposed § 26.3(f) that elect to implement the requirements in subpart I of part 26 in accordance with § 26.604 and § 26.605. Section 26.202 would establish requirements equivalent to those in current § 26.203, "General provisions," which is applicable to part 50 and 52 licensees. The NRC would add the separate § 26.202 because § 26.203 refers to various requirements under subpart B of part 26, which would not be applicable to facilities licensed under part 53 that implement subpart M of part 26.

Additionally, § 26.202(c), "Training and assessments," unlike § 26.203(c), "Training and examinations," would not include a comprehensive examination requirement because trainee assessment is conducted as part of a SAT that would be required as proposed under the FFD program training requirements in § 26.608.

Proposed changes in §§ 26.205, 26.207, and 26.211 would add references to new requirements in subparts I and M of part 26 that would be applicable specifically to licensees and other entities in § 26.3(f). The NRC would not change the specific provisions for work hour requirements in current § 26.205(d). However, as addressed in the discussion of proposed changes to § 26.4(a), whether a licensee or other entity under part 26 would need to implement work hour controls for certain individuals or groups would be dependent, in part, on determinations reached by that licensee's risk-informed evaluation process or alternative method of evaluating the safety significance of SSCs.

Proposed changes to §§ 26.207(a)(1)(ii) and 26.211(b) would allow licensees and other entities in § 26.3(f) to perform face-to-face assessments to support the approval of work hour control waivers and the conduct of fatigue assessments, respectively, using electronic communications. These proposals would allow supervisors to conduct such assessments from a remote location under appropriate circumstances. Such remotely conducted assessments would need to be supported by someone who is present in-person with the individual being assessed and who is trained in accordance with the requirements of either §§ 26.29 and 26.203(c) or §§ 26.608 and 26.202(c). The reasoning for these proposals and the associated need for in-person support to augment electronic communications is addressed further in the preamble discussion of proposed § 26.619.

Proposed Requirements for Part 26, Subpart M

The proposed rule would add a new subpart M to part 26 that would provide alternative FFD requirements for part 53 licensees and other entities.

Proposed § 26.601 would make subpart M of part 26 applicable to part 53 licensees and other entities, at their discretion. If a licensee or other entity in § 26.3(f)

does not elect to implement an FFD program that demonstrates compliance with the requirements of subpart M, then the individuals specified in § 26.4 would be subject to an FFD program that demonstrates compliance with all part 26 requirements, except for those requirements in subparts K and M.

Proposed § 26.603(a) would require an applicant to provide a description of its FFD program and its implementation within its application for a license. This requirement is equivalent to the existing requirements in §§ 26.401(b) and 52.79(a)(44). The entities that would be required to submit these FFD program descriptions are certain applicants that would comply with the ~~Framework A and Framework B~~part 53 application requirements in subpart~~s~~ H ~~and R, respectively~~. In subpart H, § 53.1309(a)(6) would require an applicant for a CP to provide a description of its FFD program in its PSAR. Under §§ 53.1279(b)(4), 53.1369(x), and 53.1416(a)(24), an applicant for an ML, OL, and COL, respectively, would be required to provide a description of its FFD program in its FSAR. ~~In subpart R, § 53.4730(a)(24) would require an applicant for a CP, an OL, a COL, or an ML to include in a safety analysis report a description of its FFD program, to the extent required by § 53.4909(a)(7)(xv) for a CP applicant to provide a description of its FFD program in its PSAR, and §§ 53.4879(f), 53.4969(a)(6)(xii), and 53.5016(a)(3)(xii) for an applicant for an ML, OL, and COL, respectively, to provide a description of its FFD program in its FSAR.~~

Unlike an application for a license, a description of an FFD program does not receive NRC review for possible approval. The applicant provides the NRC with information about the applicant's proposed FFD program to inform the NRC's inspection program and to demonstrate that the FFD program will be effectively implemented before a licensee or other entity commences any activity making individuals at the NRC-licensed facility subject to the FFD program.

Proposed § 26.603(a)(1) would require a summary description of the analysis described in § 26.603(c), if performed. The analysis should describe the operation of the facility. This would include informing the Commission of: (1) the principal individuals assigned by job title (work category) and a summary description of the human actions (e.g., monitoring, operating, responding, surveillance, oversight, etc.) that they perform to maintain the facility in a safe operating or shutdown condition; (2) the principal individuals by job title and a summarized description of the human actions to secure and protect the facility (without providing sensitive information); (3) the estimated total population of individuals subject to the FFD program and per shift by job description; and (4) references to supporting documentation. The purpose of these descriptions is to enable an NRC assessment of the licensee's or other entity's analysis and the required human actions to operate, monitor, surveil, maintain, and secure the facility within its design and licensing basis so that if an operational or security-related event were to occur, the facility would respond as designed and licensed and the calculated radiological dose consequences would not exceed the consequences described in § 53.860(a)(2) ~~or § 53.4330(a)(2)~~. This is important because facilities that implement § 26.604 are expected to have very small staff sizes and may be sited in geographically remote locations, both of which could challenge effective implementation of the FFD program.

Proposed § 26.603(a)(2) would require the applicant to state what FFD program it plans to implement.

Proposed § 26.603(a)(3) would require a discussion that informs the NRC of the applicability of the applicant's FFD program to individuals who perform safety- or security-significant activities. This description should summarize any key differences between the staff at the site and any remote facility and the categories of individuals in

§ 26.4. The principal purpose of providing this description would be to inform the NRC of any substantial differences in the applicability of the FFD program to the categories of individuals in § 26.4.

Proposed § 26.603(a)(4) would require a description of the drug and alcohol testing and fitness determination process to be implemented through the licensee's or other entity's procedures, including the collection and testing facilities to be used, biological specimens to be collected, and sanctions to be imposed upon a confirmed FFD policy violation. This process includes how individuals who test positive for a drug or alcohol will be evaluated before being afforded unescorted access to the protected area to perform or direct those duties or responsibilities making them subject to the FFD program. The principal purpose of describing this return-to-duty process is to inform the NRC of the behavioral observation strategy (for those facilities that implement § 26.604) and/or drug screening and testing strategy.

Proposed § 26.603(a)(5) would require a summary description of the applicant's planned PMRP. This description must provide the performance measures and thresholds that the applicant intends to use.

Proposed § 26.603(b) would establish when the FFD program must be implemented and the longevity of the FFD program. This proposal is equivalent to the current § 26.3, which states, in part, when licensees and other entities must begin implementing their FFD programs. Unlike the current part 26 regulations, proposed § 26.603(b) would expressly state that an FFD program would not be applicable during decommissioning of a part 53 facility for licensees and other entities specified in § 26.3(f). However, licensees of facilities licensed to operate a reactor should be aware that the physical protection program under § 73.55, "Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage,"

and under proposed § 73.100 include a requirement for the implementation of an IMP, even during decommissioning.

Proposed § 26.603(b) would also require the holder of an ML to implement its FFD program no later than the start of activities that assemble a reactor. The holder of the ML should establish in its procedures when reactor assembly commences and what constitutes assembly. For example, the FFD program would not need to be implemented for the receipt, storage, inspection, and staging of components and systems used to assemble (i.e., build or fabricate) the reactor because this is not a current requirement for LWR facilities licensed under part 50 or 52. Furthermore, the NRC currently does not require that an FFD program be applied to the assembly or manufacturing of components (or basic components as defined in § 21.3), or systems that were fabricated or assembled outside the footprint of a commercial power reactor, and this regulatory position would also apply to a manufacturing facility.

~~Proposed § 26.603(c) would require the applicant, licensee, or other entity seeking to implement an FFD program under § 26.604 to perform a site-specific analysis to determine whether the facility and its operation satisfy the criterion in § 53.860(a)(2) or § 53.4330(a)(2), as applicable. If the analysis is performed and demonstrates that the radiological consequences presented by the facility and its operation satisfy the criterion, then the licensee or other entity could implement the FFD program detailed in § 26.604. If the analysis does not demonstrate that the facility and its operation satisfy the criterion, then the licensee or other entity must implement the FFD program described in either § 26.605 or subparts A through I, N, and O of part 26.~~

~~Proposed § 26.603(c) would also require licensees and other entities that implement proposed § 26.604 to update the technical analysis used to justify compliance with the criterion in § 53.860(a)(2) or § 53.4330(a)(2), as applicable. This analysis would~~

~~be updated to reflect changes made to the staffing, FFD programs, or offsite support resources described in the analysis to show that the facility and its operation continue to satisfy the criterion. This is important because facility, operation, or staffing changes outside FFD program implementation (e.g., changes in the facility safety analysis, physical protection strategies, or the security plan, implementing procedures, or contingency response strategies) could adversely impact the licensee's or other entity's documented analysis demonstrating that the facility and its operation satisfy the criterion if event sequences require human action.~~

Proposed § 26.603(c~~d~~) would require the establishment of a PMRP. The concept of a PMRP is not new. This requirement would consolidate for part 53 the requirements in current §§ 26.41, "Audits and corrective actions"; 26.415, "Audits"; 26.717, "Fitness-for-duty program performance data"; and 26.183(c), which describes MRO responsibilities. The proposal would state that the licensee or other entity must monitor the effectiveness of its FFD program by comparing performance data against performance measures and thresholds. The development of quantitative thresholds would be new, but this is born from licensees and other entities with facilities licensed under parts 50 or 52 already collecting, reviewing, and reporting FFD performance data. Additionally, the benefit of quantitatively measuring FFD program performance against established thresholds benefits a licensee's and other entity's determination of whether they are maintaining FFD program performance in a manner that demonstrates compliance with the performance objectives in § 26.23.

The NRC is proposing the PMRP because the subpart M of part 26 requirements would enable a high degree of flexibility in FFD program implementation (e.g., drug testing). A licensee or other entity would not only have options in the type of FFD program they may implement under part 26, but they would have options in the types of

biological specimens they may test for drugs, where to collect the biological specimens (e.g., at the NRC-licensed facility or offsite at a local hospital or clinic), and the use of collection and assessment devices to screen individuals for drugs and alcohol. These FFD program flexibilities could cause FFD programs under subpart M of part 26 to become very site-specific, necessitating performance measures to enable the licensee or other entity to maintain the effectiveness of its FFD program.

FFD program effectiveness would be determined by comparing actual performance against the performance measures and thresholds. The result of that comparison would inform licensee or other entity decisions whether to change FFD program elements to address a performance deficiency. Also, the thresholds would have sufficient margin, based on operating experience, before conditions adverse to safety and security may occur should an individual be identified as impaired or not trustworthy and reliable. The potential of a human-related failure causing a condition adverse to safety and security is dependent on the duties and responsibilities of the individual and the defense-in-depth designed to prevent or mitigate an adverse consequence. The PMRP would account for this by requiring the review of FFD performance data, in part, by work category, C/V, and individuals employed by the licensee who are not a C/V as defined in § 26.5 (i.e., a licensee employee).

Proposed § 26.603(c~~d~~)(1) would require the licensee or other entity to document and maintain its PMRP. Proposed § 26.603(c~~d~~)(1)(i) would require that the performance measures be identified and designed to monitor FFD program performance. Proposed § 26.603(c~~d~~)(1)(i)(A) would require the FFD program of a licensee or other entity subject to the requirements of § 26.604 to include monitoring of the BOP. The purpose of this monitoring is to help ensure that individuals subject to the FFD program are observing the behaviors of others, are being observed themselves, and are reporting FFD

concerns to licensee- or other entity-designated individuals. The other performance measures would include occurrence of FFD policy violations evaluated by licensee employee, C/V, and labor category, and occurrence of individuals with potentially disqualifying information or who possessed an FFD prohibited item.

Proposed § 26.603(c~~d~~)(1)(i)(B) would require the FFD program of a licensee or other entity that is either subject to the requirements of § 26.604 and has implemented a drug testing program at its discretion, or is subject to the requirements of § 26.605, to include the performance measures identified in § 26.603(c~~d~~)(1)(i)(A) and those necessary to monitor the effectiveness of the drug and alcohol testing program. The drug and alcohol measures would include the monitoring of FFD performance data for pre-access and random testing and subversion attempts by the categories of licensee employee, C/V, and labor category.

Proposed § 26.603(c~~d~~)(1)(ii) would require the licensee or other entity to establish thresholds for each performance measure. Initial thresholds must be based on FFD performance data from comparable facilities subject to part 26, the licensee's or other entity's fleet-level program performance if applicable, and industry FFD performance data. This provision introduces the requirement to "maintain FFD program effectiveness." This terminology describes a performance-based regulatory strategy in which the licensee or other entity must initially establish a level of performance that is representative of other facilities in the licensee's fleet of facilities subject to part 26, if applicable, and the FFD performance of comparable facilities subject to part 26.

Proposed § 26.603(c~~d~~)(1)(iii) would require that the licensee or other entity evaluate FFD data as it is received to determine whether a threshold has been exceeded. Historical FFD performance data for the current LWR fleet indicates that, for particular work categories and employment types, few FFD policy violations occur per

year. Therefore, for work categories that may be significant to worker safety (e.g., radiation protection technicians), physical protection (i.e., security personnel), or safety (i.e., NRC-licensed operators and individuals who perform or direct the performance of activities that a risk-informed evaluation process or alternative method for evaluating safety significance has shown to be significant to public health and safety), a single FFD policy violation could be a significant occurrence and warrant corrective actions. Based on licensee-submitted FFD-related reports under §§ 26.417, 26.419, 26.717, and 26.719, licensees and other entities with facilities licensed under parts 50 or 52 implement some form of corrective action that is typically scaled to the significance of the violation. These corrective actions have included counseling, follow-up drug and/or alcohol testing, remedial training, generic announcements to the workforce, and reviews of recently performed or directed work by the individual suspected of being impaired. Proposed § 26.603(c~~d~~)(1)(iii) would require that the PMRP include a year-to-year comparison of FFD performance data to help provide assurance that an adverse trend in FFD program performance would be identified if occurring. This proposed requirement was developed from the annual FFD performance data reporting requirements in §§ 26.417(b)(2) and 26.717. In particular, the proposed year-to-year comparison of FFD performance data is equivalent to § 26.717(c), which requires, in part, licensees and other entities to analyze their performance data at least annually and take appropriate actions to correct any identified program weaknesses.

Proposed § 26.603(c~~d~~)(1)(iv) would require the licensee or other entity to perform and document quantitative and qualitative reviews. These reviews would be performed in three program areas: protections afforded to individuals subject to the FFD program, laboratory test results and MRO performance, and change control. The purpose of these reviews would be to specifically target performance within the three program areas to

assess whether the outcomes resulting from the implementation of procedure requirements are contributing to FFD program effectiveness. The proposed reviews would not require the establishment of measures and thresholds because the reviews are expected to result in qualitative findings regarding program effectiveness. Qualitative findings and observations could still result in the consideration of corrective actions in the targeted program areas.

Proposed § 26.603(cd)(1)(iv)(A) would require the licensee or other entity to monitor whether its FFD program is affording appropriate protections to individuals subject to the FFD program. The review of these protections would include, in part, assessing the licensee's or other entity's protection of the following: privacy during the specimen collection process; specimen integrity, custody, and control; information gathered from FFD program implementation; and due process during appeals of FFD policy violations.

Proposed § 26.603(cd)(1)(iv)(B) would require, in part, a review of laboratory test results and MRO performance. Effective performance by the laboratory (e.g., obtaining and communicating accurate test results) and MRO (e.g., correct evaluation of the laboratory test results based on § 26.185 or HHS Guidelines) would result in three significant outcomes: (1) protection of the donor from an inaccurate FFD policy violation determination; (2) protection of the donor, other individuals, and the facility from potential harm should the donor be impaired or not trustworthy and reliable; and (3) a performance-based assessment of both the laboratory and MRO. This last outcome could facilitate actions to improve laboratory performance, MRO training under § 26.607(m), or both. Proposed § 26.603(cd)(1)(iv)(B) would also require a comparative analysis between the POCTA screening result(s) and the corresponding specimen test results obtained from the HHS-certified laboratory if the POCTA indicated a positive,

adulterated, substituted, or invalid screening result or discrepant biological marker, to assess the effectiveness of the POCTA and to inform MRO decisions under § 26.185 or § 26.607(m)(6). The results of this biennial review could also inform the conduct of laboratory audits.

Proposed § 26.603(c~~d~~)(1)(iv)(C) would require that the change control requirement in proposed § 26.603(e) be included in the biennial program review to help ensure that changes implemented over the life of the facility do not result in a reduction in program effectiveness even if a mitigating action was implemented for the specific change. This requirement was developed from §§ 26.137(f) and 26.713(d). This part of the review would require an assessment of all changes since the last review and their potential aggregated impact on FFD program effectiveness. For example, if last year the licensee elected to contract with a different MRO and this year the licensee implemented a new type of POCTA device, each of those program changes probably would not have resulted in a recognizable reduction in FFD program effectiveness. But, if the drug testing positivity rate (or FFD policy violations) for C/Vs decreased markedly during a future maintenance outage that required many C/Vs, then the reduction could indicate, for example, that the POCTA device was not as effective as determined by a forensic toxicologist review under §§ 26.603(e) and 26.607(h) or that the new MRO was improperly crediting prescription medication for laboratory-confirmed positive test results.

Proposed § 26.603(c~~d~~)(2) would state when the licensee or other entity must implement corrective actions. This requirement would be equivalent to the requirement in current § 26.415(b) and was developed from requirements contained in §§ 26.41(a) and (f), 26.127(e), 26.129(b)(1)(i), 26.137(f)(3) through (5), 26.155(a)(6), 26.157(e), 26.159(b)(1)(i), and 26.203(e)(2). Corrective actions must be implemented to correct root causes, contributing causes, or both. There is margin built into the FFD performance

thresholds and qualitative factors (e.g., to account for potential changes in drug and alcohol testing performance data when there is a large influx of C/Vs to perform maintenance) that may influence a licensee or other entity's causal determination for an occurrence. Thus, generalized or qualitative corrective actions may be implemented like informing management and placing a sufficiently descriptive summary of the occurrence in a corrective action program for future monitoring to assess recurrence.

However, should the occurrence challenge safety or security or significantly exceed a performance threshold even when considering qualitative factors and margin, the licensee or other entity should implement more robust corrective actions to resolve the cause. An example of a challenge to safety or security would be the situation when an NRC-licensed operator or maintenance professional had operated, surveilled, or maintained safety-significant SSCs and was determined to have been impaired by behavioral observation or potentially under the influence of a narcotic as determined by an alcohol or drug test or screening result. Immediate corrective actions could include, but would not be limited to, a licensee or other entity assessment of the duties and responsibilities recently performed by the individual. Operating experience within the LWR operating reactor community demonstrates few FFD policy violations per year per site have been caused by individuals who perform or direct the performance of safety or security-significant activities. Therefore, any such violations of the FFD policy in a particular work category in one year could be a significant performance deficiency. These violations could be even more significant at part 53 facilities that have a very small workforce subject to part 26.

Proposed § 26.603(c~~d~~)(3) would require the licensee or other entity to biennially assess and document its FFD performance monitoring program; this requirement was developed from § 26.41(b). This documented review would demonstrate that the

performance measures and thresholds are appropriate based on site- and licensee's fleet-level program performance, if applicable, and industry performance and adjusted to maintain FFD program effectiveness. Also, as a result of this effort, the licensee or other entity would be in possession of lessons learned from fleet-level performance, if applicable, and industry performance that could contribute to their own performance assessment to maintain program effectiveness.

Under proposed § 26.603(cd)(3)(i), the identified program weaknesses and corrective actions resulting from the biennial review would be required to be summarized in the licensee's or other entity's annual report to the NRC in compliance with either § 26.417(b)(2) or § 26.717, as applicable. This information would inform the NRC of FFD program weaknesses to facilitate regulatory oversight and enable the NRC to aggregate industry data for use in a licensee or other entity PMRP.

Proposed § 26.603(cd)(3)(ii) would establish when the biennial PMRP review must be completed and when corrective actions from the review must be implemented. The NRC selected the May 15th date of odd-numbered years to help ensure that all FFD programs will maintain their previously determined performance measures and thresholds or reset them based on FFD program performance early in the year in which the biennial review was conducted. This would assist in obtaining quality FFD performance data over two annual reporting cycles and evaluating whether previous corrective actions were effective.

In proposed § 26.603(de), the NRC proposes a change control requirement for subpart M of part 26 FFD programs. Requiring licensees and other entities to demonstrate compliance with certain requirements before implementing changes to their FFD programs would be necessary for two primary reasons. First, proposed changes to a licensee's or other entity's FFD program could affect the analysis performed by the

licensee or other entity under proposed § 26.604~~3~~(a~~e~~), which helps determine the FFD program requirements that must be implemented. If this analysis changes, then the licensee's or other entity's FFD program requirements might change. Second, the requirements in subpart M of part 26 are performance based. Therefore, FFD program implementation may change periodically in response to societal changes in substance abuse or from PMRP implementation. Change control therefore relies on the licensee or other entity maintaining its procedures in a manner that details how its FFD program is to be implemented while incorporating changes, with documentation that justifies the changes to support the PMRP, audits, and NRC inspection.

Proposed § 26.603(d~~e~~)(1) would permit the licensee or other entity to implement changes to its FFD program if it performs and retains an analysis demonstrating that the change does not reduce the effectiveness of the FFD program or the change was necessitated or justified by a change to part 26, laboratory processes, or guidance issued by the HHS or NRC. The proposed change control requirement would enable flexibility in program implementation should the NRC or HHS change its drug testing procedures (as implemented by the licensee or other entity through its procedures) in response to changes in societal substance abuse or drug testing technologies.

The proposed change control requirement was developed from the change control requirements in § 50.54(p) and (q)—the change control requirements for security and emergency plans, respectively. However, unlike these two requirements, the NRC does not review and approve a licensee's or other entity's FFD program or its implementing procedures, and the FFD program is not licensing basis information as described in § 53.1300 or § 53.4900.

Proposed § 26.603(d~~e~~)(2) would require that if a change reduces FFD program effectiveness, then the licensee must implement a mitigating strategy so the FFD

program, as revised, will continue to demonstrate compliance with the performance objectives in § 26.23 and not result in a reduction in program effectiveness.

Proposed § 26.603(dе)(3) would prohibit, with one exception, the use of the change control process to reduce the minimum panel of drugs to be tested and would reference the drugs listed in proposed § 26.607(c)(1). Proposed § 26.607(c)(1) would reference current § 26.31(d)(1), which states that, at a minimum, licensees and other entities shall test for marijuana metabolite, cocaine metabolite, opiates (codeine, morphine, 6-acetylmorphine), amphetamines (amphetamine, methamphetamine), phencyclidine, adulterants, and alcohol. The testing of these drugs and drug metabolites, except phencyclidine, and alcohol is necessary for the FFD program to remain effective. Also, there is no proposed subpart M of part 26 requirement stating that this panel of drugs and drug metabolites needs to consist of only scheduled drugs.[10] This flexibility would account for the situation where an impairing substance becomes prevalent in society and a licensee or other entity elects to add the substance to their panel of substances to be tested prior to it being scheduled by the Drug Enforcement Administration.

The exception in proposed § 26.603(dе)(3) would be that, should HHS elect to remove phencyclidine from the panel of drugs and drug metabolites to be tested, a licensee or other entity could make this change in its FFD program without resulting in a reduction in FFD program effectiveness. This outcome would be justified based on the

[10] The Drug Enforcement Administration classifies drugs, substances, and certain chemicals used to make drugs into five (5) distinct categories, depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. These categories appear as Schedules I through V of section 202 of the Controlled Substances Act [(21 U.S.C. 812)]. Schedule I drugs have a high potential for abuse, have no currently accepted medical uses in treatment in the United States, and lack accepted safety for use under medical supervision. At the other end of the classification scheme, Schedule V drugs have the least potential for abuse among the five categories of drugs, have a currently accepted medical use in treatment in the United States, and abuse of the drug may lead to limited physical dependence or psychological dependence. For more information, see https://www.dea.gov/drug-information/drug-scheduling.

very infrequent occurrence rate of FFD policy violations due to phencyclidine use since 2010. However, if HHS proposes to remove a class of drugs from the panel of drugs to be tested that is listed in § 26.31(d)(1), except for phencyclidine, then a licensee or other entity may not make a similar change to its panel of drugs to be tested, because this change would be a reduction in FFD program effectiveness even with a mitigative strategy implemented.

Changes in the HHS panel of drugs and drug metabolites to be tested may also shift from one metabolite to a different metabolite for the same drug class (e.g., amphetamines, opioids) to be tested. Should HHS issue such a change to its panel, this would not be expected to result in a reduction in FFD program effectiveness because HHS would be targeting a more prevalent or effective metabolite in its drug testing program. This situation could occur as HHS gathers more operating experience from Federal Government implementation of its HHS Guidelines, or data generated by drug testing laboratories and Federally mandated drug testing programs required by Federal agencies such as the NRC or U.S. Departments of Transportation, Energy, or Defense.

Proposed § 26.603(de)(4) would require that change control records be maintained for a 5-year record retention period based on the current NRC practice to conduct triennial inspections of licensees' and other entities' FFD programs. This would afford the NRC an opportunity to review the licensee's or other entity's determination that FFD program changes have not reduced the effectiveness of their FFD program. Licensees and other entities would also be required to summarize each change made under proposed § 26.603(e) in their annual FFD performance reports required by § 26.617(b)(2) or § 26.717, as applicable.

Proposed § 26.604 would establish the minimum set of FFD program requirements for licensees and other entities who have a documented analysis that

demonstrates that the facility and its operation satisfy the criterion in § 26.604(a) ~~53.860(a)(2) or § 53.4330(a)(2), as applicable~~. For these licensees, compliance with the performance objectives in § 26.23 would be ensured through the BOP; defense-in-depth measures proposed in subpart M of part 26 like the PMRP, change control, and audits; and other requirements, such as those for AA, physical protection, and licensed operators. The adequacy of these measures in satisfying the performance objectives is supported by operating experience, which demonstrates margin between an FFD-related occurrence and a condition adverse to safety or security, as illustrated by for-cause, post-event, and random testing data. A facility that satisfies the criterion in proposed § 26.604(a)~~53.860(a)(2) or § 53.4330(a)(2), as applicable,~~ would present a smaller potential radiological consequence than a facility that does not satisfy the criterion, so the requirements in proposed § 26.604 are scaled to the lower risk presented consistent with the Commission's Advanced Reactor Policy Statement.

The disadvantages of implementing the FFD program described in proposed § 26.604 would be few. Since drug and alcohol testing would not be required, behavioral observation would be the keystone requirement in this performance-based framework to provide that individuals are fit for duty, trustworthy, and reliable, and can safely and competently perform the duties and responsibilities making them subject to the FFD program. If not, the individuals would be assessed in accordance with the licensee's or other entity's procedures similar in manner to that required by subpart K of part 26, and the proposed PMRP would require corrective actions should a threshold be exceeded.

If a licensee or other entity elects not to perform the analysis in proposed § 26.6043(ac) to determine whether it satisfies the criterion ~~in proposed § 53.860(a)(2) or § 53.4330(a)(2), as applicable~~; performs the analysis and finds that the facility and its

operation does not satisfy the criterion ~~in proposed § 26.603(c)~~; or is a holder of an ML, the licensee or other entity could not implement the FFD program described in § 26.604. Instead, the licensee or other entity would implement either the program described in proposed § 26.605 or an FFD program that demonstrates compliance with all the requirements in current subparts A through I, N, and O of part 26.

Proposed § 26.605 would establish requirements in a graded manner similar to the regulatory framework established by the requirements in subparts A through I, N, O, and K of part 26. This existing graded approach consists of an FFD program for construction of a commercial nuclear plant and a more robust program that must be implemented before reactor operation. The former is the FFD program in proposed § 26.605(a), and the latter is proposed § 26.605(b). Like that for an FFD program under § 26.604, the FFD program under § 26.605 would include FFD program elements similar to those in subpart B of part 26, but the proposed requirements are less prescriptive, enabling more flexibility in program implementation like that offered in subpart K of part 26. For example, the requirements in subpart B of part 26 are explicit requirements for, in part, the collection and analysis of urine specimens. Subpart B of part 26 does not enable the use of oral fluid for drug testing or screening, except under very limited situations as described in subpart E of part 26, or the use of hair specimens, unlike proposed § 26.605. Proposed § 26.605 would require drug and alcohol testing based on either the requirements in part 26 or the HHS Guidelines. The principal benefit of the proposed § 26.605 FFD program is that it would provide a regulatory framework that is consistent with the radiological consequences for a facility that does not satisfy the criteria in proposed § 26.604(a)~~53.860(a)(2) or § 53.4330(a)(2), as applicable,~~ while affording flexibilities in the conduct of drug and alcohol testing.

Proposed § 26.605(a) would apply to licensees and other entities who perform the § 26.6043(ac) analysis and satisfy the criterion ~~in § 53.860(a)(2) or § 53.4330(a)(2)~~ but decide not to implement the FFD program described in proposed § 26.604, licensees and other entities who do not perform the § 26.6043(ac) analysis, and licensees and other entities who perform the analysis but their analysis does not demonstrate that their facility and its operation satisfy the criterion in § 26.604(a)~~53.860(a)(2) or § 53.4330(a)(2)~~. These entities must establish, implement, and maintain an FFD program under § 26.605(a) either during construction activities as defined in § 26.5, or during activities performed under an ML that allows the assembly, testing, or both, of a manufactured reactor. This FFD program implements all the FFD program requirements in § 26.604 plus drug and alcohol testing.

The timing element of the proposed applicability statement of § 26.605(a) is equivalent to that for an LWR licensee or other entity who is performing those same activities at a facility licensed under part 50 or 52 and helps provide assurance that those individuals who assemble, test, or perform construction activities as defined in § 26.5 or direct these activities are fit for duty and trustworthy and reliable. This is important because assembly and testing a manufactured reactor and the construction and testing of SSCs required for facility operation require, in part, adherence to procedures, possible implementation of unique and precise assembly techniques, and quality assurance and controls. Additionally, SSCs within a manufactured reactor may not be accessible, testable, or available for quality assurance and verification after the reactor is assembled. This requirement is also proposed to address solo-assembly activities that may cause latent failures and passive SSCs located internal to a reactor (for example, a fusible link designed to melt at a particular temperature to trigger an actuation mechanism) that are relied upon for safe operation but cannot be inspected or

tested for proper installation, configuration, or operation after installation. A § 26.605(a) FFD program for these types of activities is equivalent to the FFD program applicable to the assembly of the reactor vessel internals and testing of the SSCs internal to the reactor at an LWR licensed under part 50 or 52.

Proposed § 26.605(b) would apply to the same licensees and other entities as in proposed § 26.605(a) but before the loading of fuel onsite into a reactor vessel; before receiving a manufactured reactor; or before individuals subject to part 26 operate, test, perform maintenance of, or direct the maintenance or surveillance of security-related equipment or equipment that a risk-informed evaluation process or alternative method for evaluating safety significance has shown to be significant to public health and safety. These entities must establish, implement, and maintain an FFD program that implements all the requirements in § 26.605(a), except proposed §§ 26.610, “Sanctions”; 26.617, “Recordkeeping and reporting”; and 26.619, “Suitability and fitness determinations”; plus additional requirements due to the increased radiological consequences presented by a part 53 commercial nuclear plant as the licensee readies it for operation. These additional requirements include those in subparts C, D, H, and N of part 26, some of which would replace §§ 26.610, 26.617, and 26.619.

Proposed § 26.605(b) would also enable the licensee or other entity to better integrate its facility into the LWR fleet and Category I fuel cycle facilities because subparts C, D, and H of part 26 would be required. These subparts would be required, in part, because it is expected that: (1) individuals will be able to work at any part 50, 52, or 53 commercial nuclear plant and will possess a nuclear safety culture and desirable qualifications, skills, expertise, or services; and (2) licensees and other entities of facilities licensed under parts 50, 52, and 70 may venture to construct or operate a facility licensed under part 53. Therefore, the implementation of these subparts would

help ensure that all individuals subject to part 26, except those individuals subject to an FFD program under § 26.604, § 26.605(a), or subpart K of part 26, would be subject to FFD programs that provide reasonable assurance that the individuals are fit for duty, trustworthy, and reliable.

Proposed § 26.606, "Written policy and procedures," would require licensees and other entities to implement and maintain an FFD policy and procedures for their FFD programs. This section would establish requirements equivalent to those in current § 26.403, "Written policy and procedures," of subpart K. However, a principal difference is that proposed § 26.606 is written to enable the use of urine, oral fluid, and hair for drug testing and screening.

Proposed § 26.606(a)(1) would require each licensee and other entity to provide a written FFD policy statement to individuals subject to the FFD program before the individuals are subjected to behavioral observation and any FFD program drug and alcohol test. This would be a protection measure afforded to individuals subject to the FFD program to help ensure that they know what is expected of them before being subject to the FFD program and potential consequences should they violate the FFD policy or procedures. This requirement would also contribute to safety and security because understanding FFD program responsibilities may enhance an individual's safety culture or the individual may self-select out of the licensee's or other entity's hiring process.

Proposed § 26.606(a)(2) would require that the FFD policy statement describe the performance objectives in § 26.23, which are the same FFD program performance objectives required for facilities licensed under parts 50, 52, or 70. Having a standard performance outcome based on a licensee or other entity satisfying the § 26.23 performance objectives would enhance consistency in FFD program implementation

across all entities subject to part 26. It would also generate confidence that individuals subject to part 26 will safely and competently perform their duties and responsibilities and use NRC-licensed materials in a manner that will protect the public health and safety and common defense and security.

Proposed § 26.606(a)(3) would require that the FFD policy statement describe the minimum days off requirements in § 26.205(d)(3) or maximum average work hours requirements in § 26.205(d)(7), if applicable.

Proposed § 26.606(a)(4) would require the FFD policy statement be written in sufficient detail to provide affected individuals with information on what is expected of them and what consequences may result from a lack of adherence to the policy, including those elements described in § 26.603(b), part 26-required sanctions, and required medical/clinical treatment and follow-up testing for FFD policy violations. This requirement is equivalent to § 26.403(a) of subpart K but includes an additional description of what the policy statement must include. For example, the policy would describe the NRC-required sanctions to help deter substance abuse and required medical/clinical treatment and follow-up testing for FFD policy violations. This provision would provide a protection measure by helping the individual get the assistance they need and help ensure that the individual refrains from substance abuse.

Proposed § 26.606(a)(5) would require that the FFD policy statement describes the individual's responsibilities to report for work in a physiological and psychological condition that enables the safe and competent performance of assigned duties and responsibilities and inform a licensee- or other entity-designated representative when the individual determines that this cannot be accomplished.

Proposed § 26.606(b) would require licensees and other entities implementing a FFD program in accordance with subpart M of part 26 to establish, implement, and

maintain written procedures for their FFD programs. This requirement would be equivalent to that in § 26.403(b) of subpart K.

Proposed § 26.606(b)(1) would establish requirements for a subpart M of part 26 FFD program in which the licensee or other entity implements a drug and alcohol testing program. This provision would be equivalent to the requirements in current § 26.403(b)(1) of subpart K, but § 26.606(b)(1)(i) through (iv) proposes additional clarity and specificity that licensees and other entities must detail in their procedures to address new testing methods in subpart M of part 26 that are not permitted under the current part 26 framework. Clarity and specificity in procedural instructions would support consistent program implementation, which protects all individuals subject to the program.

Proposed § 26.606(b)(1)(iv) would require that if the licensee or other entity elects to use the HHS Guidelines for the conduct of drug testing, the FFD program procedures must include the name of the specific HHS Guideline and revision being implemented by the licensee or other entity and a description of the specific sections in the guideline that are being implemented, including specimen collections, drug testing, laboratory procedures, and evaluation of test results. This requirement would help ensure the following: the validity and accuracy of drug testing because the specimens would be subject to laboratory testing that has been certified by the HHS; protection of worker rights equivalent to the privacy, information, and due process protections afforded to Federal workers under the HHS Guidelines because the HHS Guidelines are used in the Federally mandated drug testing programs; consistency in program implementation because all individuals subject to the FFD program would be subject to the same collection, testing, and evaluation processes; and FFD program effectiveness because the effectiveness of the HHS Guidelines have been verified by HHS's National Laboratory Certification Program (NLCP). Detailed procedures would enhance MRO and

FFD program personnel reviews of individual test results because instructions would be provided for, in part, the evaluation of specific test results (e.g., positive, negative, biological markers), the conduct of additional testing for invalid or dilute specimens, and the assessment of subversion attempts (e.g., adulterated or substituted). This would benefit FFD program effectiveness and help prevent misunderstanding of program requirements and processes.

Proposed § 26.606(b)(2) would require licensees and other entities to include in their written procedures the immediate and follow-up actions that would be taken, and the procedures that would be used, in certain situations specified in proposed § 26.606(b)(2)(i) through (vi). Proposed § 26.606(b)(2) would be equivalent to the requirements in current § 26.403(b)(2), which provides the same requirement under an FFD program for construction for part 50 or 52 licensees and other entities. This would help ensure the effectiveness of the FFD program and its consistent implementation, because part 53 licensed facilities would be implementing procedures to address the same requirements and with individuals who would understand what is expected of them no matter what part 53 facility they were assigned.

The situation specified in proposed § 26.606(b)(2)(i) would arise when individuals subject to the FFD program have been involved in the use, sale, or possession of illegal substances, illegal drugs, or illicit substances. This provision would be equivalent to current § 26.403(b)(2)(i), except that the phrase “illegal drugs” would be replaced with “illegal substances, illegal drugs, or illicit substances.” Illegal substances would include legal substances used in a manner inconsistent with Federal or State law.

The situation specified in proposed § 26.606(b)(2)(ii) would arise when individuals who are subject to the FFD program are impaired by any substance or the consumption of alcohol as determined by behavioral observation or a test that measures

blood alcohol concentration, as defined in § 26.5. Except for a few differences, this provision would be equivalent to current § 26.403(b)(2)(ii) of subpart K. The NRC would not include the phrases “to excess” and “accurately” in proposed § 26.606(b)(2)(ii). Subpart M of part 26 is a performance-based framework that focuses on impaired human performance, and for alcohol, impairment is determined by behavioral observation or by blood alcohol concentrations exceeding the limits in § 26.103, “Determining a confirmed positive test result for alcohol,” using an evidentiary breath testing (EBT) device for alcohol (not whether an individual drank “to excess”). If impairment is determined by an individual’s behavior, it must be based on physiological indications of alcohol impairment. These indications are well established in medical, clinical, and law enforcement organizations, and could be used by the licensee or other entity through its procedures and training.[11]

The NRC would include the phrase “illegal substances, illegal drugs, and illicit substances” in proposed § 26.606(b)(2)(ii) based on operating experience and the terminology in current § 26.23(b). There are far more substances that may cause impairment than just drugs, drug metabolites, and alcohol. The phrase “before or while constructing or directing construction of safety- or security-related SSCs” in current § 26.403(b)(2)(ii) would not be included in proposed § 26.606(b)(2)(ii) because proposed § 26.606 would apply during construction, operation, and decommissioning, if applicable. The NRC would include the term “behavioral observation” in proposed § 26.606(b)(2)(ii) because impairment can be visibly or audibly observed in an individual, and individuals

[11] By “well established” the NRC means that there are Federal, State, and non-governmental organizations with reputable and scientifically based resources available for a licensee or other entity to use in its procedures or training to inform individuals of the physiological indications of alcohol impairment or intoxication.

subject to subpart M of part 26 would be trained in behavioral observation under proposed § 26.608.

The situation specified in proposed § 26.606(b)(2)(iii) would arise when individuals who are subject to an FFD program that includes drug and alcohol testing attempt to subvert the testing process by adulterating or diluting specimens (*in vivo* or *in vitro*), substituting specimens, or by any other means. Except for one difference, this provision would be equivalent to current § 26.403(b)(2)(iii). The NRC would include the phrase "if drug and alcohol testing is conducted" to address the licensee or other entity who implements § 26.604, which does not require drug and alcohol testing. The purpose underlying this requirement has increased in significance since issuance of the 2008 part 26 final rule because subversion attempts have accounted for about one-third of all FFD policy violations every year since 2016.

The situation specified in proposed § 26.606(b)(2)(iv) would arise when individuals, who are subject to an FFD program that includes drug and alcohol testing, refuse to provide a specimen for analysis or refuse to follow instructions provided by FFD program personnel. Except for two differences, this provision would be equivalent to current § 26.403(b)(2)(iv). As with proposed § 26.606(b)(2)(iii), the NRC would include the phrase, "If drug or alcohol testing is conducted," to account for an FFD program implemented under § 26.604. The NRC would include the phrase "or follow the instructions provided by FFD program personnel" based on an existing requirement in § 26.89(c) that the collector must inform the donor that if the donor refuses to cooperate in the specimen collection process, then such refusal will be considered a refusal to test and sanctions for subverting the testing process will be imposed.

The situation specified in proposed § 26.606(b)(2)(v) would arise when individuals who are subject to an FFD program had legal action taken relating to drug or alcohol use. This requirement would be equivalent to current § 26.403(b)(2)(v).

The situation specified in proposed § 26.606(b)(2)(vi) would be when individuals subject to an FFD program demonstrated character or actions indicating that the individual cannot be trusted or relied upon to perform those duties and responsibilities or maintain access to NRC-licensed facilities, SNM, or sensitive information. This includes character traits beyond those attributed to drug or alcohol use. This proposal would help ensure that the licensee or other entity will implement an FFD program designed to demonstrate compliance with the § 26.23(c) performance objective that FFD programs must provide "reasonable measures for the early detection of individuals who are not fit to perform the duties that require them to be subject to the FFD program." An individual who is not trustworthy and reliable is not fit to perform or direct the performance of those duties and responsibilities or be afforded those types of access that make the individual subject to an FFD program.

This proposed requirement also would help to align the subpart M of part 26 BOP with the BOP implemented under § 73.56(f) and proposed § 73.120 and the purpose of the IMP as described in § 73.55(b)(9) and proposed § 73.100(b)(9).[12] The demonstrated character and actions of an individual can indicate whether the individual can be trusted and relied upon to safely and competently perform assigned duties and responsibilities or be afforded those types of access making the individual subject to the FFD program.

[12] The IMP must monitor the initial and continuing trustworthiness and reliability of individuals granted or retaining unescorted AA to a protected or vital area and implement defense-in-depth methodologies to minimize the potential for an insider to adversely affect, either directly or indirectly, the licensee's capability to protect against radiological sabotage.

This holds true for any demonstrated adverse character indication or action on- or offsite.

The phrase “character or actions” would be used in proposed § 26.606(b)(2)(vi) to focus on observed examples that indicate an individual subject to subpart M of part 26 may not be fit for duty or trustworthy and reliable. Character traits include but are not limited to personality, temperament, honesty, carelessness, apathy, psychosis, and commitment to safety culture. Assessment of an individual’s character should consider the potential for changes in these traits when compared to a previous baseline. Actions would include a physical or verbal demonstration of a character trait that could call into question an individual’s fitness, trustworthiness, or reliability. For example, the individual does something physically, verbally, or in writing (e.g., falsifying records, driving while impaired, or harming or threatening to harm oneself, others, or property) that compels another individual to conclude that the observed individual cannot be trusted or relied upon. Unlike the background investigation and reviews of “character and reputation” in § 73.56(d)(6) and (k)(1)(v) and proposed § 73.120, which are principally retrospective reviews of an individual and may be based on third-party information (i.e., information from individuals not subject to NRC requirements), the “character or action” focus of proposed § 26.606(b)(2)(vi) would be a present observation of an individual subject to the FFD program and performed by an individual who is also subject to the FFD program. Whether the information would be received from an individual subject to the FFD program or someone who is not subject to the FFD program, the licensee or other entity would need to review this information (i.e., determine if the information and its source are credible) to determine whether the individual should maintain authorization.

Proposed § 26.606(b)(3) would require licensees and other entities to address in their procedures the process, including the duties and responsibilities of FFD program

personnel, to be followed if an individual's behavior or condition raises an FFD concern. This provision would also require a process to be conducted when credible information is received by the licensee or other entity that the individual is not fit for duty, trustworthy, and reliable.

With a few exceptions, proposed § 26.606(b)(3) would be equivalent to current § 26.403(b)(3). Instead of the phrase "while constructing or directing the construction of safety- or security-related SSCs" in current § 26.403(b)(3), the NRC would use "on the NRC-licensed facility" in proposed § 26.606(b)(3) because this provision would apply during commercial nuclear plant construction, operation, and decommissioning, if applicable, in addition to holders of an ML as described in § 26.3(f). The requirement that the roles and responsibilities of FFD program personnel be described was developed from current §§ 26.4(g) and 26.31(b) and operating experience, which has demonstrated that clear job descriptions help ensure that individuals know who is designated by the licensee or other entity to make decisions regarding FFD program implementation and who can be approached when physiological or psychological help is needed. This is principally a protection consideration afforded to individuals subject to the FFD program.

The proposed requirement would also include two conditions not found in current § 26.403(b) that would clarify the initiation of the fitness determination process should an individual's behavior or condition raise an FFD concern. The phrase, "impairment from any cause that in any way could adversely affect the individual's ability to safely and competently perform the individual's duties," would reflect the § 26.23(b) performance objective. The condition, "the receipt of credible information indicating that the individual cannot be trusted or relied on to perform those duties and responsibilities making the individual subject to this part," would reflect the § 26.23(a) performance objective. In

either case, as required by § 26.23(c), the FFD program must provide reasonable measures for the early detection of individuals who are not fit to perform the duties that require them to be subject to the FFD program.

Proposed § 26.606(b)(4) would require licensees and other entities to have written procedures that address the operation and oversight of an onsite or offsite collection facility. This requirement would be equivalent to current §§ 26.403(b) and 26.405(e) and is developed from § 26.41(b), which states that each licensee and other entity who is subject to subpart B of part 26, shall ensure that the entire FFD program is audited, which is part of a licensee's or other entity's oversight of the facility, and § 26.87(a), which states that each FFD program must have one or more designated collection sites that have all necessary personnel, materials, equipment, facilities, and supervision to collect specimens for drug testing and to perform alcohol testing. Having procedures for the operation and oversight of the onsite or offsite collection facility would enhance consistency in program implementation, protect individuals subject to testing, and account for the flexibilities afforded in the types of biological specimens than may be collected under an FFD program subject to subpart M of part 26. Section 26.606(b)(4), when used with the PMRP described in § 26.603(d) and the proposed audit requirement in § 26.605(a), would help maintain FFD program effectiveness and prevent subversion attempts at facilities that may not be under the direct day-to-day oversight of FFD program personnel.

Proposed § 26.606(b)(5) would require licensees and other entities to have written procedures that address the fatigue management requirements in §§ 26.202(b), "Procedures"; 26.205(d)(3); and 26.205(d)(7), if applicable.

Proposed § 26.606(b)(6) would require licensees and other entities to have written procedures that provide measures to prevent subversion of drug and alcohol tests conducted onsite and offsite. This proposal was developed from § 26.27(c)(1).

Proposed § 26.607, "Drug and alcohol testing," would establish drug and alcohol testing requirements for licensees and other entities implementing proposed § 26.604, at their discretion, and licensees and other entities implementing proposed § 26.605. Except for a few differences, proposed § 26.607 would be equivalent to current § 26.405, which requires licenses and other entities implementing an FFD program under subpart K of part 26 to have a drug and alcohol testing program that demonstrates compliance with the requirements in § 26.405(b) through (g). The differences are commensurate with the risk consequences presented by a part 53-licensed facility as compared to a part 50 or 52 nuclear power plant. These proposed requirements would improve flexibility in the conduct of drug and alcohol testing while maintaining protections afforded to individuals subject to the FFD program.

Proposed § 26.607(a) would require licensees and other entities to obtain a split specimen for all drug tests using oral fluid or urine for all test conditions in § 26.607(b), (h) and (j). Neither current subpart K nor current subparts B or E of part 26 require a split specimen. However, the majority of the LWR fleet uses split specimens for drug testing and commercially available drug screening products use a split specimen technique. Since publication of the 2008 part 26 final rule, the HHS has issued guidelines for urine and oral fluid that require split specimens, and the draft proposed HHS Guidelines for hair requires split specimens, as well.

The required use of a split specimen process would protect the individual because, upon a donor-alleged discrepant or questionable test result, the donor may provide permission to test the split specimen (specimen B) in an effort to refute the

laboratory test results for specimen A. The requirement also would enable the MRO to direct laboratory testing of specimen B if specimen A were invalid; though the NRC expects specimens becoming invalid at the laboratory to be a rare occurrence as testing would be conducted in HHS-certified laboratories with trained collectors. In the event that a specimen is determined to be invalid, then the occurrence would likely warrant further investigation by the MRO and laboratory to identify the cause. This protocol would be equivalent to the special analysis testing in current § 26.163(a)(2) for dilute specimens in that additional laboratory analysis is performed because of a questionable test result.

If a split specimen is tested by an HHS-certified laboratory, then the test result from specimen B must be used as part of the determination for an FFD policy violation as required by § 26.185(n), “Evaluating results from a second laboratory.” However, this is not to say that the test results from specimen A should be discarded. Since the HHS-certified laboratory should report all test results from all specimens tested to the MRO, like the information described in § 26.169, “Reporting results,” test result differences between specimens A and B can be used to inform the MRO as to what should be reported to the licensee or other entity to either facilitate medical or clinical assistance for the individual, inform an FFD-policy violation determination, or both.

The proposed § 26.607(a) requirement would also state that if the licensee or other entity elects to use a POCTA device for screening during random testing or portal area monitoring (e.g., pre-access screening), a split specimen would not need to be taken. The reason for this exception would be that the requirements in § 26.607(h)(4) establish the process to be implemented when a screening test indicates a presumptive positive, adulterant, or a discrepant biological marker, if applicable. This process includes collecting and testing a specimen for analysis at an HHS-certified laboratory.

Proposed § 26.607(b) would require the licensee or other entity to subject individuals identified in § 26.202 to drug and alcohol testing under the five conditions listed in § 26.607(b)(1) through (5). Proposed § 26.607(b) would be equivalent to current § 26.405(c).

Proposed § 26.607(b)(1) would require pre-access testing similar to current § 26.405(c)(1), which requires testing before assignment to construct or direct the construction of safety- or security-related SSCs. Unlike current § 26.405(c)(1), the proposed requirement would not include the phrase, “construct or direct the construction of safety- or security-related SSCs,” because, for licensees or other entities under part 53, the pre-access test condition applies to construction, operation, and decommissioning, if applicable, to help inform a licensee’s or other entity’s authorization determination. The proposal also would use “pre-access” instead of “pre-assignment,” which is used in current § 26.405(c)(1).

A pre-access test would require the collection of an oral fluid or a urine specimen no more than 14 days before the individual is granted unescorted access. Although this change has roots in the 2008 part 26 final rule, which reduced the period within which pre-access testing must be performed from 60 days to 30 days or less, the 14-day proposal is based on three lessons learned from operating experience.

First, the 14-day period would be a large enough window of time to collect the specimen and evaluate test results because licensees or other entities typically receive laboratory test results within 5 business days of laboratory receipt of the biological specimen. At the same time, the 14-day period would be small enough to help ensure that the test results are representative of the individual’s forensic toxicology before being granted authorization.

Second, the 14-day window would enable the licensee or other entity to conduct an unannounced pre-access drug and alcohol screening using a hair specimen or a POCTA. This would help prevent an individual from attempting to subvert the drug and alcohol test by temporarily abstaining from drug or alcohol abuse or adulterating or substituting their specimen to obtain a non-positive test result.

Third, the NRC does not expect licensees and other entities licensed under part 53 to have the large and periodic influxes of individuals (either licensee employees or C/Vs) that LWRs have to support facility operation, maintenance, engineering design changes, or nuclear refueling. Therefore, these licensees or other entities would not be periodically challenged to in-take a large workforce within the proposed 14-day pre-access testing window.

Proposed § 26.607(b)(2) would require the licensee or other entity to conduct random drug and alcohol testing of all individuals subject to the FFD program. With one exception, this proposed requirement would be equivalent to current § 26.405(b). Section 26.405(b) gives licensees and other entities that implement an FFD program subject to subpart K of part 26 the option to impose random drug and alcohol testing. Proposed § 26.607(b)(2) would not offer that option because subpart M of part 26, unlike subpart K, would not allow a licensee or other entity to implement a fitness monitoring program under current § 26.406 instead of a random testing program. The principal reasons for not allowing this flexibility would be that no licensee or other entity has ever implemented a fitness monitoring program (i.e., there is no operating or regulatory experience on which to judge the effectiveness of a fitness monitoring program) and the proposed subpart M framework already uses behavioral observation to help ensure FFD program effectiveness. Supplementing the proposed § 26.609 BOP with an additional observation technique (i.e., the fitness monitoring program) would not result in a level of

deterrence or detection equivalent to that which would be obtained through behavioral observation and random drug and alcohol testing.

Proposed § 26.607(b)(2)(i) through (v) would provide specific requirements for the conduct of a random testing program. These paragraphs would be equivalent to § 26.405(b)(1) through (4), although with a few differences. The similar provisions would be proposed in §§ 26.607(b)(2)(i), 26.607(b)(2)(iii), and 26.607(b)(2)(iv).

The differing provisions would include proposed § 26.607(b)(2)(ii), which would refer to an "FFD program procedure" instead of the reference to an "FFD program policy" in § 26.405(b)(2) because procedures contain the instructions that implement FFD program requirements, but the FFD policy need not contain specific instructions. Section 26.607(b)(2)(ii) would also require individuals who are selected for random testing to report to the onsite collection site, as opposed to the collection site in § 26.405(b)(2) because alcohol metabolism necessitates a relatively timely alcohol test. This change is also proposed because the NRC expects that part 53 licensees and other entities may use a combination of onsite (for random, for-cause, and post-accident testing) and offsite (for pre-access, post-accident, and follow-up testing) collection facilities for drug and alcohol testing and may have to afford reasonable accommodation to certain individuals, which would add complexity in the licensee's or other entity's procedurally determined time period in which an individual must report to the collection facility.

Another difference from § 26.405(b) would be proposed § 26.607(b)(2)(v), which would establish the random testing rate for the population of individuals subject to testing. Subpart K of part 26 does not establish a random testing rate. The proposed requirement would be equivalent to current § 26.31(d)(2)(vii), which requires that the sampling process used to select individuals for random testing provides that the number

of random tests performed annually is equal to at least 50 percent of the population that is subject to the FFD program. The NRC would revise that slightly for proposed § 26.607(b)(2)(v) to require a 50 percent random testing rate for the licensee employee population and a 50 percent random testing rate for the C/V population. The NRC proposes this change for two reasons.

First, although operating experience has demonstrated that § 26.31(d)(2)(vii) helps provide reasonable assurance that individuals are fit for duty and trustworthy and reliable through the detection and deterrence of substance abuse, this same operating experience demonstrates that, on many occasions, the C/V population has been tested at a rate lower than 50 percent, even though this population results in the majority of all FFD policy violations. This bias occurs because C/Vs are available for testing only during short periods of time or periodically throughout the year, whereas licensee employees are essentially always available for a test.

A second reason why the NRC is proposing a different 50 percent random testing protocol than in the current part 26 requirements is that the flexibilities afforded to part 53 licensees or other entities in subpart M of part 26 are not afforded to licensees or other entities that must implement an FFD program under subparts A through I, N, and O of part 26. These flexibilities include enabling the use of a POCTA device to screen individuals during the random testing process and the use of offsite collection facilities for pre-access testing. The potential reduction in FFD program effectiveness caused by licensee or other entity implementation of these options would be offset by subpart M requirements that mitigate possible challenges to the FFD program, such as the 50 percent random testing rate for the licensee employee population and 50 percent random testing rate for the C/V population.

Proposed § 26.607(b)(3) would require for-cause testing equivalent to that used in current FFD programs implementing § 26.405(c)(2). The NRC would require for-cause testing, like random testing, to be conducted onsite to ensure that the test is conducted as soon as reasonably practicable. This is an important consideration when for-cause testing for alcohol or using oral fluid for drug screening or testing because human metabolism continually lowers the concentrations of the drugs, drug metabolites, and alcohol perhaps to concentrations lower than the initial or confirmatory testing cutoffs. Additionally, for facilities that are sited in geographically remote locations, an offsite collection facility might be too far away or not readily accessible.

Proposed § 26.607(b)(4) would require post-event~~accident~~ testing in a manner equivalent to current § 26.405(c)(3) with a few adjustments. For part 53 licensees or other entities, the NRC proposes post-event~~accident~~ testing under two conditions: ~~accidents~~ events involving human errors that may have caused or contributed to the ~~accidents~~ events (proposed § 26.607(b)(4)(i)), and ~~accidents~~ events not involving human error that result in adverse health consequences or damage to any safety- or security-related SSC (proposed § 26.607(b)(4)(ii)). The ~~NRC proposes to use the word "accident" in § 26.607(b)(4) instead of "event" as used in § 26.405(c)(3)(i) for consistency with the paragraph heading, but the~~ word "significant" would not be used in § 26.607(b)(4)(ii)(A) to describe the "illness or personal injury" as used in § 26.405(c)(3)(i) because § 26.607(b)(4)(ii)(A) would describe which illnesses or injuries are covered. Proposed § 26.607(b)(4)(ii)(B), unlike § 26.405(c)(3)(ii), would not use the word "significant" to describe the damage to safety- or security-related SSCs because any damage to safety- or security-related SSCs would require testing within four hours of the ~~accident~~ event unless immediate medical intervention precludes the conduct of the test on the individual(s) who caused or contributed to the ~~accident~~event. Proposed

Commented [A28]: The edits in this document change the heading for paragraph 26.607(b)(4) to match the use of the word "event" as is used in 26.405(c)(3)(i), thus obviating the need to use the word "accident" for consistency with the heading. By accomplishing this, the proposed rule will yield better consistency with the remainder of the part.

§ 26.607(b)(4)(ii)(B) also would not use the word “construction” as in § 26.405(c)(3)(ii) because § 26.607(b)(4) would apply to construction, operation, and decommissioning, if applicable.

Proposed § 26.607(b)(4)(i) would require the licensee or other entity to define in its procedures the terms “human error” and “~~accident~~event.” These terms may take on various meanings and they are not defined in the current or proposed rule, so the licensee or other entity would be required to describe or define these terms to help ensure consistent implementation of subpart M of part 26 and that the post-~~accident~~ event test condition would be consistently applied to all individuals subject to the FFD program. The § 26.405(c)(3)(i) requirement that “the event is recordable under the Department of Labor standards contained in 29 CFR 1904.7, and subsequent amendments thereto,” would not be carried over to proposed § 26.607(b)(4). The clarification based upon the wording of 29 CFR 1904.7 was included in § 26.405(c)(3)(i) in order to reduce the number of unnecessary post-event tests performed for minor injuries and illnesses and to improve the efficiency of FFD programs. (73 FR 16966, 17019; March 31, 2008) Consistent with the Principle of Good Regulation of Reliability that regulations should not be unjustifiably in a state of transition, ~~Instead,~~ the NRC proposes to prescribe the post-accident test conditions in § 26.607(b)(4)~~,~~ and eliminate the citation to 29 CFR 1904.7 ~~in part so they would not~~ to avoid changes unless the NRC amends the requirement.

Proposed § 26.607(b)(5) would require follow-up testing. This requirement would be equivalent to current § 26.405(c)(4), although the proposed § 26.607(b)(5) would further describe follow-up testing. The NRC proposes to describe follow-up testing as part of a series of tests for drugs, alcohol, or both, which are performed after an individual subject to part 26 has violated the FFD policy on substance use or abuse, or

the sale, use, or possession of illegal drugs. Follow-up testing would be used to verify an individual's continued abstinence from substance abuse. The NRC would not include a reference to a follow-up plan as in § 26.405(c)(4) because the intent of a follow-up plan is to conduct a series of drug tests, alcohol tests, or both, to verify continuing abstinence from substance abuse. Nevertheless, individuals who violate an FFD policy on substance use or abuse, or the sale, use, or possession of illegal drugs, should have a follow-up plan that includes a definition of "abstinence" from the medical professional prescribing the plan.

Proposed § 26.607(c) would provide additional testing requirements. This proposed requirement would be equivalent to § 26.405(d) and would require implementation of select requirements from current subpart E of part 26. The proposed requirements would govern directly observed collections, shy bladder situations, special analysis testing, and alcohol testing. These requirements would be necessary to maintain FFD program effectiveness equivalent to that currently implemented by the LWR fleet.

Proposed § 26.607(c)(1) would require validity testing and establish the minimum panel of drugs and drug metabolites to be tested. This panel would be the same as those in §§ 26.31(d)(1) and 26.405(d) because, based on operating experience from LWR FFD program implementation, this panel has been determined to contribute to a licensee or other entity satisfying the FFD performance objectives in § 26.23(a) through (d).

Proposed § 26.607(c)(1) would differ from § 26.405(d) because it would require testing of oral fluid and urine specimens for validity, including at least one biological marker (developed from an HHS Guidelines provision) and one adulterant (equivalent to current validity testing for urine specimens in part 26). Section 26.405(d) requires that

urine specimens collected for drug testing be subject to validity testing. The addition of oral fluid validity testing is important because, just as there are publicly available kits to subvert a urine drug test, kits that may be used to subvert a drug test that uses oral fluid as a biological specimen are also readily available.

Proposed § 26.607(c)(2) would include requirements that already exist in the part 26 framework that provide protections for individuals subject to the FFD program and contribute to testing effectiveness when collecting and assessing a urine specimen. Specifically, current § 26.115, "Collecting a urine specimen under direct observation," describes the exclusive grounds for performing a directly observed collection and the process to be followed to protect the privacy of the individual. Section 26.119, "Determining 'shy' bladder," establishes the process to be followed when a donor is not able to produce a sufficient amount of urine for testing, and § 26.163(a)(2) requires special analysis testing when a specimen is dilute to help prevent a subversion attempt.

Proposed § 26.607(c)(3) would require implementation of all the current alcohol testing requirements in § 26.91, "Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use," through § 26.103, "Determining a confirmed positive test result for alcohol." Using the same alcohol testing framework for parts 50, 52, 70, and 53 licensees and other entities would provide for regulatory consistency, protections for individuals subject to the FFD program (e.g., the quality controls and verification applied to the EBT device), and FFD program effectiveness (e.g., accuracy of test results). For alcohol testing, unlike drug testing, there is a preponderance of evidence that correlates blood alcohol concentrations to impairment and intoxication. Furthermore, FFD performance data has demonstrated that the time-dependent alcohol cutoffs in § 26.103 have increased the detection of individuals who

are under the influence of alcohol. For these reasons, the current alcohol requirements in part 26 are proposed for FFD programs under subpart M.

Proposed § 26.607(c)(4) would establish additional testing requirements. This proposal would be equivalent to current § 26.405(f) for facilities licensed under part 53 for the conduct of drug testing. Unlike § 26.405(f), proposed § 26.607(c)(4) would not reference validity screening and initial drug and validity tests at licensee testing facilities as this would be required in proposed § 26.607(c)(1). Another minor difference between § 26.405(f) and proposed § 26.607(c)(4) would reflect the requirement in subpart M of part 26 to use an HHS-certified laboratory for all biological specimens collected and not just for urine specimens.

Consistent with § 26.405(f), proposed § 26.607(c)(4) would require the use of an HHS-certified laboratory for all test conditions listed in § 26.607(b), MRO-directed tests, and the testing of a split specimen. Further, HHS-certified laboratory test results using urine or oral fluid would be required for the issuance of an FFD policy violation and part 26-required sanction.

All drug testing would need to be performed at an HHS-certified laboratory to help ensure FFD program effectiveness and to protect the donor from a false positive test result and an unwarranted FFD policy violation. The donor would be protected because laboratory procedures for specimen accessioning, testing, custody and control, and evaluation of test results and the training and qualification of laboratory personnel are evaluated by HHS as part of the NLCP. This provides assurance that the drug testing results are accurate and attributed to the donor. Urine, oral fluid, and hair specimens may also be screened and tested for drugs and alcohol as described in § 26.607. Drug and alcohol screening results obtained from urine and oral fluid specimens collected and analyzed using a POCTA device and screening results

obtained from a hair specimen or a portal monitor may only be used as potentially disqualifying information for a licensee's or other entity's authorization determination (i.e., used to assess the fitness, trustworthiness, and reliability of the individual). These screening results may not be used for the administration of an FFD policy violation and sanction, except as proposed §§ 26.607(i)(3) and 26.610 for subversions, as defined in § 26.5, of the drug and alcohol screening process.

There are three phrases or requirements in § 26.405(f) that the NRC does not propose to use in § 26.607(c)(4). The first is the phrase, "consistent with its standards and procedures for certification," regarding the operation of an HHS-certified laboratory, because the laboratory would not be HHS-certified if it were not following "its standards and procedures for certification." The second is the requirement that urine specimens that yield positive, adulterated, substituted, or invalid initial validity or drug test results must be subject to confirmatory testing by the HHS-certified laboratory, except for invalid specimens that cannot be tested. This requirement would not be used because, under subpart M of part 26, licensees or other entities would be required to use an HHS-certified laboratory. For a laboratory to be HHS-certified, it must follow the HHS Guidelines and include procedures that describe when a specimen cannot be tested. Lastly, the § 26.405(f) requirement that other specimens that yield positive initial drug test results must be subject to confirmatory testing by a laboratory that demonstrates compliance with stringent quality control requirements that are comparable to those required for certification by the HHS, would not be used because subpart M of part 26 would require the use of an HHS-certified laboratory.

Proposed § 26.607(c)(4) would require the licensee or other entity to contract with a primary and backup HHS-certified laboratory. This provision would help ensure that specimens are processed and tested to maintain FFD program effectiveness should

the primary laboratory be unable to perform specimen testing. This would help maintain protections afforded to individuals subject to the FFD program (e.g., should the donor or MRO request testing of the split specimen, a different laboratory could be used). This requirement also would state that the primary and backup laboratories must have a different certifying scientist. Having a back-up HHS-certified laboratory and a different certifying scientist would benefit the program and donor because the drug testing instruments, technicians, and certifying scientist would be independent of the primary laboratory testing and review process. The back-up HHS-certified laboratory may be of the same corporate entity as the primary laboratory.

Proposed § 26.607(c)(4) would also state that the laboratory would be subject to inspection or audit by the licensee or other entity and that records and documents must be provided and/or able to be photocopied and removed from the premises to support the inspection or audit. This requirement would be equivalent to current § 26.41(d) except that laboratories would not be able to limit the use and dissemination of documents copied or taken from the laboratory by a licensee or other entity. This is necessary to ensure the continuing effectiveness of FFD programs, because NLCP findings and audit results could adversely impact FFD program effectiveness. Pertinent information includes and should not be limited to NLCP-identified weaknesses (e.g., custody and control, accessioning, instrumentation, procedures, training, supervision, review of test results, and resolution of previously identified corrective actions) that may impact the effectiveness of FFD programs.

Proposed § 26.607(d) would help protect the donor from mistakes made during the drug and alcohol testing processes and help ensure FFD program effectiveness. The rule would require the licensee or other entity to protect the individual's privacy and the integrity of the specimen and to implement quality controls to ensure that test results are

valid and attributable to the correct individual. This requirement would be equivalent to the first sentence of current § 26.405(e), except that the word “stringent” was removed from the phrase “stringent quality controls,” because the word “stringent” is not defined.

Proposed § 26.607(e) would describe the requirements for licensees and other entities that use offsite collection facilities. Consistent with current § 26.405(e), a licensee or other entity would be able to conduct specimen collections and alcohol testing at a local hospital or other facility. Unlike § 26.405(e), proposed § 26.607(e) would not restrict licensees and other entities to use hospitals and other facilities that meet the requirements in 49 CFR part 40, “Procedures for Transportation Workplace Drug and Alcohol Testing Programs,” because subpart M of part 26 is intended to provide flexibilities beyond those in the current part 26 framework. Licensees and other entities may use these DOT requirements to inform their procedures under § 26.606(b)(1) as long as the procedures do not conflict with the requirements in part 26 or the HHS Guidelines.

Proposed § 26.607(e) would also require licensees and other entities to audit offsite collection facilities before their use and biennially to confirm that the facility procedures are comparable to those described in subpart E of part 26 or the HHS Guidelines for urine and oral fluid. This proposed requirement is based on current § 26.41(a) and (b). The § 26.607(e) audit requirement would be a program effectiveness consideration because offsite collection facilities may not require vigilance of their collectors (e.g., identification of subversion attempts), diligence in the protection of worker rights (e.g., privacy and specimen custody and control), or procedural compliance.

The offsite facility used by a licensee or other entity under proposed § 26.607(e) would have to be licensed to conduct specimen collections and perform alcohol testing,

and be audited, by the State or a State-designated entity. This requirement would help provide assurance of adequate collection facility performance and may help reduce the burden on the licensee or other entity and the collection facility. Crediting a State audit (or State licensure, oversight, or regulation) is established in §§ 26.4(i)(4) and (j), 26.91(e)(5), 26.153(f)(1), and 26.183(a).

Proposed § 26.607(f) would provide the requirements for initial drug testing. This provision would be equivalent to § 26.405(f) except to account for the alternative biological specimens that may be tested under subpart M of part 26. For the testing of all biological specimens, the licensee or other entity under part 53 would be required to use a device that employs an immunoassay screening technique, or an alternative technology that the licensee or other entity has incorporated into its FFD program through the § 26.603(e) change control process, that demonstrates compliance with the requirements of the U.S. Food and Drug Administration (FDA) for commercial distribution. Examples of alternative technologies include liquid or gas chromatography and mass spectrometry. Licensees and other entities would use the § 26.603(e) change control process to evaluate and document a change to their collection and analysis procedures to enable the use of a better or perhaps more cost-effective collection and/or testing technology. Another difference from § 26.405(f) would be changing the word "urine" in § 26.405(f) to "biological specimens" in § 26.607(f). Lastly, proposed § 26.607(f) would include the phrase "discrepant biological marker" as a drug screening result that must be analyzed by an HHS-certified laboratory and evaluated by the MRO to help inform the MRO's determination of a subversion attempt.

Proposed § 26.607(g) would enable a part 53 licensee to use oral fluid as a biological specimen for testing. This requirement would be equivalent to § 26.31(d)(5), which enables the MRO to conduct drug and alcohol testing using alternative methods,

and § 26.405, which does not preclude the use of oral fluid specimens for FFD programs that implement subpart K of part 26 requirements. In order to provide assurance that drug testing is effective and protects the worker, § 26.607(g) would require that the licensee's or other entity's procedures incorporate the HHS Guidelines or the requirements in part 26 for the conduct of urine or oral fluid testing.

The proposed § 26.607(g) requires that the oral fluid collection device must have received premarket approval from the FDA and must not expire before laboratory testing. Also, the drugs, drug metabolites, initial and confirmatory testing cutoffs, and biological markers, if applicable, must be those established by HHS for oral fluid drug testing and the alcohol cutoffs in part 26. If they are not established by HHS or the NRC for the paneled drugs and drug metabolites, then they would be determined and documented by a forensic toxicologist review. This forensic toxicologist review would help ensure that the device accurately tests for the drug, drug metabolite, biological markers, adulterants, and/or alcohol and that the results from the device are comparable to those established in the HHS Guidelines for oral fluid testing.

Proposed § 26.607(h)(1) and (2) would enable the use of a POCTA device during the random and pre-access testing processes. These requirements are adopted from § 26.97, "Conducting an initial test for alcohol using a specimen of oral fluids," and § 26.405(f), which does not preclude the use of oral fluid testing. To use a POCTA device for urine, oral fluid, or other biological indicators (breath, sweat, etc.), a forensic toxicology review would be required to ensure that the device is forensically effective. If the POCTA device is forensically effective, then the donor would be reasonably protected from a false positive test result, the licensee or other entity would be reasonably protected from false negative test results, and the FFD program would remain effective. For a POCTA device to be forensically effective, the forensic

toxicologist would need to document an evaluation that the performance of the POCTA device must be comparable to the requirements in § 26.161(b) for a urine specimen or the procedures in the HHS Guidelines for urine or oral fluid, as implemented by the licensee or other entity through its procedures.

The use of POCTA for oral fluid and urine specimens for the pre-access and random testing processes would be acceptable because individuals in the pre-access process would be subject to an oral fluid or urine specimen collection and possible drug screening using a hair specimen, which are both required to be sent to an HHS-certified laboratory. For random testing, the individual would have also been granted authorization under the AA and FFD requirements and have been subject to behavioral observation and physical protection screening (e.g., verification of identify, and screening for explosives and contraband).

Proposed § 26.607(h)(3) would require that procedures be developed that ensure the effectiveness of the POCTA collection process, assessment of the screening results, and prevention of subversion attempts. This requirement would be equivalent to current § 26.403(b)(1) and would help ensure protections afforded to individuals subject to the FFD program and program effectiveness. The subpart M of part 26 framework enables the use of POCTA for random screening of individuals for any part 53 facility, so the licensee or other entity should exercise due diligence and implement risk management strategies to ensure the efficacy of random screening and its contribution to an effective FFD program.

Proposed § 26.607(h)(4) would provide that an individual donor who screens positive (or whose specimen is invalid or indicates a discrepant biological marker or adulterant) is removed from all duties and responsibilities making the donor subject to subpart M of part 26. Under proposed § 26.607(h)(4)(i), the donor then would be

immediately subject to a drug and alcohol test that provides quantified confirmatory test results from which an FFD policy violation may be issued. Similar to other requirements for specimen collections, except for biological specimens analyzed by a passive detection system, the licensee or other entity would be required to implement procedures that ensure that all specimens collected are uniquely assigned to the donor (i.e., procedures that provide for custody and control of the specimen). If the individual shows signs of impairment during the POCTA process, proposed § 26.607(h)(4)(ii) would require the temporary removal of the individual's authorization until the MRO reviews the laboratory test result(s), and interviews the individual, and a determination of fitness finds that authorization may be restored. Section 26.607(h)(4) is equivalent to § 26.77(b) and was informed by the requirements in §§ 26.419, 26.75(c) and (d), and 26.185(c).

Proposed § 26.607(i) would enable the collection of hair specimens for drug testing to supplement pre-access testing that uses urine or oral fluid specimens. Hair testing would be a new feature in the part 26 framework. The NRC proposes to permit the use of hair testing for only Schedule I or II drugs or their metabolites to inform a licensee's or other entity's determination whether the individual is trustworthy and reliable. For example, if an individual stated no prior use of illegal drugs or potentially addictive habits, a hair screening test could be performed during the pre-access process to ascertain the validity of the individual's statement. However, if the HHS-certified laboratory communicates a laboratory-confirmed positive test result, an FFD policy violation may not be administered. This laboratory information must be treated as potentially disqualifying FFD information, unless the individual subverts the screening process, in which case a permanent denial of authorization must be issued under proposed § 26.610. To provide assurance of testing effectiveness and protections

afforded to individuals subject to the FFD program, proposed § 26.607(i) would require that an HHS-certified laboratory must be used to analyze the hair specimen, a forensic toxicologist must review the licensee's or other entity's hair screening process, the test kit must be cleared by the FDA, and hair screening must be conducted in accordance with the HHS Guidelines. The forensic toxicologist review would be necessary if the panel of drug or drug metabolites to be tested and their cutoffs are not established by HHS or the NRC for hair.

Proposed § 26.607(j) would allow the use of portal area screening for drugs, alcohol, or both. This provision would result in a substantial contribution to a licensee or other entity satisfying the § 26.23 performance objectives by helping ensure that 100 percent of all individuals who arrive at the NRC-licensed facility to perform or direct those duties and responsibilities or maintain those types of access making them subject to the FFD program are fit for duty and deterred from arriving onsite in a physiological condition that may be adverse to safety and security. Additionally, screening could be conducted when an individual exits the NRC-licensed facility to provide assurance that substance abuse had not occurred on the site (see § 26.23(d)). The screening device could be electronically linked to temporarily prevent ingress or egress and could automatically inform licensee- or other entity-designated officials of the portal area alarm. The proposed requirement would enable the licensee or other entity to use innovative technologies to maintain FFD program effectiveness when their PMRP compels the licensee or other entity to implement mitigative strategies to maintain program effectiveness. The use of portal screening technologies may also represent cost savings because, for NRC-licensed facilities that have small staff sizes or are geographically remote, passive drug and alcohol screening technologies could be an

innovative alternative to a random testing program, although the license or other entity would need to request and receive an exemption.

Proposed § 26.607(j) would also provide that if the portal area screening instrument detects a substance that exceeds the instrument's established setpoint, the individual would be tested with either a collection kit that must be analyzed by an HHS-certified laboratory or a POCTA. This situational screening would be equivalent to a for-cause test. The requirements would not allow an individual to be rescreened by the portal area screening instrument following an initial screening detection that exceeded an established setpoint in order to prevent a subversion attempt. Similar to other drug and alcohol testing technologies enabled for use by subpart M of part 26, a forensic toxicology review would be required before using passive screening technology to help ensure the effectiveness of the instrument by protecting against false positive or negative screening results, which would place an unwarranted burden on the individual, licensee, or other entity. These instruments and alcohol screening devices, already in the marketplace, may also be used to determine true identity to facilitate implementation of the FFD BOP, which may be very practicable at facilities that operate with small staff sizes.

Proposed § 26.607(k) would enable the use of a blood specimen for drug, alcohol, or other testing for certain medical conditions as determined by the licensee- or other entity-designated MRO. This requirement would be equivalent to current § 26.31(d)(5). The use of a licensee- or other entity-designated MRO and not one designated by a third party, such as an MRO employed by an offsite specimen collection facility, is important because the MRO must be familiar with the subpart M of part 26 requirements. To help ensure testing effectiveness and protect the worker, the blood test would need to be conducted by a laboratory that demonstrates compliance with quality

control requirements that are comparable to those required for certification by the HHS, such as a hospital or clinic certified by the State, Commonwealth, or territory.

Proposed § 26.607(l) would require licensee and other entities to use a Federal custody-and-control form (CCF) approved by the OMB for the collection and packaging of a hair, oral fluid, or urine specimen. This proposed requirement is based on the CCF documentation requirements in current subpart E of part 26 because subpart K of part 26 does not require the use of a CCF under § 26.117(e). Additionally, when using a POCTA device, the licensee or other entity would be required to implement a licensee- or other entity-approved and -maintained procedure that ensures the reliability of the tracking, handling, and storage of a specimen from the point of specimen collection to final disposition of the specimen and the reliability of an identification system to uniquely assign the specimen to the donor. Both requirements would help protect the worker by helping ensure chain of custody and by contributing to program effectiveness.

Proposed § 26.607(m) would establish requirements for the licensee- or other entity-designated MRO. Section 26.607(m)(1) would be equivalent to § 26.405(g), however, the word “designated” would be added to the first sentence to clarify that the MRO would be designated by the licensee or other entity, and not by a third party. As stated with regard to proposed § 26.607(k), this change would clarify that it is the licensee’s or other entity’s responsibility, through their designated MRO, to determine whether an individual is fit for duty and trustworthy and reliable. This would be consistent with the description of FFD program personnel in current § 26.31(b) and help provide FFD program effectiveness and protections to individuals subject to the FFD program. The paragraph was also modified from § 26.405(g) to address the determinations of FFD policy violations and fitness required by subpart H for a part 53 licensee or other entity that implements the FFD program described in § 26.605(b).

Proposed § 26.607(m)(2) would help ensure that MRO reviews are consistent with those MRO reviews conducted at other NRC-licensed facilities subject to part 26 and that the MRO maintains knowledge of drug collection, testing processes and procedures, and evaluation of testing results.

The NRC also proposes that if an MRO performed the duties and responsibilities in §§ 26.185 and 26.187 for at least three continuous years in the last 10 years prior to being hired or contracted by the licensee or other entity, then the MRO would not need to repeat the initial training and examination requirements. The basis for 3 years is that the MRO would have experienced three annual cycles of evaluating drug and alcohol test results, contributed to the FFD annual report to the NRC, experienced a refueling or maintenance outage, understood the duties and responsibilities of individuals subject to the FFD program to make informed determinations of fitness, demonstrated a safety culture that helps ensure FFD program effectiveness, and been subject to NRC inspection. The basis for 10 years is the relatively long periods between significant changes to part 26 and the HHS Guidelines.

Proposed § 26.607(m)(3) would require that the MRO attend a medical- or clinical-based training session on a triennial basis. This proposal was developed from Section 13.1 of the HHS Guidelines for urine and oral fluid with two substantial differences: the HHS Guidelines state that “requalification training,” including an exam, must be conducted “at least every 5 years from initial certification,” whereas the proposed § 26.607(m)(3) would require a training session every three years. The proposed requirements are justified because changes in societal drug use or forensic toxicology could occur more frequently than every 5 years, which could compel MROs to attend training in areas of forensic toxicology, determinations of fitness, or other part 26

technical areas on a more frequent periodicity than every 5 years to improve their knowledge and expertise.

Proposed § 26.607(m)(4) would require the MRO to evaluate drug testing results by implementing the requirements in § 26.185 or the HHS Guidelines through the licensee's or other entity's procedures. This requirement would help ensure FFD program effectiveness and enhance consistency across the commercial nuclear industry for the evaluation of drug testing results. This also would help protect individuals because they would be subject to the same evaluation criteria. If § 26.185 provides insufficient information for an MRO to make a determination on a drug testing result (including adulterant and discrepant biological markers), the guidance issued by a State agency in the state in which the NRC-licensed facility is located, Federal agency, or nationally recognized MRO training and certification organization may be used to inform an MRO determination. This provision would ensure that the MRO has the flexibility to inform their evaluation of the drug testing results and fitness determination, if necessary, considering the drug- and alcohol-related flexibilities afforded in subpart M of part 26.

The proposed requirement would also state that an MRO need not review a confirmed alcohol positive test result determined by an EBT device under § 26.607(c)(3)(vi) and (vii), which are equivalent to the current requirements in §§ 26.101 and 26.103, respectively. The results of an EBT device are precise and accurate enough to support the issuance of an FFD policy violation without an MRO review of an EBT test result if the instrument demonstrates compliance with the requirements in § 26.91. The NRC acknowledges that there are physiological conditions that may cause an abnormally high blood alcohol concentration, such as diabetes, acid reflux, gastroesophageal reflux disease, and perhaps certain diets (high protein and low carbohydrates). However, operating experience has not demonstrated a compelling

need to require an MRO review of all EBT test results. For consistency, a licensee or other entity may elect to require its MRO to review all EBT test results when a donor communicates a testing concern or physiological condition. If the donor has a testing concern, the occurrence could be appealed under the proposed § 26.613. If the donor presents a physical condition to the MRO that may have caused an elevated EBT test result, the MRO may direct an alternative testing process (see § 26.607(m)(5)) should it be medically necessary.

Proposed § 26.607(m)(5) would require the licensee- or other entity-designated MRO to determine and approve the use of oral fluid or urine as an alternative biological specimen when the donor cannot provide a requested specimen for testing. This proposed requirement is equivalent to § 26.31(d)(5), which enables the use of an alternative specimen collection if a medical condition makes the collection of the biological specimen difficult. This determination and the retest must be completed as soon as reasonably practicable and documented to support recordkeeping, auditing, and NRC inspection.

Proposed § 26.607(m)(6) would require that the MRO review all specimens screened or tested associated with a drug-related FFD policy violation. This includes POCTA, split specimens, and all specimens taken to resolve a discrepant condition, such as a possible subversion attempt, impairment without a known cause, or a donor-requested or MRO-directed retest. To resolve a discrepant condition, the MRO is authorized to test a specimen for a biological marker, adulterants, or additional drugs. The broad scope of this MRO evaluation would be necessary because of the variety of different screening and testing methods that may have been associated with the FFD policy violation. All information learned from the conduct of part 26 drug and alcohol screening and testing should be used in the evaluation of an individual's trustworthiness

and reliability, issuance of a sanction, and development of a follow-up treatment and testing plan, if administered.

Proposed § 26.607(n) is equivalent to current § 26.31(d)(6) and would establish limits on the screening and testing of biological specimens. This is a protection consideration afforded to individuals subject to the FFD program and was not provided in subpart K of part 26. This requirement states that specimens collected under NRC regulations may only be designated or approved for screening and testing as described in this part and may not be used to conduct any other analysis or test without the written permission of the donor. Analyses and tests that may not be conducted include, but are not limited to, deoxyribonucleic acid (i.e., DNA) testing, serological typing, or any other medical or genetic test used for diagnostic or specimen identification purposes.

The NRC proposes to require that no biological specimens may be passively sampled and analyzed in a manner different than described in subpart M of part 26 to ensure workers are protected from non-consensual passive screening. The subpart M framework enables passive detection of drugs and alcohol, whereas passive detection is not afforded in subparts A through I, N, and O of part 26.

Proposed § 26.607(o) is equivalent to current §§ 26.31(b)(1)(iii)(A) and 26.89 and would require that all specimen collections be conducted by a licensee- or other entity-designated and -trained individual. For subpart M of part 26, this would include onsite specimen collections, except a collection by a portal area screening instrument in § 26.607(j),

Proposed § 26.608 would require licensees and other entities to provide FFD program training to individuals subject to the FFD program. The proposed performance-based § 26.608 requirement was developed from the prescriptive training requirements

in current § 26.29 and modeled on current § 50.120 and the proposed requirements in §§ 53.725 and 53.830 because there is no training requirement in subpart K of part 26.

Proposed § 26.608(a)(1) would require an FFD training program that includes the licensee's or other entity's FFD policies and procedures, including fatigue management, and the individuals' FFD program responsibilities. Individuals who collect specimens for testing or screening must also be trained in specimen collector duties and responsibilities, including, at a minimum, specimen collection, custody and control, identification and response to subversion attempts, and privacy. The fatigue management training must include the knowledge and abilities described in § 26.202(c). For individuals specified in § 26.4, a licensee or other entity of a commercial nuclear plant would be required to use a SAT as defined in proposed in § 53.725. These requirements are based on requirements in § 26.29(a)(2), (3), (9), and (10).

Proposed § 26.608(a)(2) would require training on the BOP. This requirement would be based on §§ 26.29(a)(8), (9), and (10) and 26.33. The proposal would require individuals to be trained in the detection of behaviors or conditions related to not only illegal drugs, as in the current § 26.33 BOP requirements, but also illicit drugs and substance abuse onsite and offsite. Also, in reference to impairment from fatigue or any cause if left unattended, the phrase in § 26.33, "may constitute a risk to public health and safety or the common defense and security," would be replaced in § 26.608(a)(2)(iii) with "could result in inattentiveness or human errors," because subpart M of part 26 is focused, in part, on ensuring individuals are fit for duty to safely and competently perform or direct the performance of assigned duties and responsibilities.

Proposed § 26.608(a)(2)(iv) focuses on training to inform individuals that they are responsible for their own conduct, as well as observing others. Specifically, individuals would be trained to recognize when they feel unable to safely and competently perform

assigned duties and responsibilities or act in a trustworthy and reliable manner. The proposed training requirement and the proposed reporting requirement in § 26.606(a)(5) are in the interest of safety and security because the individual is proactively announcing that assistance may be necessary. This would be consistent with the performance objectives in § 26.23(b) and (c) where certain behavior or stress conditions may be indicative of an individual not being fit for duty, trustworthy, and reliable.

Proposed § 26.608(a)(3) would help ensure that individuals subject to the FFD program understand that FFD policy violations would result in an FFD program sanction and that program information learned or generated by FFD program implementation would be used to aide licensee or other entity authorization determinations and be shared, as requested, with other licensees or other entities subject to parts 26, 53, and 73. This proposed requirement is equivalent to § 26.29(a)(1). Proposed § 26.608(a)(3) would be a protection measure afforded to individuals subject to the FFD program because they would understand that licensees and other entities subject to parts 26, 53, and 73 would be informed of, in part, an individual's character, reputation, and ability to follow policies, procedures, and instructions to safely and competently perform assigned duties and responsibilities in a trustworthy and reliable manner. FFD-related information would include drug and alcohol testing results (not quantitative testing values), issuance of any sanctions, FFD-determinations regarding trustworthiness and reliability, testing programs, treatment, and other remedial or corrective action.

Proposed § 26.608(b) would require individuals be trained and receive a trainee assessment before pre-access testing and that refresher training and trainee assessments be conducted periodically thereafter. These requirements would be equivalent to § 26.29(c)(1). However, § 26.608(b) was developed from the SAT-based training requirements in § 50.120 and training elements from the annual training

requirements in § 26.29(c)(2). The term “systems approach to training” would have the meaning in proposed § 53.~~725(c)~~020. A trainee assessment would be the same as in currently required SAT-based training programs.

Proposed § 26.608(c) would require licensees and other entities to periodically evaluate their FFD training programs and revise them as appropriate. This training focus is not required by subpart K of part 26 or § 26.29 but is proposed to address the flexibilities afforded in subpart M of part 26. This section would be equivalent to § 50.120(b)(3).

Proposed § 26.609 would require the implementation of a BOP. The proposed requirement would be equivalent to that in §§ 26.33 and 26.407, “Behavioral observation,” and would apply during construction, operation, and decommissioning, if applicable. Because subpart M of part 26 would apply during decommissioning through a licensee’s IMP, proposed § 26.609(a) and (b) were developed, in part, from proposed § 73.100(b)(9) and current §§ 73.55(b)(9) and 73.56(f) to help ensure consistency in the conduct of behavioral observation whether conducted for FFD or security purposes.

Under the FFD program, the purpose of the BOP would be to help ensure that individuals subject to the FFD program are fit for duty and trustworthy and reliable to perform or direct those duties and responsibilities and maintain those types of access that make the individual subject to the FFD program. This assurance is accomplished by requiring each individual subject to subpart M of part 26 to be subject to behavioral observation, and by requiring all individuals to perform behavioral observation of others and report FFD concerns to the licensee- or other entity-designated representative(s). The intent of the BOP requirement is not to require that all individuals be observed at all times by others; NRC-licensed operators, maintenance professionals, security officers, and others routinely perform solo operations periodically throughout the day. However,

individuals must be subject to observation while they are performing or directing the performance of duties and responsibilities or maintaining the types of access making them subject to the FFD program. Observing behavior only at the beginning of a work shift is not sufficient to ascertain whether an individual is fit for duty, trustworthy, and reliable. Controlled substances may have a delayed effect between use (e.g., ingestion) and the onset of physiological or psychological effects, and fatigue accumulates with time. Behavior must be continually observed throughout the work shift to detect any changes from baseline human performance characteristics, including mental or physical health and mannerisms, or any activities that may indicate that the individual is not trustworthy and reliable.

Proposed § 26.609(a) would differ from §§ 26.33 and 26.407 in that it would place the responsibility for performing behavioral observation on “all individuals subject to this subpart,” rather than only those “individuals specified in § 26.4(f) [who] are constructing or directing the construction of safety- or security-related SSCs” in § 26.407 or “individuals who are trained under § 26.29 to detect behaviors” in § 26.33 to improve clarity.

Proposed § 26.609(b) would require all individuals subject to the FFD program to report to the licensee- or other entity-designated representative any onsite or offsite behaviors or activities by individuals subject to this part that may constitute an unreasonable risk to the safety or security of the NRC-licensed facility or SNM, or may cause harm to others. The NRC proposes this description of reportable conduct because an individual’s activities (e.g., use of illegal substances) and communications (e.g., hate speech or threats of violence) offsite are a direct indication of the individual’s fitness, trustworthiness, and reliability and must be evaluated as to whether authorization should be granted or maintained. Proposed § 26.609(b) would include a description of this

conduct instead of the § 26.33 undefined phrase, “FFD concerns,” to enhance the clarity of the requirement. This proposed BOP reporting requirement would include any information relating to character or reputation of the individual indicating that the individual cannot be trusted or relied upon to perform those duties and responsibilities or maintain access to NRC-licensed facilities, SNM, or sensitive information. This would better align with the proposed § 73.120 BOP requirement, which states that each person subject to behavioral observation must communicate to the licensee or applicant observed behaviors or activities of individuals that may constitute an unreasonable risk to the health and safety of the public and common defense and security. Proposed § 26.609(a) and (b) were written broadly to include offsite conduct that the reporting individual considers serious enough to call into question the character or reputation of the subject individual.

Proposed § 26.609(c) would require that licensees and other entities perform behavioral observation visually, in-person, and, when necessary, remotely by live video and audible streaming and capture. This requirement was developed from the security observation requirements in § 73.55(e)(7)(i)(B) and (C), (h)(2)(v), and (i)(2) and (5)(ii). Conducting an in-person observation of another individual is the preferred method to ascertain whether the observed individual can safely and competently perform assigned duties and responsibilities. When in-person observations are not feasible (e.g., during solo operations), the proposed requirement would enable the use of video monitoring. This is addressed, for example, in proposed § 26.609(d) regarding NRC-licensed operator manipulation of reactor controls. Additionally, certain duties (such as maintenance activities performed by a single worker outside of a control room) may not present an opportunity for video monitoring; in these situations, behavioral observation

should be conducted on a sampling basis (i.e., a planned observation of the work activity) as outlined in a licensee's or other entity's FFD program.

In situations involving small staff sizes, facilities sited in geographically remote locations, or both, additional observers would enhance the effectiveness of a BOP. Technological developments in automated safety and security systems may enable licensees or other entities to reduce staff sizes to 10 to 40 percent of the staff size of an LWR facility licensed under part 50 or 52. Smaller staff sizes may translate into more solo operations, less teamwork, fewer peer checks, or infrequent management oversight of field activities, leading to fewer behavioral observations. Therefore, a licensee or other entity would have fewer opportunities to observe whether individuals are fit for duty. Enabling video and audible streaming and capture to enhance the BOP would be consistent with the security-related behavioral observation requirement in proposed § 73.120(c)(2)(ii), which would also enable video conferencing or other acceptable electronic means promoting face-to-face interaction for those individuals working remotely.

Proposed § 26.609(d) would require that licensees or other entities perform behavioral observation of NRC-licensed operators who manipulate the controls of any utilization facility licensed under part 53, remotely by live video and audible streaming capture for those part 53 utilization facilities where individual task loading does not allow for the effective conduct of behavior observation in addition to assigned operational tasks. The purpose of this paragraph would be similar to that of proposed § 26.609(c), where the possibility of in-person observation is significantly diminished because of solo operations or because the facility may only require a minimum staff size onsite.

Proposed § 26.610 would be equivalent to § 26.409, "Sanctions," and would require the licensee or other entity to establish sanctions for FFD policy violations that, at

a minimum, prohibit the individuals specified in § 26.4 from being assigned to perform or direct those duties and responsibilities or maintaining authorization making them subject to subpart M of part 26. To be consistent with § 26.75, “Sanctions,” the severity of the sanction as described in § 26.610 would escalate with the number of occurrences and severity of the FFD policy violation. The sanction would be long enough to help deter future FFD policy violations and facilitate counseling and treatment before the licensee reinstates the individual’s access to the facility. The NRC proposes this requirement because the 14-day denial described in § 26.75 may not allow sufficient time for counseling and treatment based on the particular FFD policy violation.

Equivalent to § 26.75(c), proposed § 26.610 would also require a minimum 5-year denial of access to the NRC-licensed facility for certain violations of the FFD policy within the protected area of a commercial nuclear plant and by an individual or individuals who are the operators of the conveyance to transport or use formula quantities of strategic SNM. Equivalent to § 26.75(b), proposed § 26.610 would require a permanent denial of authorization be issued for any subversion attempt.

Proposed § 26.611 would protect information collected from FFD program implementation and would be equivalent to current § 26.411, “Protection of information.” The protected information would include, but not be limited to, privacy and medical information. Section 26.611 would not include the § 26.411 requirement that FFD programs must maintain and use the personal information with the highest regard for individual privacy because such a requirement would be unnecessary in light of the proposed § 26.611(a) requirement that licensees and other entities must establish and maintain a system of files and procedures to prevent unauthorized disclosure.

Proposed § 26.611(b), although equivalent to § 26.411(b), would require licensees and other entities to have all individuals sign a consent to be subject to the

FFD program before subjecting the individual to the FFD program (e.g., before being subject to a pre-access test in § 26.607(b)(1), unlike § 26.411(b)). The purpose of this proposal would be to enhance protections afforded to individuals subject to the FFD program and their knowledge of, in part, why they are subject to drug and alcohol testing, behavioral observation, information collection, MRO reviews, and other FFD program elements. Like the consent required by § 26.411(b), the consent would authorize disclosure of the collected information. Consent would not be needed for disclosures to the individuals and entities specified in § 26.37(b)(1) through (b)(6), (b)(8), and persons deciding matters under review in proposed § 26.613, "Appeals process."

Proposed § 26.613 would be equivalent to § 26.413, "Review process." The proposed title was changed to an appeal process to clarify that § 26.613 would be the process implemented when an individual elects to appeal a licensee or other entity determination that the individual had violated the FFD policy. The proposal would also require that the process include a schedule for the completion of the review of the determination that the individual had violated the FFD policy. The NRC proposes this requirement because operating experience demonstrates that workers may not be protected from a continuous review process that does not result in an outcome.

Proposed § 26.615 would require licensees and other entities to perform audits of the FFD program. The proposed section would be equivalent to § 26.415, "Audits." Under proposed § 26.615(a), audits would be performed at a frequency that ensures the FFD program's continuing effectiveness. This would be particularly important for FFD program elements that are not part of the FFD PMRP required by § 26.603(d). Corrective actions would be taken as soon as reasonably practicable to resolve any problems identified and preclude recurrence. Proposed § 26.615(b) would require the subject matter, scope, and frequency of audits be revised as necessary to improve or

maintain program performance based on findings resulting from licensee or other entity implementation of its FFD PMRP. These requirements were developed from appendix B to part 50, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants”; criterion X, “Inspection”; and criterion XVIII, “Audits.”

Proposed § 26.615(c) would be equivalent to § 26.415(b) and would enable licensees and other entities to conduct joint audits or accept audits of C/Vs so long as the audit addresses the relevant services of the C/Vs.

Proposed § 26.615(d) would be equivalent to § 26.415(c) by establishing requirements for the auditing of HHS-certified laboratories. Unlike § 26.415(c), the proposal would not contain a reference to DOT drug and alcohol testing requirements. This would broaden the regulatory flexibility afforded to a licensee or other entity in that they may use an offsite collection or testing facility that does not meet the DOT requirements.

Proposed § 26.615(d) would state that licensees and other entities need not audit an HHS-certified laboratory if the licensee’s or other entity’s panel of drugs and drug metabolites to be tested is equivalent to the panel by which the laboratory is certified by HHS or is subject to the standards and procedures for drug testing and evaluation used by the laboratory under the HHS Guidelines. The NRC would afford this flexibility because the NRC is aware that HHS desires to streamline changes in its guidelines to its panel of drugs and drug metabolites to be tested. Therefore, if a licensee or other entity elects to implement the HHS Guidelines in its procedures and maintains the minimum panel of drugs and drug metabolites to be tested as required by subpart M of part 26, a licensee or other entity may still use (and not audit) the HHS-certified laboratory because the § 26.603(e) change control process would maintain FFD program effectiveness.

To help ensure FFD program effectiveness, § 26.615(d) would also require that collection facility procedures are comparable to those required in subpart E of part 26, including a proposed requirement that the offsite facility's specimen collection and testing procedures are audited on a biennial basis, which is also a protection consideration afforded to individuals subject to the FFD program. Conducting this audit on a biennial basis would be equivalent to that required in § 26.41(b) and would help ensure that the specimen collection process at the facility remains effective.

Proposed § 26.617 would establish recordkeeping and reporting requirements equivalent to those in current § 26.417. However, § 26.617 would require retention of records pertaining to administration of the FFD program and FFD performance data required by § 26.717 until license termination, which is based on current § 26.711(a) because § 26.417 does not provide for a retention period.

Proposed § 26.617(b)(1) would be identical to the reporting requirements in § 26.417(b)(1) regarding the licensee's or other entity's FFD program.

Proposed § 26.617(b)(2) would require the reporting of annual (i.e., January through December) program performance information to the NRC before March 1 of the following year. This reporting would be equivalent to the annual program performance requirement in § 26.417(b)(1), and the March 1 due date is based on the reporting deadline in § 26.717(e). Licensees and other entities would be required to report FFD performance information using new NRC Forms 893, "Single FFD Policy Violation Form," and 894, "10 CFR Part 26, Subpart M, Annual Reporting Form for FFD Performance Information."

Proposed § 26.617(c) would require that FFD-related information be shared within the commercial nuclear industry when requested to support authorization determinations. This requirement would help individuals seeking employment by another

NRC-licensed facility subject to subpart C of part 26, complete their NRC-required sanctions and licensee-administered or -directed drug and/or alcohol abuse treatment plans before the restoration of authorization by a licensee or other entity. Information sharing may also enhance FFD program effectiveness because FFD-related lessons learned from, for example, substance testing, subversion attempts, and laboratory and MRO performance must be shared when requested.

Proposed § 26.619 would require licensees or other entities to establish a process to evaluate individuals when their fitness or trustworthiness and reliability are in question. Section 26.619 would be equivalent to § 26.419, “Suitability and fitness determinations,” but, unlike § 26.419, would apply during the construction and operation phases. Also, proposed § 26.619 would require that a suitability or fitness determination conducted for cause be conducted face-to-face. This proposed requirement is based on current § 26.189(c); however, unlike § 26.189(c), proposed § 26.619 would not prohibit augmenting determinations via electronic means of communication. Instead, § 26.619 would explicitly permit determinations to be performed via electronic means, so long as those determinations are supported by an appropriately trained individual who is present in-person with the individual being assessed.

In considering the current restriction on the use of electronic means of communication for determinations of fitness conducted for cause, the NRC finds that since publication of the 2008 part 26 final rule, there have been developments in using electronic means of communication (i.e., “videoconferencing”) as an alternative to conducting face-to-face interactions. To address these considerations, the NRC contracted the Pacific Northwest National Laboratory (PNNL), DOE, to study whether a medical and mental health assessment via electronic communication could be an

acceptable alternative to an in-person, face-to-face assessment.[13] Based on this study, if electronic means were to be used to conduct a face-to-face assessment, an in-person element would still be integral to the assessment process. However, under certain circumstances, face-to-face determinations and assessments conducted as part of an FFD program for an entity licensed under part 53 (i.e., those determinations and assessments performed in accordance with § 26.619, § 26.207, or § 26.211) may be augmented via electronic communications. Such remotely conducted determinations and assessments would be required to be conducted with someone who is present in-person with the individual being assessed and who is trained in accordance with the requirements of either §§ 26.29 and 26.203(c) or §§ 26.608 and 26.202(c). Permitting the use of electronic communications would help ensure FFD program effectiveness, especially in instances where the part 53 commercial nuclear plant is sited in a geographically remote location or when the facility has a small staff size.

Proposed Changes to Part 26, Subpart N

Proposed § 26.709 would make the recordkeeping and reporting requirements in subpart N of part 26 applicable to licensees and other entities of facilities licensed under part 53 that elect not to implement the requirements in subpart M of part 26 or elect to implement the requirements in § 26.605(b).

Proposed § 26.711(c) and (d) would be amended to make these requirements applicable to licensees or other entities described in § 26.3(f). Section 26.711(c) provides protection to individuals subject to part 26 by enabling an individual's right to review FFD-related information and correct any inaccurate or incomplete information.

[13] PNNL, Technical Letter Report, "The Use of Electronic Communications to Perform Determinations of Fitness," dated August 2017.

Section 26.711(d) requires, in part, that any FFD-related information shared with other licensees or other entities is correct and complete.

Proposed Changes to Part 26, Subpart O

The vast majority of the proposed changes to part 26 would be new or revised substantive provisions that would establish a regulatory obligation or prohibition or would be conforming edits to reflect the addition of part 53. The only new provision that would not be substantive, such that violation of it would not result in a criminal penalty, would be proposed § 26.601. Therefore, the NRC proposes to add § 26.601 to the list of regulations in § 26.825(b) to which criminal sanctions do not apply.

10 CFR Part 73

Section 73.100: Technology-inclusive requirements for physical protection of licensed activities at commercial nuclear plants against radiological sabotage.

Proposed § 73.100 would provide a performance-based regulatory framework for the design, implementation, and maintenance of a physical protection program and security organization for certain commercial nuclear plants licensed under part 53. The current § 73.55 physical security requirements for nuclear power reactors licensed under part 50 and part 52 use a combination of performance criteria (e.g., § 73.55(b)(1) through (3)) and numerous prescriptive requirements developed to achieve performance objectives (e.g., § 73.55(k)(5)(ii)). By contrast, in the proposed performance-based approach to physical security for part 53, performance objectives and requirements would be the primary bases for regulatory decision-making, giving the licensee the flexibility to determine how to demonstrate compliance with the established performance criteria for an effective physical protection program. This proposed physical protection program would provide an optional pathway for licensees that elect not to demonstrate compliance with the provisions in § 73.55 and do not satisfy the criterion as described in

proposed § 53.860(a)(2) ~~or § 53.4330(a)(2)~~. This proposed physical protection program would provide that activities involving SNM are not inimical to the common defense and security and do not constitute an unreasonable risk to the public health and safety.

Section 73.100(a) would require each part 53 licensee that elects to demonstrate compliance with this section rather than § 73.55 to implement the requirements therein through its physical security plan, training and qualification plan, safeguards contingency plan, and cyber security plan (referred to collectively hereafter as ‘‘security plans”) prior to initial fuel load into the reactor. The security plans would need to identify, describe, and account for site-specific conditions that affect the licensee’s capability to satisfy the requirements of § 73.100. Based on experience from recent new reactor licensing reviews, the NRC recognizes that licensees may seek to receive unirradiated fuel onsite before carrying out the security requirements in § 73.100. However, these security requirements would have to be implemented at some point before fuel load to address the increased risk arising from irradiated fuel onsite. This proposed rule would make clear that part 53 applicants and licensees using § 73.100 may bring unirradiated nuclear fuel onsite and protect it in accordance with the NRC’s requirements for physical protection of SNM of moderate and low strategic significance under § 73.67 until initial fuel load into the reactor.

Section 73.100(b) would outline the general performance objective and design requirements of the licensee physical protection program. A licensee’s program would be required to provide protection against any deliberate act within the DBT of radiological sabotage, including spent fuel sabotage, which could directly or indirectly endanger the public health and safety by exposure to radiation. The physical protection program is supported by the AA program, cyber security program, and IMP to demonstrate compliance with the general performance objective of § 73.100(b).

Section 73.100(b)(2) was developed, in part, from § 73.55(b)(3). To satisfy the general performance objective of § 73.100(b)(1), the physical protection program would need to protect against the DBT of radiological sabotage. The existing fleet of LWR satisfies this objective by preventing significant core damage and spent fuel sabotage. Some non-LWR reactor licensees' physical protection programs may be designed to prevent a significant release of radionuclides from any source. Therefore, the proposed performance objective would focus on radiological sabotage in general, rather than a specific focus on core damage or spent fuel sabotage, to be technology inclusive and allow for flexibility for different reactor technologies.

Under the proposed § 73.100(b)(2)(ii), licensees must provide defense in depth in achieving performance requirements through the integration of engineered systems, administrative controls, and management measures. This requirement would apply defense-in-depth concepts as part of the physical protection program to ensure the capability to demonstrate compliance with the performance objective of the proposed § 73.100(b)(1) is maintained in the changing threat environment. The defense-in-depth philosophy applies to measures against intentional acts as required by § 73.100(b), and the designs of physical security systems should employ defense in depth through systems diversity, independence, and separation under § 73.100(b)(2). The most common defense-in-depth measures apply concepts of redundancy, diversity, independence, and safety margin to ensure systems reliability and availability. The defense-in-depth philosophy applies to the design of a physical protection program, which integrates engineered controls and administrative controls, to provide protection against the DBT for radiological sabotage.

Section 73.100(b)(3) would require the physical protection program to be designed and implemented to achieve and maintain the reliability and availability of

SSCs required for demonstrating compliance with specified performance requirements. These physical protection performance requirements were informed by § 73.55(b) and the Commission's Advanced Reactor Policy Statement.

The performance objective of protecting against the DBT of radiological sabotage is achieved by the design and implementation of the physical protection program, maintained at all times, with the following required performance capabilities proposed in the provisions in § 73.100(b)(3): intrusion detection, intrusion assessment, security communication, security response, protecting against land and waterborne vehicle bomb assaults, and access control portals. The physical protection program must maintain the reliability and availability of SSCs relied upon for demonstrating compliance with the performance requirements. The terms ''reliability and availability'' are intended to describe defense in depth in a performance-based manner and would be critical elements for demonstrating compliance with the proposed requirement for protection against the DBT of radiological sabotage as described in the proposed § 73.100(b)(2).

The first element, "intrusion detection," would be provided through the use of detection equipment, patrols, access controls, and other program elements and would provide notification to the licensee that a potential threat is present and where the threat is located.

The second element, ''intrusion assessment," would provide a mechanism through which the licensee would identify the nature of the threat detected. This would be accomplished through the use of video equipment, patrols, and other program elements that would provide the licensee with timely information about the threat for use in determining how to respond.

The third element, "security communication," would provide a mechanism through which the licensee would communicate the necessary information to the

response force to ensure effectiveness of the physical protection program. This would be accomplished through the redundant, independent, and diverse design of physical security and/or plant SSCs relied on for onsite and offsite security communications. The continuity and integrity of communications should account for the DBT's ability to affect the reliability and availability of communications.

The fourth element, "security response," would provide a mechanism through which the licensee would be capable of timely security response to interdict and neutralize threats up to and including the DBT of radiological sabotage. The security response may include the use of onsite armed responders, law enforcement responders (local, State, or Federal), or other offsite armed responders (e.g., licensee proprietary or contract security personnel who are positioned offsite), or a combination thereof, as appropriate.[14] The licensee must provide protection against any element of the DBT, to include those that do not rise to the full capability of the DBT. SSCs relied on to provide delay functions must be designed to provide for timely response to adversary attacks with adequate defense in depth. Delay would allow the licensee to take necessary actions to counter any attempt by the threat to advance towards the protected target or target set element. The overall response objective would be to place the threat in a

Commented [A29]: Footnote 14 is edited to avoid the implying in a footnote to a nearly 1200 page FRN that there is universal agreement on the first sentence in the footnote. See, e.g., the discussion provided by Commissioner Burns on the subject in his vote on SECY-17-0100 in the final paragraph of the second page of his comments (ML18283A101). Commissioner Burns thoughts on the matter deserve some consideration given his service as the Deputy General Counsel during the imposition of the current DBT rule and the Power Reactor Security Requirements rule.

[14] ~~The NRC's security regulations for commercial nuclear power reactors have historically considered onsite armed responders to be the only acceptable method for interdicting and neutralizing threats up to and including the DBT of radiological sabotage.~~ The proposed rule would permit advanced power reactor licensees to use any interdiction and neutralization method for threats up to and including the DBT of radiological sabotage, which would be an extension of the Commission's position in SRM-SECY-17-0100, "Security Baseline Inspection Program Assessment Results and Recommendations for Program Efficiencies," dated October 8, 2018 and the staff's commitment in SECY-20-0070, "(Redacted) Technical Evaluation of the Security Bounding Time Concept for Operating Nuclear Power Plants," dated November 8, 2021. Under the proposed rule, a licensee would retain the responsibility to detect, assess, interdict, and neutralize threats up to and including the DBT of radiological sabotage, but would be able to rely on law enforcement or other offsite armed responders as a method for fulfilling the required interdiction and neutralization capabilities. For licensees that choose to rely on law enforcement to fulfill these capabilities, the proposed rule would not create any NRC regulatory jurisdiction over, or requirements for, law enforcement.

condition from which the threat no longer has the potential for, or capability of, doing harm to the protected target.

The fifth element, “protecting against land and waterborne vehicle bomb assaults,” would provide a mechanism through which the licensee would be capable of protecting the plant against the DBT vehicle bomb assault. The methods that are relied on to protect against a DBT land vehicle and waterborne vehicle bomb assault must be designed to protect the reactor building, structures containing safety or security related systems, and components from explosive effects.

The sixth element, “access control portals,” would provide a mechanism through which the licensee would be capable of detecting and denying unauthorized access to persons and pass-through of contraband materials (e.g., weapons, incendiaries, explosives) to protected areas. Integrity of the access control system is maintained through licensee oversight and ensures that attempts to circumvent or bypass the established process will be detected and access denied.

The proposed performance requirements would permit the applicant or licensee to determine how to design the physical protection program to protect the plant against the DBT of radiological sabotage without prescriptive requirements such as those currently found in § 73.55. DG-5076, “Guidance for Technology Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants,” has been developed by the NRC to describe one acceptable approach to demonstrate compliance with requirements proposed in § 73.100.

Section 73.100(b)(4) would require the licensee to identify target sets in accordance with § 73.55(f). For non-LWR and SMRs, target sets would be~~are~~ defined in DG-5071, “Target Set Identification and Development for Nuclear Power Plants,” as the minimum combination of equipment, operator actions, and/or structures that, if all are

prevented from performing their intended safety function or prevented from being accomplished, barring extraordinary actions by plant operations, would likely result in a significant release of radionuclides from any source (e.g., a release to the environment exceeding that analyzed in the DBA licensing basis).

Section 73.100(b)(5) would require that each licensee perform a site-specific analysis for the purpose of identifying and analyzing site-specific conditions that affect the design of the onsite physical protection program.

Section 73.100(b)(6) would require licensees to implement a performance evaluation program, which would ensure that a licensee will periodically test and evaluate the effectiveness of the physical protection program to protect against the DBT. This program would ensure that licensees are able to demonstrate that the physical protection program satisfies the response requirements of § 73.100 and that the site's protective strategy effectively protects against the DBT. Licensee performance evaluations would include methods to assess, test, and challenge the integration of the physical protection programs functions and demonstrate the effectiveness of security plans, licensee protective strategy, and implementing procedures in accordance with § 73.100(g).

Section 73.100(b)(7) would require licensees to implement an AA program in accordance with § 73.56. Section 73.100(b)(8) would require licensees to establish, maintain, and implement protection against a cyberattack based on either the proposed cyber security program described in § 73.110 or the program described in existing § 73.54.

Section 73.100(b)(9) would require an IMP that monitors the initial and continuing trustworthiness and reliability of individuals granted or retaining unescorted access or unescorted AA to a protected or vital area. The IMP must also implement defense-in-

depth methodologies to minimize the potential for an insider (active, passive, or both) to adversely affect the licensee's capability to protect against radiological sabotage. Because no one element of the AA program, FFD program, cyber security program, or physical protection program, would, by itself, provide the level of protection against the insider necessary to demonstrate compliance with the performance objective of the proposed § 73.100(b), the effective integration of these programs is a necessary requirement to achieve defense in depth against the potential insider.

Section 73.100(b)(10) would require that the licensee have the capability to track, trend, correct, and prevent recurrence of failures and deficiencies in the implementation of the requirements of this section. Section 73.100(b)(11) would require the coordination of the security plans and associated procedures with other onsite plans to manage the safety and security interface during normal or emergency operations.

Section 73.100(c) was developed from § 73.55(c)(7), "Security implementing procedures," and § 73.55(d), "Security organization," and would outline the requirements for the composition, equipping, and training of the security organization. The purpose of the security organization is to effectively implement the physical protection program. Individuals assigned to perform physical protection or contingency response duties must be trained, equipped, and qualified to perform assigned duties and responsibilities.

Section 73.100(d) would establish a performance requirement for searches of personnel, vehicles, and materials for the protection against radiological sabotage. The requirement describes broad categories of material (explosives, firearms, incendiary devices, etc.) to be detected and prevented from entry into the protected area; specific items that will be prohibited would not be prescribed in the regulation but will be stated in the licensee security plans with detailed descriptions being identified in implementation procedures.

Section 73.100(e) would require a training and qualification program, described in the training and qualification plan, that ensures personnel are able to effectively perform their assigned security-related job duties. This high-level requirement would allow flexibility in how the licensee chooses to train its security personnel. One method for accomplishing this requirement would be to provide a training and qualification program that would be equivalent to appendix B to part 73.

Section 73.100(f) would require periodic security reviews of the physical protection program to ensure effective implementation of the program by independent individuals. The evaluation process would provide a systematized approach for assessing the physical protection program as a basis for further development and improvement. Program reviews should be designed to ensure that the physical protection program maintains effectiveness and demonstrates compliance with NRC requirements. Section 73.100(f)(1) was developed from § 73.55(m) and would require review of each element of the physical protection program. Section 73.100(f)(2) would require licensees to perform self-assessments of physical protection program functions to ensure that the capability to detect, assess, interdict, and neutralize the DBT of radiological sabotage is maintained. Section 73.100(f)(3) would require an audit of the effectiveness of the physical protection program; security plans; implementing procedures; cyber security programs; management of the safety/security interface activities; the testing, maintenance, and calibration program; and response commitments by local, State, and Federal law enforcement authorities. Section 73.100(f)(4) would require that results and recommendations, management findings, and any actions taken be documented and maintained to be available for inspection by the NRC. These reviews are independent of the ongoing performance evaluations described in § 73.100(b)(6) and 73.100(g).

Section 73.100(g) would require that licensee performance evaluations, described in § 73.100(b)(6), include methods appropriate and necessary to assess, test, and challenge the integration of the physical protection program's functions to protect against the DBT. The performance evaluations must also address the licensee's measures to protect against cyberattacks, in accordance with the required cyber security plan, and engineered systems designed to protect against the DBT standalone ground vehicle bomb attack.

Section 73.100(h) would establish performance requirements for maintaining security SSCs relied on to perform security functions to protect against the DBT. It would require that corrective actions and compensatory measures be taken by a licensee in response to a degradation of security equipment or failure of the equipment to perform its intended functions. The licensee would be required to maintain the SSCs described in its design and licensing basis to ensure that they are reliable and available.

Section 73.100(i) would establish requirements for the suspension of security measures in response to emergency and extraordinary conditions. The requirements of this paragraph, which were developed from § 73.55(p), would be intended to provide flexibility to a licensee for taking reasonable actions that depart from a security plan in an emergency when such actions are immediately needed to protect the public health and safety and no action consistent with license conditions and TS that can provide adequate or equivalent protection is immediately apparent in accordance with proposed § 53.740(h).

Section 73.100(j) would establish requirements regarding the inspection, retention and maintenance of records required to be kept by the NRC regulations, orders, or license conditions. These proposed requirements are developed from § 73.55(q).

Section 73.110: Technology-inclusive requirements for protection of digital computer and communication systems and networks.

Section~~s~~ 53.860 ~~and 53.4330~~ would require that a licensee establish, implement, and maintain a cyber security program in accordance with § 73.54 or § 73.110. Section 73.110 would establish requirements for the development and maintenance of a cyber security program for commercial nuclear plants licensed under part 53~~, for either Framework A (i.e., § 53.860(d)) or B (i.e., § 53.4330(d))~~. This proposed section would implement a graded approach to determine the level of cyber security protection required for digital computers, communication systems, and networks. The proposed new section is informed by: (1) the operating experience from power reactors and fuel cycle facilities; and (2) the existing § 73.54 framework, which addresses some of the basic issues for cyber security regardless of the type of reactor. Differences between the § 73.54 requirements and those proposed in § 73.110 are primarily based on the implementation of a consequence-based approach to cyber security to accommodate the wide range of reactor technologies to be assessed by the NRC. A graded approach based on consequences is intended to account for the differing risk levels among reactor technologies. Specifically, the proposed new section would require licensees to demonstrate protection against cyberattacks in a manner that is commensurate with the potential consequences from those attacks.

Under proposed § 73.110(a), licensees would need to ensure that digital computer and communications systems are adequately protected against a potential cyberattack that would result in: (1) a scenario where the cyberattack leads to offsite radiation doses that would endanger public health and safety (i.e., the resulting consequence exceeds the reference dose values in § 53.210); or (2) a scenario where the cyberattack adversely impacts the physical security digital assets used by the

licensee to prevent unauthorized removal of material or radiological sabotage. Security digital assets would include those used for nuclear material control and accounting (MC&A).

The proposed § 73.110(b) would require licensees to protect the communication system and networks associated with the functions described in § 73.110(a)(1) and (a)(2) from cyberattacks. To accomplish this, the licensee would establish, implement, and maintain a cyber security program for protecting digital assets within the scope of § 73.110 that would make use of risk insights, including threat information, and would consider the resulting level of consequences of the threats. If the outcome of the assessment by the licensee under § 73.110(b)(1) revealed that a potential cyberattack would not compromise any digital assets that support safety and security functions, and thus would not result in the consequences listed in § 73.110(a) (e.g., would not exceed the reference dose values), then only a narrow set of the cyber security program requirements in § 73.110(d) and (e) would apply. For example, the licensee would only need to develop a cyber security program that implements the requirements dealing with:

- Analyzing modifications of any asset before implementation to see if they demonstrate compliance with the potential consequences in § 73.110(a);
- Ensuring employees and contractors are aware of cyber security requirements and have some level of cyber security training;
- Evaluating and managing cyber security risks to the plant;
- Reviewing the cyber security plan for any required changes; and,
- Retaining records of the cyber security plan along with any plan changes.

Sections 73.110(c) through (e) of § 73.110 were developed from § 73.54(a)(2), (c) through (h), respectively.

The proposed requirements would address the need for the licensee to develop a cyber security program that implements a defense-in-depth protective strategy as required by proposed section § 73.110(d)(2). A defense-in-depth protective strategy for cyber security is represented by collections of complementary and redundant security controls that establish multiple layers of protection to safeguard critical digital assets. Under a defense-in-depth protective strategy, the failure of a single protective strategy or security control should not result in the compromise of safety and security functions.

Section 73.120: Access authorization program for commercial nuclear plants.

Section 73.120 would address AA for certain commercial nuclear plants licensed under part 53. The proposed language in § 73.120 would provide an alternate approach to the existing framework for AA under §§ 73.55, 73.56, and 73.57, commensurate with risk and consequences to public health and safety. It would be available to part 53 applicants and licensees who demonstrate in an analysis that the offsite consequences of a DBE satisfy the criterion defined in § 53.860(a)(2)~~(i) or § 53.4330(a)(2)(i)~~ (i.e., would not exceed the offsite dose values in § 53.210(b)). The proposed requirements in § 73.120 would be similar to the existing AA program elements for those NRC licensed facilities issued additional security measures (ASM) orders and for materials licensees under § 37.21. Applicants not satisfying the criterion would need to establish, implement, and maintain a full AA program, including an IMP, in accordance with § 73.56.

Proposed § 73.120(a) would be based on an applicant satisfying the eligibility criterion in § 53.860(a)(2)~~(i) or § 53.4330(a)(2)(i)~~. Section 73.120(b) would identify the categories of individuals who would be subject to an AA program in accordance with this section. The applicability statement in § 73.120(b)(1)(i) would encompass individuals whom the licensee intends to grant unescorted access to the facilities' most sensitive areas, consistent with § 73.56(b)(1)(i) for power reactors and the ASM orders and

license conditions issued to any NRC licensed facility or material licensee. Sections 73.120(b)(1)(ii) through (iv) would be consistent with § 73.56(b)(1)(ii) through (iv), respectively. The program would include individuals who may be onsite or offsite (e.g., remote operators or information technology staff) and have virtual access to important plant operational and communication systems based upon assigned duties and responsibilities. An individual who has remote access to plant equipment and communication systems may have trusted privileges greater than the personnel at the plant site. Section 73.120(b)(1)(iii) would state that offsite law enforcement personnel on official duty would not be subject to the licensee AA program.

Section 73.120(c) would provide general performance objectives and requirements largely consistent with the AA program requirements for nuclear power reactors under § 73.56 and would provide licensees and applicants the flexibility in establishing their AA program to demonstrate compliance with various performance objectives.

Section 73.120(c)(1) would include background investigation requirements consistent with § 37.25, as well as ASMs and license conditions that are applied to non-power reactor licensees. Background investigations include important elements to establish the trustworthiness and reliability of an individual, such that they do not constitute an unreasonable risk to public health and safety or the common defense and security. These include the following: (1) personal history disclosure, (2) verification of true identity, (3) employment history evaluation, (4) unemployment/military service/education, (5) credit history evaluation, (6) character and reputation evaluation, and (7) Federal Bureau of Investigation criminal history record check.

Section § 73.120(c)(2) would establish behavioral observation requirements, which are an awareness initiative for recognizing behaviors adverse to the safe

operation and security of the facility through observing the behavior of others in the workplace and reporting aberrant behavior or changes in behavior that might reflect negatively on an individual's trustworthiness or reliability. Maintaining behavioral observation would assist and/or improve worker safety and reduce the risk of an insider threat. This proposed requirement in § 73.120(c)(2) would be a scaled version of the full BOP required under § 73.56(f).

Section § 73.120(c)(2) would provide licensees greater flexibility to implement behavioral observation options for individuals granted unescorted access to the commercial nuclear plant's protected area. Such options on reporting questionable behavior may include a program similar to the Department of Homeland Security's program, "If you see something, say something," or to a corporate behavioral awareness program. Commensurate with the potential lower safety and security risks of a commercial nuclear plant that meets the criterion in § 53.860(a)(2)~~(i) or § 53.4330(a)(2)(i)~~, § 73.120(c)(2) would not require the establishment of a comprehensive training program for behavioral observation (i.e., initial and refresher training including knowledge checks) as required for power reactors under § 73.56 and part 26. Under § 73.120(c)(2)(ii), behavioral observation would be able to be performed in-person or remotely by video, and identified behavior of concern would need to be reported to plant supervision. The remote access alternative to face-to-face interactions provides substantial flexibility for licensees and applicants. Any video conferencing or other acceptable electronic means promoting face-to-face interaction for those individuals working remotely would demonstrate compliance with this regulation.

Section 73.120(c)(3) captures and maintains the self-reporting of legal actions as an essential performance element to enhance the licensee's behavioral observation

initiative similar to the current requirements under § 73.56(g), assuring that personnel who are granted and who maintain unescorted access are trustworthy and reliable.

Section 73.120(c)(4) would provide a scalable approach for granting and maintaining unescorted access. One component not included from § 73.56 is the need for a psychological assessment and reassessment under § 73.56(e) for granting unescorted access and § 73.56(i)(v)(B) for individuals who perform one or more of the job functions described in § 73.120(b)(1)(ii) for maintaining unescorted access. Moreover, the requirement would permit criminal history updates to be completed within 10 years of the last review, compared to the three- or five-year reinvestigation periodicity for personnel at an operating commercial nuclear plant. In addition, no credit check re-evaluation would be required for these individuals.

The continued need to maintain unescorted access would be evaluated on an annual basis by the reviewing official. Guidance in DG-5074, “Access Authorization Program for Commercial Nuclear Plants,” would specify that this evaluation should be based on a compilation of personnel interactions as described in the licensee’s or applicant’s policy and procedures for behavioral observation and the maintenance of an approved AA list.

Section 73.120(c)(5) would require licensees and applicants to determine when a person no longer requires the need for unescorted access or no longer satisfies the AA requirement found within this section. Guidance in DG-5074 would further explain that licensees have the flexibility to terminate unescorted access to specific areas of the site if individuals lack the continued need for that access to perform their duties and responsibilities.

Section 73.120(c)(6) would be consistent with the purpose of § 37.23(e) and would include the individual’s right to correct and complete information as required under

§ 37.23(g). The section would include a requirement for designating a reviewing official. The language would provide clarity regarding the roles and responsibility of a reviewing official, who would be the only individual authorized to make unescorted access determinations.

Section 73.120(c)(7) would align with the corresponding requirements under § 37.23(f), and § 73.120(c)(8) would align with the corresponding requirements under § 37.31. These requirements would encompass the roles and responsibilities for licensees, applicants, and if applicable, the contractor/vendors to establish, implement, and maintain a system of files and records to ensure personal information is not disclosed to unauthorized persons.

Section 73.120(c)(9) would align with the requirements of § 37.33. Section 73.120(c)(10) would require licensees, applicants, and contractors or vendors to maintain the records that are required by the regulations in this section and retain them for a period of 3 years after the record is superseded or no longer needed. The record retention period of three years would be consistent with § 37.23(h), contrasting with the five-year retention period under § 73.56(o). Records maintained in any database(s) would need to be available for NRC review, consistent with the requirements found under § 73.56(o)(6)(ii).

~~VII.~~VI. Specific Requests for Comments

The NRC is seeking advice and recommendations from the public on the proposed rule. We are particularly interested in comments and supporting rationale from the public on the following:

Part 26 – Fitness for Duty Program

1. The proposed rule under § 26.604~~3~~(a~~c~~) would enable a licensee or other entity to implement an FFD program under proposed § 26.604, “FFD program

requirements for low consequence facilities ~~that satisfy the § 26.603(c) criterion~~," if the licensee or other entity performs a site-specific analysis to demonstrate that the facility and its operation satisfy the criterion in § 26.604(a) ~~53.860(a)(2) or § 53.4330(a)(2)~~.

Should the NRC consider replacing its proposed § 26.60~~43~~(a~~c~~) criterion ~~referencing § 53.860(a)(2) or § 53.4330(a)(2), as applicable,~~ with an alternative requirement that if the commercial nuclear plant is of the class described in § 53.800, "~~Facility licensees for s~~Self-reliant-mitigation facilities," ~~and either § 53.800(a)(1) or (2) is satisfied,~~ then drug and alcohol testing would not be required? This proposal would align the § 26.603(c) criterion with that proposed in the NRC-licensed operator regulatory framework of part 53. Please provide your considerations and rationale for your recommendation.

Commented [A30]: Deleted as unnecessary because the provisions of the draft proposed 53.800 would have required that both 53.800(a)(1) and (2) be met for a facility to be a self-reliant-mitigation facility.

Should the NRC also consider making a conforming change to the proposed § 73.120 criterion used for the AA program? Please provide your considerations and rationale for your recommendation.

Part 26 – Technology-Inclusive Approaches to Fatigue Management Requirements Applicable to Unit Outages

In establishing the outage minimum days off requirement of § 26.205(d)(4), the NRC's objective was to ensure that individuals performing the duties described in § 26.4(a)(1) through (a)(4) have sufficient periodic long-duration breaks to prevent cumulative fatigue from degrading their ability to safely and competently perform their duties. In addition to the science of fatigue management, the NRC considered several factors in establishing the existing requirements. These additional factors were practical and safety considerations associated with the management of refueling outages for large LWRs, including the following: (1) the typical duration and frequency of outages; (2) the availability of contract personnel to perform the work; (3) the risk presented by the

outage work while the reactor is shut down; and (4) the controls applied to the work that may limit the potential for latent errors to challenge reactor safety when the reactor is returned to power. The details of such considerations may differ for new reactor technologies or designs. Such considerations may not be relevant for some reactor designs (e.g., reactors capable of on-line refueling) and there may be additional, more pertinent factors to consider for other designs.

The NRC is seeking stakeholder input on whether alternative fatigue management requirements applicable to outages should be adopted to support technology--inclusive approaches that would be appropriate to support the licensing and regulation of future commercial nuclear plants. Please provide your considerations and rationale for your recommendation.

Part 26 – Draft Regulatory Guidance Approach for Fatigue Management

In support of this proposed rule, the NRC has issued DG-5078, “Fatigue Management for Nuclear Power Plant Personnel at Commercial Nuclear Plants Licensed Under 10 CFR Part 53.” This DG describes methods the NRC staff considers acceptable for addressing certain aspects of FFD programs at commercial nuclear facilities licensed under part 53.

The NRC staff also intends to eventually transition this draft guide into an update to RG 5.73, “Fatigue Management for Nuclear Power Plant Personnel,” or the development of a new RG. At this point, NRC staff is considering four options for future RG development:

- *Option 1: Amend the existing RG.* The NRC may develop an updated version of RG 5.73 that continues to endorse (with clarifications, additions, and exceptions) the guidance contained in NEI 06-11, “Managing Personnel Fatigue at Nuclear Power

Reactor Sites," Revision 1, and incorporates the topics discussed within DG-5078 as new NRC staff positions in section C of RG 5.73.

- *Option 2: Issue a new RG specific to part 53 licensees.* The NRC may develop an entirely new RG applicable specifically to facilities licensed under part 53. This new RG would capture the guidance contained in DG-5078 and incorporate existing guidance (e.g., selected guidance in RG 5.73 and NEI 06-11) that is considered to be technology inclusive in nature. The existing guidance (i.e., RG 5.73) would remain in place as the guidance for facilities licensed under parts 50 and 52.
- *Option 3: Review and potentially endorse new or revised industry-developed guidance*. The NRC may engage with the industry regarding a potential update to industry guidance document NEI 06-11 or the development of new, separate industry-developed guidance specific to facilities licensed under part 53. The NRC would then review the new or revised industry-developed guidance within the NRC's RG process, which includes opportunities for public participation. New or revised industry-developed guidance could incorporate DG-5078 or propose alternatives for the NRC to consider.
- *Option 4: Develop a comprehensive revision of the existing RG*. The NRC may develop a more comprehensive revision of RG 5.73 that would explicitly detail all NRC positions reflected in the existing RG (including those endorsed positions currently contained in NEI 06-11, Revision 1), along with the guidance of DG-5078. Such a revision would thereby be a "stand-alone" document, without reference to or explicit endorsement of separate, industry-developed guidance.

The NRC is seeking stakeholder input regarding which of the four options listed above would be optimal (or whether there are other options that the NRC should consider). Please provide your considerations and rationale for your recommendation.

Part 53—Overall Organization

Part 53 is structured as two separate and generally independent frameworks with the subparts in each framework providing technical, licensing, and administrative requirements for the various stages of the life cycle of a commercial nuclear plant. The organization of part 53 in this manner puts the complete set of requirements in one place for each framework but results in the duplication of certain requirements in the two largely independent frameworks.

The NRC is seeking comment on the proposed organization of the requirements in part 53 and possible improvements to how specific requirements (e.g., examples of which specific sections) could be consolidated or otherwise reorganized to make the rule clearer or more concise.

1. There are numerous references in both proposed Frameworks A and B to other NRC regulations. Examples of such references include those in proposed §§ 53.610 and 53.4110 to NRC regulations related to radiation protection (part 20), FFD (part 26), physical security (part 73), and MC&A (10 CFR part 74, "Material Control and Accounting of Special Nuclear Material") for facilities receiving byproduct or SNMs.

The NRC is seeking comment on whether such references to other regulations in various sections in the proposed part 53 provide benefits to applicants and licensees, or to other stakeholders seeking to understand the regulatory framework under part 53, or whether such references could be removed to reduce the length of part 53.

Part 53, Subpart B—Quantitative Health Objectives

The NRC is proposing to use the QHOs from the Commission's Safety Goals Policy Statement as one of several performance standards in Framework A. Specifically, the QHOs would be used as a cumulative risk measure and provide one element of the safety criteria for LBEs other than DBAs in proposed § 53.220. The QHOs were similarly

included in the LMP as a cumulative risk measure to ensure that other evaluation criteria were conservatively defined and for use as a tool for focusing attention on matters important to managing the risks posed by nuclear power plants. The use of the QHOs as a performance standard in an integrated risk-informed decision-making process is similar to that used in RG 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," Revision 3.

The NRC is seeking comment on the use of the QHOs in Framework A as one of several performance standards; if appropriate, what other performance standard could be used instead of, or in addition to, the QHOs as part of an integrated decision-making process to inform the safety criteria in § 53.220 and, in turn, to address the cumulative risks posed by proposed commercial nuclear plants? Please provide your considerations and rationale for your recommendation.

Part 53, Subparts B and R – As Low as Reasonably Achievable

The NRC is proposing in both Frameworks A and B that a combination of design features and programmatic controls be used to maintain doses to the public from normal plant operation and to plant workers ALARA.

The NRC is seeking comment on whether there is a means other than including requirements in part 53 to maintain ALARA as a guiding principle for radiation protection during normal plant operation. If so, please explain how an alternative would be considered in the licensing, certification, or approval of reactor designs or specific commercial nuclear plants licensed under part 53 and what, if anything, would be appropriate to address potential inconsistencies between designs licensed or certified under a part 53 that does not contain ALARA as a guiding principle and designs licensed or certified under parts 50 and 52.

Part 53, Subpart B – Defense in Depth

Proposed § 53.250 would establish requirements based on the longstanding NRC philosophy of providing defense in depth to address uncertainties concerning the design, operation, and performance of commercial nuclear plants during LBEs.

The NRC is seeking comment on the inclusion of the proposed requirements to assess and provide defense in depth. The NRC is also seeking comment on whether to include specific provisions in § 53.250 and subpart B to more explicitly address the possible role of inherent characteristics of some SSCs in preventing or mitigating unplanned events. The proposed § 53.250 is worded to preclude relying on a single engineered design feature to address the range of LBEs other than DBAs, which could possibly allow crediting inherent characteristics without further lines of defense. How could possible inherent characteristics of SSCs be considered in the proposed requirements in § 53.250 or in any alternative requirements for defense in depth provided in response to this item? Please provide your considerations and rationale for your recommendation.

Part 53, Subparts C and D ~~and N and R~~ – Earthquake Engineering

Proposed § 53.480 would establish requirements related to seismic design considerations ~~in Framework A~~. ~~Proposed § 53.4733 would provide alternative requirements for seismic design in Framework B that are similar to § 53.480.~~ Th~~ese~~is ~~proposed sections are~~ is intended to provide a clear connection between siting activities and seismic design activities and to support various approaches to presenting seismic hazards and addressing those hazards in designs~~. Both Frameworks A and B are~~ and~~intended to~~ provide sufficient flexibility to allow approaches like those currently in parts 50 and 100 or approaches that might be endorsed by the NRC in the future that could incorporate more risk insights ~~from PRAs~~.

The NRC is seeking comment on whether the proposed requirements for earthquake engineering provide appropriate flexibility in addressing seismic risks while also ensuring that the regulations continue to adequately address seismic hazards. Please provide your considerations and rationale for your recommendation.

Part 53, Subpart~~s~~ E ~~and O~~ – Construction and Manufacturing

1. Proposed §~~§~~§ 53.610(b)(1)(iii) ~~and 53.4110(b)(1)(iii)~~ would require procedures that describe how construction will be controlled so as not to impact other features important to the design (e.g., dewatering, slope stability, backfill, compaction, and seepage).

The NRC is seeking comment on whether such specific requirements are useful or whether these requirements could be met through other existing requirements such as ~~proposed in part 53 (e.g.,~~ quality assurance requirements ~~in subparts K and U~~under appendix B to part 50~~)~~.

Part 53, Subparts E and H~~, and O and R~~ – Manufacturing Licenses

~~1. Although the NRC updated the part 52 requirements for MLs somewhat, the NRC is not yet proposing significant changes in this area. The proposed requirements are equivalent in Frameworks A and B, with the proposed requirements governing manufacturing set forth in subparts E and O, and the proposed requirements governing the licensing processes contained in subparts H and R. Some of the proposed changes are intended to state requirements to govern a factory-style model that has been suggested for some microreactor designs.~~

~~The NRC is seeking comment on whether the proposed regulations are necessary and sufficient to govern various scenarios for the possible manufacturing and deployment of manufactured reactors.~~

2.1. The proposed regulations in subparts H and R allow holders of or applicants for a COL to reference an ML but do not include such a provision for the holder of a CP. This proposed change from the current relationship between subparts in part 52 and the part 50 licensing process was made to simplify the provisions in the proposed part 53 for licensing and deploying manufactured reactors.

The NRC seeks comment on whether the possible references to an ML by holders of a CP is a relationship that should be included in part 53 and, if so, how it would be used.

3. Proposed §§ 53.1295 and 53.4895 state that the holder of an ML could not begin manufacture of a manufactured reactor less than 6 months before the expiration of the license. This limitation is similar to the current restriction in § 52.177, which states that the manufacture of a reactor cannot begin less than 3 years before the expiration of the license. The restriction was revised from 3 years to 6 months in the proposed part 53 in recognition of the likely use of MLs to support a factory-type model for microreactors.

The NRC seeks comment on whether it is necessary or appropriate to revise the existing 3-year restriction on when manufacturing activities could begin in relation to license expiration and, if so, what that restriction should be.

4.2. Proposed §§ 53.1288 and 53.4888 provides the finality provisions for MLs and include, as does existing § 52.171, limitations on the NRC's imposition of new requirements on either the design or the requirements for the manufacture of a manufactured reactor. No MLs have been issued under part 52 and there is no practical experience with the proposed finality sections. While the implications of the finality provisions related to the design of a manufactured reactor can reasonably be inferred from experience with DCs and COLs, there is no experience or available guidance regarding finality for "requirements for the manufacture of the manufactured reactor."

The NRC is seeking comment on the proposed finality provisions for MLs and specifically if and how finality for manufacturing processes might be requested and used.

~~53~~. The Atomic Energy Commission developed requirements for MLs in part 50 as part of a broader effort to encourage standardization of plant designs. The requirements were subsequently moved to part 52 by rulemakings undertaken by the NRC. Although the NRC and some developers have explored the potential uses of MLs, the concept has never been fully exercised through issuance and implementation of such a license. This rulemaking includes proposals to align MLs with possible adoption of a factory-style model for building and deploying transportable microreactors. ~~However, t~~The proposed rule would ~~not~~ include provisions for loading of fuel into manufactured reactors at a manufacturing facility as suggested by some stakeholders. The NRC has historically viewed operation as including fuel load and existing NRC regulations reflect this view. While the AEA authorizes the NRC to issue licenses to manufacture production or utilization facilities, it does not contain specific provisions on fueling or operating facilities licensed under an ML.

The NRC is ~~continuing to consider possible provisions for MLs that could differ from existing regulations in part 52. This could include an option for the loading of fuel into a manufactured reactor module, without a COL, for subsequent transport and use at a commercial nuclear plant with a COL.~~

~~For example, the NRC is~~ considering whether one way to allow fuel to be loaded into a manufactured reactor could be to require the ML holder to modify the manufactured reactor to include certain design features to preclude criticality. These design features could be two independent mechanisms, each of which could be sufficient to prevent criticality assuming that maximum reactivity of the fissile material would be attained from possible fuel configurations, neutron moderation, and neutron

reflection from the manufactured reactor~~module~~ and surrounding materials. The NRC is considering whether such a ~~module~~ fueled manufactured reactor would be a utilization facility as defined under the AEA, and if not, whether fuel load could be governed by part 70 and the ML, and not a COL. If ~~at some point~~ the fueled manufactured reactor~~module~~ is not considered a utilization facility, the NRC is considering when it might become, or should be considered, a utilization facility. For example, should a ~~module~~ fueled manufactured reactor be considered a utilization facility after installation at the site specified in the COL, completion of corresponding ITAAC, and after all requirements necessary for operation are met, at which point it would be subject to all applicable COL provisions and regulations. Further, the NRC is considering whether such a regulatory approach should include requirements for the ML holder to establish and install certain programs and equipment prior to receipt of SNM. For example, should the following be in place prior to receipt of SNM: (1) radiation monitoring instrumentation and alarms; (2) measures to prevent and detect criticality accidents in accordance with §§ 70.61 and 70.64; (3) procedures, equipment, and personnel qualified to handle and load fresh fuel, monitor reactivity, and secure the fuel and ~~module~~ manufactured reactor for shipment; (4) a physical security program in accordance with § 73.61; and (5) an MC&A program in accordance with part 74? Also, the NRC is contemplating whether any loading or unloading of fresh fuel into a manufactured reactor ~~module~~ and any changes to the configuration of reactivity-related systems would need to be performed by a certified fuel handler demonstrating compliance with the requirements in subpart F.

As an additional matter, the NRC is considering whether the FSAR for an ML applicant proposing to load fuel in the factory would need to include things like a description of the safety program and integrated analysis required by subpart H of part 70, including the procedures used for receipt, storage, and loading of the fuel into

the ~~module~~manufactured reactor; and procedures for transferring the authority and responsibility for the ~~module~~ manufactured reactor to the COL holder at the installation site. Also, the NRC is considering whether other programs required by proposed § 53.620 should be modified to account for fuel loading including the Radiation Protection Program under § 53.620(a)(4), the FFD program under § 53.620(a)(5), the information security program under § 53.620(a)(8), the fire protection program under § 53.620(c)(2), the emergency plan under § 53.620(c)(3), and the physical security program under § 53.620(c)(5).

Finally, the NRC is considering how to best define operations and fuel load at a manufacturing facility, and whether changes to NRC's policies and practices may be needed to accommodate fuel load without a COL. For example, the NRC has historically defined operation to begin at fuel load, and the AEA contemplates that all ITAAC will be closed prior to operation. In light of the potential use of mechanisms to prevent criticality, the NRC is considering the possibility that the Commission could determine that fuel load into a manufactured reactor ~~module manufactured~~ at a manufacturing facility does not constitute operation in the circumstances described above, and operation could be deemed to begin at a later date when the fueled manufactured reactor ~~module~~ is installed at the site specified in the site-specific COL, all corresponding ITAAC have been met, and all other requirements necessary for operation have been met.

The NRC is seeking comments on the desirability of redefining operation, fuel load, or some other term to facilitate ML factory fuel loading, and if so, what other points in the regulatory process would be reasonable places to conclude that operations have commenced or that fuel load has occurred. The NRC is also seeking comment on how the hearing process would be conducted if fuel load were allowed at the ML facility without a COL. Further the NRC is seeking comment on whether it would be desirable or

feasible to issue a certificate of compliance for ~~modules~~ fueled manufactured reactors under these circumstances under 10 CFR part 71, "Packaging and Transportation of Radioactive Material," and whether technical features of a ~~module~~ fueled manufactured reactor would require further changes to that part of 10 CFR Chapter I. Finally, the NRC is seeking comments on technical and policy concerns that allowing fuel load at the ML facility without a COL would raise with respect to the transportation, storage, and disposal of the fuel and module after use.

6. In addition to the considerations in question 5, the NRC is also seeking comment on whether provisions supporting the low power nuclear physics testing of fueled manufactured reactors ~~modules~~ in the manufacturing facility should be included in part 53 and, if so, what would be reasonable in terms of being practical for the holder of an ML while also ensuring the activity poses no undue risks to public health and safety. One possibility could be COLs that would be issued to the holders of an ML to support low power (e.g., <1% rated thermal power) nuclear physics testing of fueled manufactured reactors ~~modules~~ within the manufacturing facility prior to the ~~modules~~ fueled manufactured reactors being transported to and incorporated into a commercial nuclear plant for the purpose of energy production. The NRC recognizes configuration changes are needed to perform nuclear physics testing and is considering what requirements should apply to the fueled manufactured reactors ~~modules~~ and the manufacturing facility during such testing.

While an ML holder could accomplish low power nuclear physics testing by applying for a COL under subpart H ~~or R~~, stakeholders have indicated that many of the subpart H ~~or R~~ requirements would likely be unnecessary, given the reduced risk profile posed by such activities. Therefore, NRC is considering what requirements in subparts H ~~and R~~ should apply to applicants for a COL to support low power nuclear physics testing

of fueled manufactured reactors ~~modules~~. Examples of proposed requirements that might be relaxed or modified to support applications for low power testing at ML facilities include those related to selection of licensing basis events to reflect limited inventory of radionuclides and decay heat, aircraft impact assessments, and earthquake engineering.

Additionally, the NRC is considering whether several other requirements in part 53 could be modified for applications for a low power testing COL at a manufacturing facility. For example, the NRC is considering whether § 53.610 (construction) should apply to all portions of the ML facility used to support low power testing; whether §§ 53.710 and 53.715 (SSC configuration control) must be implemented to ensure portions of the ML facility relied on to limit potential radiological consequences from licensing basis events are available to perform their safety functions; and whether the requirements of § 53.730 could be modified to reflect low power physics testing.

Moreover, the licensing mechanism for the facility could present unique challenges. One option could be to issue a low power testing COL for each fueled manufactured reactor ~~module~~ to be tested. This would comport with the agency's practice of issuing one license per reactor but could prove prohibitive from a cost standpoint and may provide very little safety benefit if all modules are the same. Alternatively, one low power testing COL could be issued for the portions of the ML facility used to test the fueled manufactured reactors ~~modules~~. However, the ~~modules~~ manufactured reactors themselves would be completed over the course of the ML licenses. For this reason, any ITAAC related to physics testing of the ~~modules~~ manufactured reactors would need to be closed after they were manufactured but prior to testing. This may introduce unwarranted delays in the manufacturing process.

The NRC is particularly interested in comments on whether specific COL provisions in subpart~~s~~ H ~~or R~~ should not apply to or be modified for low power testing.

Also, the NRC is interested in comments on using one COL to support testing for all or a group of fueled manufactured reactors ~~modules~~ at an ML facility and the process for closing ITAAC for those modules as they are manufactured.

Part 53, Subpart F – Staffing and Generally Licensed Reactor Operators

Under AEA Sections 106 and 107, the NRC is proposing to group commercial reactors into classes upon the basis of the similarity of operating and technical characteristics of the facilities, and then to prescribe uniform conditions for licensing individuals as operators of any of the various classes; determine the qualifications of such individuals; and, for certain classes of commercial reactors, issue general licenses (i.e., licenses for which no application is needed) to such individuals allowing the individuals to operate the commercial reactor.

1. *Categories of Individuals Who May Manipulate Facility Controls*: The NRC is proposing requirements that would allow the manipulation of the controls of certain facilities by GLROs in lieu of specifically licensed reactor operators and senior reactor operators. Reactor operators and senior reactor operators are the only categories of individuals currently allowed to be licensed to manipulate the controls of utilization facilities under part 55.

The NRC is interested in public perspectives on this proposed addition of the GLRO category, particularly in light of new reactor technologies and concepts of operations.

2. *Criteria for GLRO Staffing*: The NRC is proposing criteria under which facilities would be staffed by GLROs in lieu of specifically licensed reactor operators and senior reactor operators. These criteria~~, which are proposed for both Framework A and Framework B~~, establish a new class of self-reliant-mitigation facilities, as defined in part 53, for which distinct GLRO licensing and staffing requirements would apply.

The NRC is soliciting public feedback regarding whether these proposed criteria are appropriate and what, if any, alternative criteria should be considered. Please provide your considerations and rationale for your answer.

3. *Medical Requirements for GLROs*: Based on the proposed criteria that a self-reliant-mitigation facility, as defined in part 53, must meet, the NRC is proposing not to subject GLROs to requirements for medical fitness and medical examination. This is in contrast with the proposed requirements associated with specifically licensed reactor operators and senior reactor operators, as well as the existing requirements for reactor operators and senior reactor operators under part 55.

The NRC is soliciting public feedback regarding whether GLROs should be subject to medical fitness and/or medical examination requirements like reactor operators and senior reactor operators. Please provide your considerations and rationale for your answer.

4. *Onshift Engineering Expertise*: The NRC is proposing to require that engineering expertise be accounted for within facility staffing plans. This proposed requirement would be in lieu of the traditional position of the Shift Technical Advisor. The NRC is further proposing that individuals providing such engineering expertise would need, among other things, to possess either a qualifying 4-year degree or licensure as a Professional Engineer.

The NRC is interested in feedback from the public regarding the appropriateness of this requirement, including any alternatives that should be considered. Please provide your considerations and rationale for your answer.

5. *Use of Simulation Facilities as HFE Testbeds*: The NRC is proposing to establish regulations pertaining to the use of simulation facilities within the context of the licensing programs both for specifically licensed reactor operators and senior reactor

operators as well as for GLROs. However, these regulations, as currently proposed, do not address the use of simulation facilities within the context of serving as testbeds HFE-related analyses and assessments. Rather, the NRC currently envisions that the use of simulation facilities as HFE testbeds is more appropriately addressed via guidance documents.

The NRC is soliciting public feedback regarding whether simulation facility requirements should also address the use of simulation facilities as HFE testbeds. Please provide your considerations and rationale for your answer.

~~Part 53, Subpart F – Facility Safety Programs~~

~~The NRC is proposing to include a requirement in Framework A for holders of OLs and COLs to develop, implement, and maintain an FSP. The FSP concept is being proposed, in part, to address the advantages of periodically assessing possible risk reduction measures given the proposed role of PRA in the licensing process under Framework A and the resultant need to routinely update the PRA.~~

~~The NRC is soliciting public feedback on whether the FSP concept could contribute to improving the NRC's overall regulatory program that includes licensing, various programmatic requirements, NRC inspections, NRC hazard assessment and generic safety programs, NRC backfit assessments, and NRC annual fees. If so, should the NRC develop and include similar provisions in Framework B? Please provide your considerations and rationale for your answer.~~

~~Part 53, Subpart F – Integrity Assessment Program Requirements~~

~~Decades of operating experience with LWRs suggests that phenomena such as environmentally assisted fatigue and chemical interactions could impact certain SSCs during the life of a commercial nuclear plant. Under the existing regulatory framework, historically, some of these phenomena were not addressed during early licensing~~

~~reviews but were identified and addressed later when significant safety issues arose (e.g., see numerous generic letters, bulletins, orders, and development and implementation of vessel integrity and materials reliability programs) or a licensee voluntarily pursued renewal of an OL under part 54. The NRC is proposing to include a new set of programmatic requirements for an Integrity Assessment Program that would ensure these phenomena are addressed early in the life of a commercial nuclear plant licensed under part 53. The requirements would be provided in §§ 53.870 and 53.4400 under Framework A and Framework B, respectively.~~

~~The NRC is seeking comment on whether the proposed requirements under the Integrity Assessment Program appropriately complement design requirements to address concerns regarding aging, cyclic or transient load limits, and degradation mechanisms related to chemical interactions, operating temperatures, effects of irradiation, and other environmental factors. In addition, the NRC is interested in views on whether, and if so how, degradation mechanisms are or could be addressed in other programs.~~

Part 53, Subpart~~s~~ G ~~and Q~~ – Decommissioning

1. On March 3, 2022, the NRC published the proposed rule entitled “Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning” (87 FR 12254). This rulemaking would amend the NRC’s current regulations to provide an appropriate regulatory framework for nuclear power reactors transitioning from operations to decommissioning. The rulemaking would address lessons learned from licensees that have completed or are currently in the decommissioning process.

What aspects of this proposed rule, if any, should be incorporated in a part 53 final rule and why?

2. Proposed § 53.1060(b) in subpart G would require that, "No later than 30 days after the Commission publishes notice in the *Federal Register* under § 53.1452(a), the licensee must submit an updated decommissioning report ~~containing a certification that financial assurance for decommissioning is being provided in an amount specified in the licensee's most recent updated certification~~, including a copy of the financial instrument obtained to satisfy § 53.1040." This is similar to the current requirement in § 50.75(e)(3) for part 52 COL holders. The NRC is seeking comment on whether advanced reactor COL holders under part 53 should have the same requirement as COL holders under part 52 to demonstrate that they have financial assurance in place no later than 30 days after the Commission issues the notice of intended operation under § 53.1452. Please provide your considerations and rationale for your answer.

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Part 53, Subparts H and I – ~~Probabilistic~~ Risk Evaluation~~Assessment~~ Information

Proposed § 53.1239(a)(18) in subpart H and the related references to this proposed requirement for the holders of OLs and COLs would require a description of the risk evaluation~~PRA~~ required by § 53.450(a), and its results to be included in FSARs. However, guidance documents may further clarify the division of risk~~PRA~~-related information needed to be in the FSAR, in other possible licensing basis documents, and controlled as plant records subject to inspections and audits. For example, a possible approach for ~~Framework A~~part 53 could be to include a summary of the ~~PRA~~ risk evaluation results in the FSAR and control that information under § 53.1545 and create a separate document related to the broader ~~PRA~~ risk evaluation, analyses and related processes as a program document under § 53.1560. The program document would provide more detail than the summaries in the FSAR but still be a much-condensed source of information in comparison to the documentation of a~~the~~ PRA. This possible approach would reflect the role of ~~the PRA~~risk in the licensing process under part

53~~Framework A~~ and in maintaining margins to the safety and evaluation criteria in subparts B and C but may allow a more appropriate evaluation process to address the particulars and complexities of the risk~~PRA~~-related documents.

The NRC is seeking comment on the appropriate placement of risk~~PRA~~-related information among various licensing basis documents and plant records. In addition to the placement of risk~~PRA~~-related information, the NRC is seeking comment on the appropriate control of that information and on the routine submittal of updates to the NRC. Please provide your considerations and rationale for your answer.

Part 53, Subparts H and I – Changes to Manufacturing Licenses

Proposed §§ 53.1530 ~~and 53.6030~~ would not allow the holder of an ML or the holder of a COL using a manufactured reactor to make changes to the design of the manufactured reactor without requesting a license amendment from the NRC. The proposed requirements do not include a specific mention of the manufacturing processes for which the NRC could possibly provide finality under proposed §§ 53.1288 ~~and 53.4888~~.

The NRC is seeking comment on the appropriate change control provisions for MLs, including whether criteria could be developed to determine when a license amendment request would not be required and whether those criteria should address changes in manufacturing processes as well as changes in the design. Please provide your considerations and rationale for your recommendation.

~~Part 53, Subpart P – Specific Requirements for Technical Specifications~~

~~The NRC is proposing to include requirements for TS in Framework B that are largely equivalent to those under § 50.36, with some minor exceptions. One exception relates to the third criterion for determining whether a LCO needs to be established for a particular item. Specifically, the NRC proposes to add the phrase "or acts as a precursor~~

to identify an issue that would affect" to the third criterion under § 53.4213(b)(2)(ii)(C). This criterion is used to establish LCOs for SSCs that are used to mitigate accidents and transients such that their failure could ultimately impact the integrity of a fission product barrier. The additional phrase would account for the potential use of functional containment SSCs that may not be part of the primary success path or actuate to mitigate a DBA for non-LWRs that may be licensed under Framework B. This phrase does not currently appear in the existing requirements under § 50.36(c)(2)(ii)(C) but is necessary to account for the variety of functional containment concepts that may exist in a commercial nuclear plant that would be licensed under Framework B.

The NRC is seeking comment on whether the proposed language in § 53.4213(b)(2)(ii)(C) effectively addresses the need for an LCO if an item is credited as part of a functional containment. Please provide your considerations and rationale for your recommendation.

Part 53, Subpart R – Alternative Evaluation for Risk Insights

1. The NRC is proposing to include a requirement in Framework B for identified applications for licenses, certifications, or approvals to include a description of risk evaluations based on either a PRA or an AERI. The AERI approach would use the analyses of postulated bounding events as surrogates for the more detailed PRA analyses and related comparisons of the estimated risks to the NRC's safety goals. The use of the AERI approach would be limited to those applicants showing that the offsite consequences from bounding events were less than criteria in proposed § 53.4730(a)(34)(ii).

The NRC is seeking comment on whether the NRC should retain this AERI approach under Framework B. If so, what changes, if any, would be recommended to

the proposed criteria and approach in proposed Framework B? Please provide the considerations and rationale for your answer.

Could the AERI criteria as written or potentially as revised and the related analyses of bounding events be used to support other regulatory decisions in Framework B (e.g., physical security, cyber_security, AA, FFD and emergency preparedness)? If so, which design areas and programs could logically use the AERI criteria and related analyses and how could requirements in those areas be scaled or graded based on the proposed § 53.4730(a)(34)(ii) or a similar concept?

2. Proposed § 53.4730(a)(34)(ii) would establish the AERI criteria and would support decisions on allowing alternatives to PRAs and on allowing use of GLROs under proposed § 53.800. The proposed criteria involve demonstrating the consequence from a postulated bounding event is less than stated values and identifying the postulated bounding event through a systematic and comprehensive search for severe accident scenarios.

The NRC is seeking comment on the criteria and how they are used in both justifying an alternative to PRAs and in allowing the use of GLROs, as well as possible alternatives to the proposed criteria. Please provide your considerations and rationale for your recommendation.

Part 53, Subpart T – Reporting

Proposed § 53.6340(a)(2)(iv) would require that licensees report any event or condition that results in manual or automatic actuation of a SR system. A similar proposed requirement in Framework A is provided by § 53.1640(a)(2)(iv) and includes inadvertent operation of any SSC classified as SR for an identified safety function under § 53.460 or the unplanned sole reliance on a SR system for those systems that are in constant operation.

~~The NRC is seeking comment on these proposed reporting requirements and how best to address possible actuation or use of safety systems for reactor designs that differ significantly from the LWRs, for which the reporting requirements were developed. Please provide your considerations and rationale for your answer.~~

Operating Experience Programs

Proposed §§ 53.440, 53.610(a)(4), 53.620(a)(4), and 53.730(e) would require that licensees establish programs that evaluate and apply experience in the design, construction, manufacturing, and operating areas during the design, construction, manufacturing, and operation phases respectively. These programs parallel the unified requirement that was codified for licensees under parts 50 and 52 in § 50.34(f)(3)(i) with the addition of the coverage of manufacturing experience element in § 53.620(a)(4).

The NRC is seeking comment on whether there could be synergistic gains from unifying these as a single program under the quality assurance program requirements or elsewhere. Such a unified program might result in a greater degree of consideration of operating experience in the design, construction, or manufacturing phases, for example, although it could result in a broader scope of experience to be considered. Please provide your considerations and rationale for your answer.

Financial Qualifications

Utility new reactor applicants are exempt under § 50.33(f) from financial qualification reviews because they are generically presumed to be financially qualified for operations. In contrast, merchant power plant new reactor applicants are required under § 50.33(f)(2) to submit information that demonstrates they possess or have reasonable assurance of obtaining the funds necessary to cover estimated construction and operating costs for the period of the license. A “merchant power plant new reactor applicant” is a non-rate-regulated entity (e.g., a nonutility) that engages in the business

of production, manufacturing, generating, buying, aggregating, marketing, or brokering electricity for sale at wholesale or for retail sale to the public. Over the past decade, the agency has heard some concerns about the challenges that merchant power plant applicants face in demonstrating compliance with the current financial qualification requirements.

Does this standard continue to pose challenges for merchant power plant applicants? If so, please provide a detailed explanation of these challenges.

Should part 53 have the same financial qualification requirements as parts 50 and 52? Why or why not?

Are there categories of merchant new reactor applicants for which a part 70 "appears to be financially qualified" standard would be more appropriate?[15] If so, please explain what types of applicants should be able to use the part 70 financial qualification standard and what distinguishes these applicants from ones that should not be able to use this standard.

If a part 70 financial qualification standard were to apply to a category of merchant new reactor applicants, should it also apply to pre-construction license transfer applications for these reactors? Why or why not?

Is there another standard the agency should consider for financial qualification of merchant new reactor applicants? Commenters are encouraged to provide specific suggestions and the basis for those suggestions.

Part 73, Section 73.100 – Physical Security

The proposed § 73.100 would identify the proposed performance-based physical security requirements with which future commercial power reactor applicants or licensees' physical protection programs would need to demonstrate compliance, without

Commented [A32]: Edited to use a single hyphen rather than two hyphens.

[15] Section 70.23(a)(5).

prescribing the specific methods that must be used to satisfy them. Applicants and licensees would have increased flexibility regarding the modern technologies and methods that they could use. Implementing guidance in DG-5076 (proposed RG 5.97), "Guidance for Technology Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants," would be available to assist applicants and licensees. For example, DG-5076 provides detailed guidance, including performance standard recommendations, on the probability of detection and alternative sources of power for exterior intrusion detection systems (subsection 4.1.1.1.A), interior intrusion detection (subsection 4.1.1.1.B), intrusion assessment (subsection 4.1.1.2.A), security response/neutralization subsection (4.1.1.4.A), security communication (subsection 4.1.1.3.A), and security delay (subsection 4.1.1.4.C).

Does the NRC's proposed approach in § 73.100 provide a sufficient level of detail to be readily understood and easily applied to the licensing and oversight of new and advanced power reactors, or should the NRC consider moving some objective and measurable security performance standard recommendations from the draft implementing guidance in DG-5076 into proposed § 73.100? If so, which objective and measurable security performance standard recommendations should be moved from DG-5076 to § 73.100? Please provide the basis for your response.

Part 73, Section 73.110 – Cyber ~~s~~Security

The proposed § 73.110 would require licensees to demonstrate protection against cyber attacks in a manner that is commensurate with the potential consequences from those attacks, without prescribing the specific methods that must be used to demonstrate protection. Under proposed § 73.110(a), licensees would need to ensure that digital computer and communications systems are adequately protected against a potential cyber attack that would, for example, result in adverse impacts to the

physical security digital assets used by the licensee to prevent unauthorized removal of material per § 53.860(a). Protecting against such a potential cyber attack would involve requiring cyber security for SNM at a commercial nuclear reactor licensed under part 53. Applicants and licensees would have increased flexibility regarding the modern technologies and methods that they could use for protecting against such a potential cyber attack. Detailed implementing guidance in DG-5075 (proposed RG 5.96), "Establishing Cyber Ssecurity Programs for Commercial Nuclear Plants licensed under 10 CFR part 53," would be available to assist applicants and licensees. For example, DG-5075 provides guidance on the implementation of security by design features (e.g., facility design) for negating the potential consequences from such a potential cyber attack.

Commented [A33]: Staff should make conforming changes in the guidance documents for clarity.

If a cyber attack were to compromise the availability, integrity, or confidentiality of data or systems associated with security systems/measures for the protection of SNM at a commercial nuclear reactor licensed under part 53, do the potential consequences warrant requiring cyber security for such material? Please provide the basis for your response including a detailed explanation of challenges, if any, posed by requiring cyber security for SNM at a commercial nuclear reactor licensed under part 53.

~~VIII.~~VII. Section-by-Section Analysis

The following paragraphs describe the specific changes proposed by this rulemaking.

10 CFR part 1

Section 1.43 Office of Nuclear Reactor Regulation.

This proposed rule would revise § 1.43(a)(2) to extend the authority of the Office of Nuclear Reactor Regulation to regulate source, byproduct, and SNM at facilities licensed under part 53.

10 CFR part 2

Section 2.1 Scope.

This proposed rule would revise § 2.1(e) to apply to standard design approvals under part 53.

Section 2.4 Definitions.

This proposed rule would revise § 2.4 to update the definition of "Contested proceeding" to include NRC enforcement actions against applicants for a standard DC under part 53. It would also update the definition of "Facility" to encompass ~~production facilities and~~ utilization facilities as defined in § 53.020 (there are no production facilities under part 53).

Section 2.100 Scope of subpart.

This proposed rule would revise § 2.100 to extend the scope of subpart A to licenses and standard design approvals issued under §§ 53.1200 through 53.1221~~, or §§ 53.4800 through 53.4821~~.

Section 2.101 Filing of application.

This proposed rule would revise § 2.101 to be applicable to part 53 applicants in addition to part 50 and 52 applicants by adding references to part 53 in paragraphs (a)(3)(i), (a)(5), and (a)(9).

Section 2.104 Notice of hearing.

This proposed rule would extend the hearing notice requirement in § 2.104(a) to applications concerning facilities covered under part 53. Footnote 1 to § 2.104 would be revised in a corresponding manner.

Section 2.105 Notice of proposed action.

This proposed rule would revise § 2.105 to extend the requirement in § 2.104 to publish a notice of intended operation or a notice of proposed action, as applicable, to

part 53 applicants in addition to part 50 and 52 applicants by adding corresponding references to part 53 in paragraphs (a), (a)(4), (a)(10), (a)(12), (a)(13), and (b)(3).

Section 2.106 Notice of issuance.

This proposed rule would revise § 2.106 to extend the issuance notice requirement to applications concerning facilities covered under part 53 through updated references in paragraphs (a)(2) and (3), and (b)(2).

Section 2.109 Effect of timely renewal application.

This proposed rule would revise § 2.109 to add references to part 53 in paragraphs (b), (c), and (d) regarding the timing of license renewal applications.

Section 2.110 Filing and administrative action on submittals for standard design approval or early review of site suitability issues.

This proposed rule would revise § 2.110 to include references to part 53 in paragraphs (a)(1) and (b).

Section 2.202 Orders.

This proposed rule would revise § 2.202(e) to add references to part 53 regarding the requirements to be followed for orders involving the modification of a license, COL, ESP, standard DC rule, standard design approval, or ML.

Section 2.309 Hearing requests, petitions to intervene, requirements for standing, and contentions.

This proposed rule would revise § 2.309 to include references to part 53 in paragraphs (a), (f)(1)(i), (f)(1)(vi) and (vii), (g), (h)(2), (i)(2), and (j) regarding a request for hearing under § 53.1452 ~~or § 53.5052~~.

Section 2.310 Selection of hearing procedures.

This proposed rule would amend § 2.310 by revising paragraph (a), the introductory text for paragraph (h) and paragraphs (i) and (j) to incorporate references to part 53 regarding hearing procedures.

Section 2.329 Prehearing conference.

This proposed rule would revise § 2.329(a) to extend the timing requirements for prehearing conferences involving CPs and licenses under part 53.

Section 2.339 Expedited decisionmaking procedure.

This proposed rule would revise § 2.339(d) to include references to part 53 regarding expedited decisionmaking procedures.

Section 2.340 Initial decision in certain contested proceedings; immediate effectiveness of initial decisions; issuance of authorizations, permits and licenses.

This proposed rule would amend § 2.340 regarding initial decisions of a presiding officer in certain contested proceedings, the effective date of those decisions, and the issuance of authorizations, permits, and licenses, by incorporating references to part 53 in paragraphs (b), (c), (d), (d)(1), (d)(2), (f), (i), (j), and (j)(1).

Section 2.341 Review of decisions and actions of a presiding officer.

This proposed rule would revise § 2.341(a)(1) to include an updated reference to part 53 regarding the allowance of a period of interim operation.

Section 2.400 Scope of subpart.

This proposed rule would revise § 2.400 to extend the scope of subpart D or part 2 to part 53 applicants for licenses to construct or operate nuclear power reactors of identical design at multiple sites.

Commented [A34]: Inserted to clarify what subpart D is the subject of this sentence.

Section 2.401 Notice of hearing on construction permit or combined license applications ~~pursuant to appendix N of 10 CFR parts 50, 52, or 53~~for nuclear power plants of identical design at multiple sites.

This proposed rule would revise the section heading and § 2.401 to extend the hearing notice requirement to applications concerning facilities covered under part 53.

Section 2.402 Separate hearings on separate issues; consolidation of proceedings.

This proposed rule would revise § 2.402 to apply provisions regarding separate hearings and the consolidation of proceedings to part 53 applicants.

Section 2.403 Notice of proposed action on applications for operating licenses ~~pursuant to appendix N of 10 CFR part 50~~for nuclear power plants of identical design at multiple sites.

This proposed rule would revise the section heading and § 2.403 to require the Commission to publish a notice of proposed action in the *Federal Register* after applications under part 53 are docketed.

Section 2.404 Hearings on applications for operating licenses ~~pursuant to appendix N of 10 CFR part 50~~for nuclear power plants of identical design at multiple sites.

This proposed rule would amend the section heading and § 2.404 to apply to applications for an OL under part 53.

Section 2.405 Initial decisions in consolidated hearings.

This proposed rule would revise § 2.405 to be applicable to CPs, full-power OLs, and COLs under part 53.

Section 2.406 Finality of decisions on separate issues.

This proposed rule would revise § 2.406 to be applicable to proceedings conducted pursuant to part 53.

Section 2.500 Scope of subpart.

This proposed rule would revise § 2.500 to extend the provisions of subpart E of part 2 to applications for a license to manufacture nuclear power reactors under part 53.

Section 2.501 Notice of hearing on application under ~~subpart F of~~ 10 CFR part~~s~~ 52 or 53 for a license to manufacture nuclear power reactors.

This proposed rule would amend the section heading and § 2.501(a) by extending its provisions to applications for a license to manufacture nuclear power reactors under part 53~~ and revise the section title to include part 53~~.

Section 2.643 Acceptance and docketing of application for limited work authorization.

This proposed rule would revise § 2.643(b) regarding the acceptance and docketing of an application for a CP for a utilization facility of the type specified in part 53.

Section 2.645 Notice of hearing.

This proposed rule would amend § 2.645(a) to incorporate a reference to part 53.

Section 2.649 Partial decisions on limited work authorization.

This proposed rule would revise § 2.649 to extend its provisions to LWAs issued under part 53.

Section 2.800 Scope and applicability.

This proposed rule would amend § 2.800 by revising paragraphs (c) and (d) to incorporate references to part 53 regarding the scope and applicability of the rulemaking procedures contained in this subpart.

Section 2.801 Initiation of rulemaking.

This proposed rule would revise § 2.801 to include a reference to part 53.

Section 2.813 Written communications.

This proposed rule would revise § 2.813(a) to apply general requirements for correspondence with the Commission to communications concerning part 53, in addition to parts 50, 52, and 100.

Section 2.1103 Scope of subpart K.

This proposed rule would revise the first sentence of § 2.1103 to extend the provisions of subpart K of part 2 to licenses under part 53 to expand the spent fuel capacity at the site of a civilian nuclear power plant.

Section 2.1202 Authority and role of NRC staff.

This proposed rule would amend § 2.1202 by revising paragraphs (a)(1), (a)(2), (a)(3), and (a)(6) to include references to part 53.

Section 2.1301 Public notice of receipt of a license transfer application.

This proposed rule would revise § 2.1301(b) to include a corresponding reference to license transfers under part 53 in addition to parts 50 and 52.

Section 2.1403 Authority and role of the NRC staff.

This proposed role would update § 2.1403 to specify that “significant hazards considerations” has the same meaning as defined in part 53.

Section 2.1500 Purpose and scope.

This proposed rule would update § 2.1500 to extend the scope of subpart O of part 2 to DC rulemaking hearings under part 53.

Section 2.1502 Commission decision to hold legislative hearing.

This proposed rule would revise § 2.1502, paragraphs (a) and (b)(1) to incorporate references to part 53 regarding the Commission's decision to hold a DC rulemaking.

10 CFR part 10

Section 10.1 Purpose.

This proposed rule would revise § 10.1(a)(3) to include a reference to part 53.

Section 10.2 Scope.

This proposed rule would revise § 10.2(b) to extend the scope of subpart A to applicants and holders of licenses, certificates, and standard design approvals under part 53 in addition to part 52.

10 CFR part 11

Section 11.7 Definitions.

This proposed rule would revise § 11.7 such that terms defined in part 53 have the same meaning when used in part 11.

10 CFR part 19

Section 19.2 Scope.

This proposed rule would revise § 19.2(a)(1) through (4) to include references to part 53.

Section 19.3 Definitions.

This proposed rule would revise the definitions of "License" and "Regulated entities" in § 19.3 to incorporate references to part 53.

Section 19.11 Posting of notices to workers.

This proposed rule would revise § 19.11 to be applicable to applicants and holders of licenses, permits, standard design approvals, and standard DCs under part 53 in addition to part 52.

Section 19.14 Presence of representatives of licenses and regulated entities, and workers during inspections.

This proposed rule would revise § 19.14(a) to apply to applicants and holders of a license, standard design approval, ESP, or standard DC under part 53 in addition to part 52.

Section 19.20 Employee protection.

This proposed rule would revise § 19.20 to include a reference to protected activities under part 53.

10 CFR part 20

Section 20.1002 Scope.

This proposed rule would revise the first sentence of 10 CFR part 20, "Standards for Protection Against Radiation," § 20.1002 to extend the scope of part 20 to apply to persons licensed by the Commission to receive, use, transfer, or dispose of byproduct, source, or SNM or to operate a production or utilization facility under part 53.

Section 20.1003 Definitions.

This proposed rule would revise § 20.1003 to update the definition of "License" to include those issued under part 53.

Section 20.1101 Radiation protection programs.

This proposed rule would revise § 20.1101(d) to exclude licensees subject to § 53.260(b) ~~or § 53.4730(a)(3)~~ from its requirements.

Section 20.1401 General provisions and scope.

This proposed rule would revise § 20.1401, paragraphs (a) and (c) to extend the scope of subpart E of part 20 to apply to the decommissioning of facilities licensed under part 53 and the release of part of a facility or site for unrestricted use in accordance with § 53.1080 ~~or § 53.4680~~.

Section 20.1403 Criteria for license termination under restricted conditions.

This proposed rule would revise § 20.1403(d) to include decommissioning plans under part 53.

Section 20.1404 Alternate criteria for license termination.

This proposed rule would revise § 20.1404(a)(4) to include a reference to part 53 regarding alternate criteria for license termination.

Section 20.1406 Minimization of contamination.

This proposed rule would revise § 20.1406(a) to include references to applicants for licenses other than ESPs or MLs under part 53. It would also revise § 20.1406(b) to include references to standard DCs and standard design approvals under part 53 in addition to part 52.

Section 20.1501 General.

This proposed rule would revise § 20.1501 regarding the requirement for retention of records from surveys describing the location and amount of subsurface residual radioactivity at a site to include a reference to the retention requirements under part 53.

Section 20.1905 Exemptions to labeling requirements.

This proposed rule would revise § 20.1905(g) to apply to facilities licensed under part 53 in addition to parts 50 and 52 regarding exemptions to labeling requirements.

Section 20.2004 Treatment or disposal by incineration.

This proposed rule would revise § 20.2004(b)(1) to include references to part 53 regarding the treatment or disposal of waste oil by incineration.

Section 20.2201 Reports of theft or loss of licensed material.

This proposed rule would revise § 20.2201 to include references to part 53 in paragraphs (a)(2)(i), (b)(2)(i) and (c) regarding requirements for reports of theft or loss of licensed material.

Section 20.2202 Notification of incidents.

This proposed rule would revise § 20.2202(d)(1) to add references to part 53 regarding reports to the NRC Operations Center.

Section 20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

This proposed rule would revise § 20.2203(c) to refer to procedures under part 53 for reporting occurrences of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

Section 20.2206 Reports of individual monitoring.

This proposed rule would revise § 20.2206(a)(1) to include a reference to part 53.

10 CFR part 21

Section 21.2 Scope.

This proposed rule would revise § 21.2, paragraphs (a)(2) through (4), (b) and (c) to include references to part 53 regarding the scope and applicability of part 21 requirements.

Section 21.3 Definitions.

This proposed rule, in § 21.3 would revise the definitions of “Basic component,” “Commercial grade item,” “Critical characteristics,” “Dedicating entity,” “Dedication,” “Defect,” and “Substantial safety hazard” with references to part 53.

Section 21.21 Notification of failure to comply or existence of a defect and its evaluation.

This proposed rule would amend § 21.21, by incorporating references to part 53, to update the requirements for notifying the Commission of a failure to comply or defect in paragraphs (a)(3) and (d)(1).

Section 21.51 Maintenance and inspection of records.

This proposed rule would revise § 21.51 to apply to applicants for standard DC and applicants or holders of a standard design approval under part 53, in addition to part 52, regarding the retention of records.

Section 21.61 Failure to notify.

This proposed rule would revise § 21.61(b) to include references to part 53 licensees and applicants regarding failure to provide the notice required in § 21.21.

10 CFR part 25

Section 25.5 Definitions.

This proposed rule would update the definition of “License” § 25.5 to include those issued under part 53.

Section 25.17 Approval for processing applicants for access authorization.

This proposed rule would revise § 25.17(a) to add a reference to part 53 regarding AAs for individuals who need access to classified information in connection with activities under part 53.

Section 25.35 Classified visits.

This proposed rule would update § 25.35(a) to apply the requirements for classified visits to licensees, certificate holders, and applicants under part 53 in addition to part 52.

10 CFR part 26

Section 26.3 Scope.

This proposed rule would revise § 26.3 by adding new paragraph (f) which would establish the phase of construction or operation by which applicants and licensees under part 53 would be required to comply with subpart M of part 26, or all of the requirements of part 26 except subparts K and M. The proposed rule would also update paragraphs (a) through (c) to reflect that entities described in those paragraphs do not need to comply with subpart M.

Section 26.4 FFD program applicability to categories of individuals.

The proposed rule would update paragraphs (a), (b), (c), (e), (f), (g), and (h) of § 26.4 to include references to part 53 and provisions for implementing an FFD program under subpart M.

Section 26.5 Definitions.

The proposed rule would amend § 26.5 by adding definitions for “biological marker,” “change,” “illicit substance,” reduction in FFD program effectiveness,” and “Special Nuclear Material.” It would also update definitions of “constructing or construction activities,” “contractor/vendor (C/V),” “other entity,” “questionable validity,” “reviewing official,” “safety-related structures, systems, and components (SSCs),” “security-related SSCs,” and “unit outage” within this section.

Section 26.8 Information collection requirements: OMB approval.

The proposed rule would update § 26.8 with the new information collection requirements contained in proposed §§ 26.202, 26.603, 26.604, 26.605, 26.606, 26.607, 26.608, 26.609, 26.611, 26.613, 26.617, and 26.619.

Section 26.21 Fitness-for-duty program.

The proposed rule would update § 26.21 to include a reference to § 26.3(f).

Section 26.51 Applicability.

The proposed rule would update § 26.51 to extend the requirements of subpart C of part 26 to licensees and other entities identified in § 26.3(f) that do not implement the requirements of subpart M of part 26, as well as licensees and other entities that implement the requirements of § 26.605.

Section 26.53 General provisions.

The proposed rule would update paragraphs (e), (g), (h), and (i) of § 26.53 to include references to § 26.3(f).

Section 26.63 Suitable inquiry.

The proposed rule would update § 26.63(d) with a reference to § 26.3(f).

Section 26.73 Applicability.

The proposed rule would update § 26.73 to extend the requirements of subpart D of part 26 to licensees and other entities identified in § 26.3(f) that do not implement the requirements of subpart M of part 26, as well as licensees and other entities that implement the requirements of § 26.605.

Section 26.81 Purpose and applicability.

The proposed rule would update § 26.81 to extend the requirements of subpart E of part 26 to licensees and other entities identified in § 26.3(f) that do not implement the

requirements of subpart M of part 26, as well as licensees and other entities that implement the requirements of § 26.605.

Section 26.201 Applicability.

The proposed rule would update § 26.201 to include references to the proposed provisions in §§ 26.3(f) and 26.202, as well as revise the applicability of requirements in subpart I of part 26.

Section 26.202 General provisions for facilities licensed under part 53.

This proposed rule would add new § 26.202, which would require applicable licensees under part 53 to incorporate a policy for fatigue management into their FFD program in accordance with the provisions of this section.

Section 26.205 Work hours.

The proposed rule would update paragraphs (d)(7)(iii) and (d)(8) of § 26.205 to incorporate references to §§ 26.606 and 26.202(a) and (b).

Section 26.207 Waivers and exceptions.

The proposed rule would update § 26.207(a)(1)(ii) to include references to §§ 26.608 and 26.202(c) and to include provisions for implementing certain face-to-face supervisor assessments using electronic communications.

Section 26.211 Fatigue assessments.

The proposed rule would update § 26.211, paragraphs (a)(1), (a)(3), and (b) to incorporate references to §§ 26.202(c), 26.607(b), 26.608, and 26.619 and to include provisions for implementing certain face-to-face assessments using electronic communications.

Subpart M – Fitness for Duty Programs for Facilities Licensed Under Part 53

This proposed rule would add new Subpart M of part 26 ~~containing new §§ 26.601, 26.603, 26.604 through 26.611, 26.613, 26.615, 26.617, and 26.619, which~~

adds an optional technology-inclusive, risk-informed, and performance-based approach for the application of drug and alcohol testing and fatigue management requirements for facilities licensed under part 53.

Section 26.601 Applicability.

This proposed rule would add § 26.601, which would allow a licensee or other entity in § 26.3(f) to establish an FFD program in accordance with the requirements of subpart M of part 26.

Section 26.603 General provisions.

This proposed rule would add § 26.603, which would establish the general requirements for implementing an FFD program under subpart M of part 26.

Section 26.604 FFD program requirements for facilities that satisfy the § 26.603(c) criterion.

This proposed rule would add § 26.604, which would establish the FFD program elements for a licensee or other entity whose facilities and operations demonstrate compliance with the criterion in § 26.603(c).

Section 26.605 FFD program requirements for facilities that do not implement § 26.604.

This proposed rule would add § 26.605, which would establish the FFD program elements for a licensee or other entity that does not demonstrate compliance with the criterion in § 26.603(c), or otherwise chooses to maintain an FFD program under this section.

Section 26.606 Written policies and procedures.

This proposed rule would add § 26.606, which would require licensees and other entities that implement an FFD program under subpart M of part 26 to develop a written FFD policy statement and provide it to all individuals subject to the FFD program, and to

establish, implement, and maintain written procedures addressing the topics outlined in this section.

Section 26.607 Drug and alcohol testing.

This proposed rule would add § 26.607, which would establish requirements for licensees and other entities performing drug and alcohol testing as part of an FFD program under subpart M of part 26.

Section 26.608 FFD program training.

This proposed rule would add § 26.608, which would require individuals who are subject to the FFD program under subpart M of part 26 to receive periodic training on FFD policies and procedures, including their duties and responsibilities under the BOP.

Section 26.609 Behavioral observation.

This proposed rule would add § 26.609, which would establish the requirements for a BOP under subpart M of part 26.

Section 26.610 Sanctions.

This proposed rule would add § 26.610, which would require licensees and other entities implementing an FFD program under subpart M of part 26 to establish sanctions for FFD policy violations.

Section 26.611 Protection of information.

This proposed rule would add § 26.611, which would require licensees and other entities implementing an FFD program under subpart M of part 26 to establish a system to protect personal information against unauthorized disclosure.

Section 26.613 Appeals process.

This proposed rule would add § 26.613, which would require licensees and other entities that implement an FFD program under subpart M of part 26 to establish procedures for an individual to appeal a policy violation determination.

~~**Section 26.615 Audits.**~~

~~This proposed rule would add § 26.615, which would establish provisions for licensees and other entities that implement an FFD program under subpart M of part 26 to conduct audits to monitor the effectiveness of FFD program elements.~~

~~**Section 26.617 Recordkeeping and reporting.**~~

~~This proposed rule would add § 26.617, which would require licensees or other entities implementing an FFD program under subpart M of part 26 to retain records pertaining to the administration of the program and to make reports in accordance with the requirements of this section.~~

~~**Section 26.619 Suitability and fitness determinations.**~~

~~This proposed rule would add § 26.619, which would require licensees and other entities that implement FFD programs to develop, implement, and maintain procedures to assess whether individuals are fit to perform the duties that make them subject to the FFD program.~~

Section 26.709 Applicability.

This proposed rule would add paragraph (b) to § 26.709, which would extend the requirements of subpart N of part 26 to licensees and other entities identified in § 26.3(f) that do not implement the requirements of subpart M of part 26, as well as licensees and other entities that implement the requirements of § 26.605(b).

Section 26.711 General provisions.

This proposed rule would revise § 26.711 to incorporate references to § 26.3(d) and (f).

Section 26.825 Criminal penalties.

The proposed rule would update § 26.825(b) to include a reference to the proposed § 26.601.

10 CFR part 30

Section 30.4 Definitions.

This proposed rule would revise the definition for "Utilization facility" in § 30.4 to include utilization facilities defined in the regulations under part 53 in addition to part 50.

Section 30.50 Reporting requirements.

This proposed rule would revise § 30.50 to include references to part 53 in addition to part 50.

10 CFR part 40

Section 40.60 Reporting requirements.

This proposed rule would revise § 40.60(c)(3) to include references to part 53 in addition to part 50 regarding reporting requirements.

10 CFR part 50

Section 50.11~~44~~ Exceptions and exemptions from licensing requirements~~Combustible gas control for nuclear power reactors~~.

This proposed rule would revise § 50.11~~44(c) and (d)~~ to incorporate the appropriate references to ~~Framework B of~~ part 53.

~~**Section 50.46 Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors.**~~

~~This proposed rule would amend § 50.46, paragraphs (a)(1)(i) and (a)(3)(i) through (iii) to incorporate the appropriate references to Framework B of part 53.~~

Section 50.47 Emergency plans.

This proposed rule would amend § 50.47 by revising paragraph (a)(1)(ii) to apply to COLs under part 53 and adding paragraphs (a)(1)(v) and (vi) regarding proposed emergency plans under part 53 in connection with an application for an ESP under part 53.

Section 50.55a Codes and standards.

This proposed rule would amend § 50.55a, by revising paragraphs (b)(1), (b)(2)(xxi)(B)(3), (b)(3)(iii), (b)(4), (c), (d), (d)(1), (e), (e)(1), (f), (f)(3), (f)(3)(iii)(B), (f)(3)(iv)(B), (f)(4)(i), (g), (g)(2)(ii), (g)(3)(ii), (g)(4)(i), and (g)(4)(v) to incorporate the appropriate references to boiling or pressurized water-cooled commercial nuclear plants under Framework B of part 53.

Section 50.60 Acceptance criteria for fracture prevention measures for lightwater nuclear power reactors for normal operation.

This proposed rule would revise § 50.60 to incorporate the appropriate references to Framework B of part 53.

Section 50.61 Fracture toughness requirements for protection against pressurized thermal shock events.

This proposed rule would revise § 50.61(b)(1) to extend the requirements of this section to pressurized-water nuclear power reactors with a license or permit issued under Framework B of part 53.

Section 50.62 Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants.

This proposed rule would revise § 50.62, paragraphs (a), (b), (c)(4), (c)(6), and (d) to include the appropriate references to Framework B of part 53.

Section 50.63 Loss of all alternating current power.

This proposed rule would revise § 50.63(a)(1) and (c)(2) with the appropriate references to Framework B of part 53.

Appendix BA to 10 CFR part 50 – General Design Criteria for Nuclear Power PlantsQuality Assurance Criteria for Nuclear Power Plants and Ruel Reprocessing Plants

This proposed rule would revise appendix BA to part 50 by revising the Introduction and Criterion 19the first paragraphs of section III, "Design Control," and section IV, "Procurement Document Control," to incorporate the appropriate terminology and references to Framework B offor part 53.

Appendix G to 10 CFR part 50 – Fracture Toughness Requirements

This proposed rule would update appendix G to part 50 with a reference to part 53.

Appendix H to 10 CFR part 50 – Reactor Vessel Material Surveillance Program Requirements

This proposed rule would update appendix H to part 50 by revising sections III.B.3 and IV.A with references to § 53.040 where appropriate.

Appendix J to 10 CFR part 50 – Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors

This proposed rule would revise appendix J to part 50 by adding references to Framework B of part 53 where appropriate.

Appendix S to 10 CFR part 50 – Earthquake Engineering Criteria for Nuclear Power Plants

This proposed rule would revise appendix S to part 50 by updating the introduction and definitions to include references to part 53.

10 CFR part 51

Section 51.20 Criteria for and identification of licensing and regulatory actions requiring environmental impact statements.

This proposed rule would revise § 51.20(b)(1) and (2) to require an environmental impact statement prior to the issuance of a CP, LWA, or ESP under part 53, or the issuance to renewal of a full power or design capacity license to operate a nuclear power reactor, testing facility, or fuel reprocessing plant under part 53.

Section 51.22 Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.

This proposed rule would revise § 51.22 to include corresponding references to part 53 in paragraphs (c)(3), (c)(9), (c)(12), (c)(17), (c)(22) and (23).

Section 51.26 Requirement to publish notice of intent and conduct scoping process.

This proposed rule would revise § 51.26(d) to add a reference to part 53.

Section 51.30 Environmental assessment.

This proposed rule would revise the introductory text to paragraph (a) and revise paragraphs (d) and (e) of § 51.30 to incorporate the appropriate references to part 53 regarding environmental assessments.

Section 51.31 Determinations based on environmental assessment.

This proposed rule would revise § 51.31(a) to include a reference to part 53.

Section 51.32 Finding of no significant impact.

This proposed rule would revise § 51.32(b)(1) and (3), finding there is no significant environmental impact associated with the issuance of standard DCs and MLs under part 53.

Section 51.49 Environmental report-limited work authorization.

This proposed rule would revise the introductory text of § 51.49(c) to require applicants for an ESP under part 53 requesting a LWA to include the environmental report required by § 51.50(b).

Section 51.50 Environmental report – construction permit, early site permit, or combined license stage.

This proposed rule would revise § 51.50, paragraphs (a), (b)(4), and the introductory text for paragraph (c) to incorporate the appropriate references to part 53.

Section 51.53 Postconstruction environmental reports.

This proposed rule would revise § 51.53(d) to include the appropriate references to part 53 regarding a license termination plan or decommissioning plan and related requirements for postconstruction environmental reports.

Section 51.54 Environmental report – manufacturing license.

This proposed rule would update § 51.54(a) to require applicants for MLs under part 53 to submit an environmental report with the application.

Section 51.55 Environmental report – standard design certification.

This proposed rule would update § 51.55(a) to require applicants for a standard DC under part 53 to submit an environmental report with the application.

Section 51.58 Environmental report – number of copies; distribution.

This proposed rule would revise § 51.58(b) to incorporate the appropriate references to part 53.

Section 51.77 Distribution of draft environmental impact statement.

This proposed rule would revise the introductory text for § 51.77(a) to add a reference to part 53.

Section 51.92 Supplement to the final environmental impact statement.

This proposed rule would revise § 51.92(b) to apply to COL applications referencing an ESP under part 53.

Section 51.95 Postconstruction environmental impact statements.

This proposed rule would revise the introductory text for § 51.95(c) to include a reference to part 53 regarding the Commission's obligations to prepare an environmental impact statement following the renewal of an operating or COL for a nuclear plant under part 53.

Section 51.101 Limitations on actions.

This proposed rule would revise § 51.101(a)(2) to include the corresponding references to part 53 where appropriate.

Section 51.103 Record of decision – general.

This proposed rule would update § 51.103(a)(6) to apply to the issuance of a LWA in connection with a CP or COL under part 53.

Section 51.105 Public hearings in proceedings for issuance of construction permits or early site permits; limited work authorizations.

This proposed rule would update § 51.105(c)(1) to include the appropriate reference to LWAs under part 53 for CPs or ESPs.

Section 51.107 Public hearings in proceedings for issuance of combined licenses; limited work authorizations.

This proposed rule would amend § 51.107 by revising the introductory text for paragraphs (a) and (b) and updating paragraph (d)(1) to include the appropriate corresponding references to part 53.

Section 51.108 Public hearings on Commission findings that inspections, tests, analyses, and acceptance criteria of combined licenses are met.

This proposed rule would revise § 51.108 to incorporate the appropriate references to part 53.

10 CFR part 53— RISK-INFORMED, TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK FOR COMMERCIAL NUCLEAR PLANTS

~~**Section 53.000 Purpose.**~~

This proposed rule would add a new part 53, "Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants," to Title 10, "Energy," of the Code of Federal Regulations after part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." The new part would provide an alternative licensing framework ~~§ 53.000, which would state the purpose of part 53, which is to provide optional frameworks for the issuance, amendment, renewal, and termination of licenses, permits, certifications, and approvals~~ for commercial nuclear plants licensed under Section 103 of the AEA.

Commented [A35]: Edited to replace the draft proposed section-by-section analysis using a concise discussion modeled on that provided for 50.160 in SECY-22-0001 in light the detailed discussion of the individual proposed sections in section IV of this document. This eliminates 84 pages from the draft proposed FRN and the concomitant risk of misalignment between the text of the section-by-section analysis and the rule text as well as the remainder of the preamble. Staff should adopt this type of approach in future complex rulemakings particularly when there is a possibility of contracting out the preparation of the text in order to avoid expending resources that do not provide any additional value to the product.

~~**Section 53.010 Frameworks.**~~

~~This proposed rule would add § 53.010, which would provide an overview of the two distinct frameworks under which part 53 applicants may seek a license, certificate, or permit.~~

~~**10 CFR part 53, subpart A—General Provisions**~~

~~This proposed rule would add subpart A, to establish a set of general provisions, which apply to all applicants and licensees under part 53.~~

~~**Section 53.015 Scope.**~~

~~This proposed rule would add § 53.015, which would extend the provisions of subpart A to all applicants and licensees under part 53.~~

Section 53.020 Definitions.

This proposed rule would add § 53.020, which would define terms common to Frameworks A and B of part 53. These terms are: "applicant," "certified fuel handler," "combined license," "commercial nuclear plant," "commercial nuclear reactor," "Commission," "consensus code or standard," "custom combined license," "decommission or decommissioning," "defense in depth," "design features," "electric utility," "event sequence," "exclusion area," "fission product," "fuel," "license," "licensee," "licensing basis information," " low population zone," "manufactured reactor," "manufacturing license," "person," "population center distance," "probabilistic risk assessment," "prototype plant," "quality assurance," "safety function," "site characteristics," "site parameters," "Special nuclear material," "standard design," "standard design approval or design approval," "standard design certification or design certification," "total effective dose equivalent," and "utilization facility."

Section 53.024 Definitions specific to Framework A.

This proposed rule would add § 53.024, which would define terms that would be applicable to Framework A.

Section 53.028 Definitions specific to Framework B.

This proposed rule would add § 53.028, which would define terms that would be applicable to Framework B.

Section 53.040 Written communications.

This proposed rule would add § 53.040, which would govern how applicants and licensees submit written communications to the NRC, including applications, submissions related to the security plans, emergency plan, and quality assurance, certifications of permanent cessation of operations and permanent fuel removal, and other submittals required under part 53.

Section 53.050 Deliberate misconduct.

This proposed rule would add § 53.050, which would prohibit licensees, applicants, contractors and subcontractors, or employees of those entities, from deliberately violating NRC rules, regulations, or orders, or the terms, conditions, and limitations of a part 53 license. This proposed rule would also prohibit deliberate submissions of incomplete or inaccurate information. Violations would be subject to enforcement actions under subpart B of part 2.

Section 53.060 Employee protection.

This proposed rule would add § 53.060, which would prohibit applicants and licensees from discriminating against employees for engaging in the protected activities listed in this section and provide remedial procedures for employees who believe they are the subjects of discrimination.

Section 53.070 Completeness and accuracy of information.

This proposed rule would add § 53.070, which would require licensees and applicants under part 53 to provide complete and accurate information in accordance with all applicable laws, Commission regulations, and the terms and conditions of their license. This proposed rule would also require licensees to notify the Commission within two days of identifying information with material implications for public health and safety or common defense and security.

Section 53.080 Specific exemptions.

This proposed rule would add § 53.080, which would establish the special circumstances under which the Commission could grant exemptions to part 53 licensees and the Commission's criteria for making such a determination.

Section 53.090 Standards for review.

This proposed rule would add § 53.090 to establish the standards that the Commission would consider when determining whether to issue a permit or license under part 53.

Section 53.100 Jurisdictional limits.

This proposed rule would add § 53.100, which would provide that permits, licenses, standard design approvals, and standard DCs are solely issued for activities within the jurisdiction of the United States.

Section 53.110 Attacks and destructive acts.

This proposed rule would add § 53.110, which would exempt licensees or applicants under part 53 from providing design features to protect against attacks or destructive acts directed at the facility by United States adversaries.

Section 53.115 Rights related to special nuclear material.

This proposed rule would add § 53.115, which would establish provisions regarding the rights to SNM under a part 53 license.

Section 53.117 License suspension and rights of recapture.

This proposed rule would add § 53.117, which would provide that the Commission may suspend licenses and recapture material or control of a facility in a state of war or national emergency declared by Congress.

Section 53.120 Information collection requirements: OMB approval.

This proposed rule would add § 53.120, which would establish requirements for information collection requirements and Office of Budget and Management approval.

10 CFR part 53, subpart B—Technology-Inclusive Safety Requirements

This proposed rule would add subpart B, to establish a set of technology-inclusive performance standards that would be used throughout Framework A within

part 53 to determine appropriate regulatory controls for SSCs, human actions, and programs.

Section 53.200 Safety objectives.

This proposed rule would add § 53.200 to establish the overall safety objectives of minimizing the possibility of an immediate threat to public health and safety and ensuring additional measures are taken as may be appropriate when considering potential risks to public health and safety in the design, construction, operation, and decommissioning of commercial nuclear plants within Framework A.

Section 53.210 Safety criteria for design-basis accidents.

This proposed rule would add § 53.210 to set dose values to ensure that plants are designed to limit the public's radiation exposure in the event of a DBA.

Section 53.220 Safety criteria for licensing-basis events other than design-basis accidents.

This proposed rule would add § 53.220 to require plants to implement a combination of design features and programmatic controls to minimize risks to the public in the event of a LBE other than a DBA.

Section 53.230 Safety functions.

This proposed rule would add § 53.230, which specifies that limiting the release of radioactive materials from the facility is the primary safety function of a commercial nuclear plant, and that additional safety functions must be defined to support the retention of radioactive materials during LBEs.

Section 53.240 Licensing-basis events.

This proposed rule would add § 53.240 to require commercial nuclear plants to conduct an analysis of LBEs to confirm that design features and programmatic controls satisfy the safety criteria under §§ 53.210 and 53.220, or alternatively, under § 53.470.

Section 53.250 Defense in depth.

This proposed rule would add § 53.250 to establish a performance-based, defense-in-depth approach to address uncertainties about the effectiveness and reliability of plant SSCs, personnel, and programmatic controls.

Section 53.260 Normal operations.

This proposed rule would add § 53.260, requiring plants to be designed to ensure that the public's exposure to doses of radiation is ALARA, and not to exceed the limits provided in subpart D to part 20, during normal plant operation.

Section 53.270 Protection of plant workers.

This proposed rule would add § 53.270 to require that plants use a combination of design features and programmatic controls to ensure that occupational exposure to doses of radiation is ALARA, and not to exceed the limits provided in subpart C to part 20.

10 CFR part 53, subpart C—Design and Analysis Requirements

This proposed rule would add subpart C, which requires the implementation of certain design features and the performance of risk assessments and analyses to demonstrate compliance with the safety criteria and safety functions in subpart B.

Section 53.400 Design features for licensing-basis events.

This proposed rule would add § 53.400, which would require design features that satisfy the safety criteria defined in §§ 53.210 and 53.220 or § 53.470 and fulfill the safety functions identified in § 53.230 during LBEs.

Section 53.410 Functional design criteria for design-basis accidents.

This proposed rule would add § 53.410, which would stipulate that functional design criteria must be defined for each design feature required by § 53.400 to demonstrate compliance with the safety criteria defined in § 53.210 for DBAs.

Section 53.415 Protection against external hazards.

This proposed rule would add § 53.415, which would require SR SSCs to be designed to withstand the effects of natural phenomena and constructed hazards while performing the intended safety functions.

Section 53.420 Functional design criteria for licensing-basis events other than design-basis accidents.

This proposed rule would add § 53.420, which would require functional design criteria to be defined for each design feature required by § 53.400 to demonstrate compliance with the safety criteria defined in § 53.220 for LBEs other than DBAs.

Section 53.425 Design features and functional design criteria for normal operations.

The proposed rule would add § 53.425, which would require commercial nuclear plants to implement design features and define functional design criteria sufficient to demonstrate compliance with §§ 53.260(a) and 53.260(b) and conduct monitoring to ensure the public's exposure to radiation does not exceed the limits established in §§ 53.260(a) and 53.260(b).

Section 53.430 Design features and functional design criteria for protection of plant workers.

The proposed rule would add § 53.430, which would require commercial nuclear plants to implement design features and define functional design criteria sufficient to demonstrate compliance with §§ 53.270(a) and 53.270(b) and conduct monitoring to ensure the occupational exposure to radiation does not exceed the limits established in §§ 53.270(a) and 53.270(b).

Section 53.440 Design requirements.

The proposed rule would add § 53.440, which would establish various design feature requirements, including protection against fires and explosions, criticality accidents, and the impact of a large commercial aircraft.

Section 53.450 Analysis requirements.

The proposed rule would add § 53.450, which would require commercial nuclear plants to perform PRAs in combination with other analytical methods to identify and assess risks and determine compliance with the safety criteria in subpart B. In addition, § 53.450 would require analysis of DBAs and other analyses to assess the adequacy of protections against fire, aircraft impact, and the release of effluents.

Section 53.460 Safety categorization and special treatment.

The proposed rule would add § 53.460 to address the safety classification of SSCs and determine appropriate special treatments.

Section 53.470 Maintaining analytical safety margins used to justify operational flexibilities.

The proposed rule would add § 53.470 to permit applicants and licensees to implement more restrictive criteria than that defined in §§ 53.220 and 53.450(e) to support operational flexibilities.

Section 53.480 Earthquake engineering.

The proposed rule would add § 53.480 to provide overall seismic design considerations based on the safety criteria in subpart B and siting requirements in subpart D to ensure that SSCs are able to withstand the effects of earthquakes without loss of capability to fulfill safety functions.

10 CFR part 53, subpart D—Siting Requirements

The proposed rule would add subpart D, which would address requirements associated with the siting of commercial nuclear facilities under Framework A, including considerations of external hazards and potential adverse impacts on the surrounding population.

Section 53.500 General siting and siting assessment.

The proposed rule would add § 53.500, which would require a siting assessment for each commercial nuclear plant to ensure that design features and programmatic controls are sufficient to address LBEs and mitigate potential adverse impacts of the plant on the surrounding environs.

Section 53.510 External hazards.

The proposed rule would add § 53.510, which would require site-specific assessments, including an evaluation of geological and seismic siting factors, to identify and characterize the external hazard level for a range of natural and constructed hazards.

Section 53.520 Site characteristics.

The proposed rule would add § 53.520, which would require the design and analyses conducted under subpart C to consider how site characteristics may contribute to LBEs.

Section 53.530 Population-related considerations.

The proposed rule would add § 53.530, which would establish requirements related the facility's exclusion area, low population zone, and population center distance.

Section 53.540 Siting interfaces.

The proposed rule would add § 53.540, which would require that external hazards and site characteristics must be accounted for in the design features,

programmatic controls, and supporting analyses used to demonstrate compliance with the safety criteria in §§ 53.210 and 53.220.

10 CFR part 53, subpart E—Construction and Manufacturing Requirements

The proposed rule would add subpart E, which would establish requirements for the construction of an advanced nuclear plant.

Section 53.600 Construction and manufacturing – scope and purpose.

The proposed rule would add § 53.600, which would indicate that this subpart applies to construction and manufacturing activities authorized by a CP, COL, ML, or LWA issued under this part.

Section 53.605 Reporting of defects and noncompliance.

The proposed rule would add § 53.605, which would describe the procedures, notification requirements, and records retention requirements that each CP, ML, and COL is subject to with respect to reporting of defects and noncompliance.

Section 53.610 Construction.

The proposed rule adds § 53.610 to address the management and control of the construction of a commercial nuclear plant, including specific requirements for procedures and quality assurance, control of radioactive materials, and post construction inspections.

Section 53.620 Manufacturing.

This proposed rule would add § 53.620, which would ensure that the holders of an ML under Framework A develop plans, programs, and organizational units to manage and control manufacturing activities.

10 CFR part 53, subpart F—Requirements for Operation

This proposed rule would add subpart F, which would establish regulatory requirements to ensure that the safety criteria in subpart B are satisfied whenever a

commercial nuclear plant licensed under Framework A is operational. This includes periods of normal operation and unplanned events.

Section 53.700 Operational objectives.

This proposed rule would add § 53.700, which would establish general operational objectives to ensure that licensees under Framework A have implemented and maintained the SSCs necessary to demonstrate compliance with the safety functions identified in subpart B for addressing normal operations and responding to LBEs.

Section 53.710 Maintaining capabilities and availability of structures, systems, and components.

This proposed rule would add § 53.710, which would require licensees under Framework A to demonstrate compliance with the safety criteria in subpart B by establishing TS for all SR SSCs and developing documents and procedures for all NSRSS SSCs.

Section 53.715 Maintenance, repair, and inspection programs.

This proposed rule would add § 53.715, which would require licensees to develop, implement, and maintain programs to assess and manage any risks posed by maintenance activities and to evaluate the efficacy of performance, condition monitoring, and maintenance activities to ensure compliance with the safety criteria of subpart B.

Section 53.720 Response to seismic events.

This proposed rule would add § 53.720, which would establish requirements for licensees to respond to a seismic event during the operating phase of the life cycle of a commercial nuclear plant.

Section 53.725 General staffing, training, personnel qualifications, and human factors requirements.

This proposed rule would add § 53.725, which would provide an overview of the staffing, training, personnel qualifications, and human factors requirements established in §§ 53.725 through 53.830 and would provide definitions of "automation," "auxiliary operator," "controls," "generally licensed reactor operator," "load following," "operator," "performance testing," "reference plant," "self-reliant mitigation facility," "senior operator," "simulation facility," and "systems approach to training." Proposed §§ 53.725 through 53.830 would apply to applicants for or holders of OLs or COLs under Frameworks A and B.

Section 53.726 Communications.

This proposed rule would add § 53.726, which would contain communications requirements applicable to sections §§ 53.725 through 53.830. It also contains requirements to notify the Commission within 30 days should a specifically licensed operator or senior operator be reassigned, terminated, or suffer permanent disability or illness.

Section 53.727 Information collection requirements: OMB approval.

This proposed rule would add § 53.727, which would contain information collection requirements and OMB clearance information.

Section 53.728 Completeness and accuracy of information.

This proposed rule would add § 53.728, which would require submitted information to be complete and accurate in all material respects.

Section 53.730 Defining, fulfilling, and maintaining the role of personnel in ensuring safe operations.

This proposed rule would add § 53.730, which would establish technical requirements for applicants or holders of OLs or COLs within the areas of HFE, human-system interface design, concept of operations, functional requirements analysis, function allocation, operating experience, procedures, staffing, operator training, operator examinations, and operator proficiency.

Section 53.735 General exemptions.

This proposed rule would add § 53.735, which would establish general exemptions for licensed operators.

Section 53.740 Facility licensee requirements – General.

This proposed rule would add § 53.740, which would establish staffing requirements for interaction-dependent mitigation facilities and self-reliant mitigation facilities.

Section 53.745 Operator license requirements.

This proposed rule would add § 53.745, which would require individuals to be licensed to perform certain functions.

Section 53.760 Operator licensing.

This proposed rule would add § 53.760, which would address the applicability of the requirements of §§ 53.760 through 53.795 for specifically licensed operators and senior operators.

Section 53.765 Medical requirements.

This proposed rule would add § 53.765, which would establish medical requirements for specifically licensed operators and senior operators.

Section 53.770 Incapacitation because of disability or illness.

This proposed rule would add § 53.770, which would establish requirements to address permanent medical conditions for specifically licensed operators and senior operators.

Section 53.775 Applications for operators and senior operators.

This proposed rule would add § 53.775, which would establish the application process and requirements for individuals applying for specific operator and senior operator licenses.

Section 53.780 Training, examination, and proficiency programs.

This proposed rule would add § 53.780, which would contain the requirements associated with specifically licensed operator and senior operator initial training, initial examinations, requalification training, requalification examinations, examination integrity, simulation facilities, waivers, and proficiency.

Section 53.785 Conditions of operator and senior operator licenses.

This proposed rule would add § 53.785, which would establish conditions for specific operator and senior operator licenses.

Section 53.790 Issuance, modification, and revocation of operator and senior operator licenses.

This proposed rule would add § 53.790, which would contain requirements associated with the issuance, modification, or revocation of specific operator and senior operator licenses.

Section 53.795 Expiration and renewal of operator and senior operator licenses.

This proposed rule would add § 53.795, which would contain requirements associated with the expiration and renewal of specific operator and senior operator licenses.

Section 53.800 Facility licensees for self-reliant-mitigation facilities.

This proposed rule would add § 53.800, which would establish the technical criteria by which commercial nuclear plants under Framework A or B are determined to be of the self-reliant mitigation class of facilities that would be staffed by GLROs in lieu of specifically licensed operators and senior operators.

Section 53.805 Facility licensee requirements related to generally licensed reactor operators.

This proposed rule would add § 53.805, which would establish requirements that apply to the facility licensee at those facilities staffed by GLROs.

Section 53.810 Generally licensed reactor operators.

This proposed rule would add § 53.810, which would issue and describe the general license for GLROs that manipulate the controls of a self-reliant mitigation facility.

Section 53.815 Generally licensed reactor operator training, examination, and proficiency programs.

This proposed rule would add § 53.815, which would contain the requirements for GLRO initial training, initial examinations, continuing training, requalification examinations, examination integrity, simulation facilities, examination waivers, and proficiency.

Section 53.820 Cessation of individual applicability.

This proposed rule would add § 53.820, which would address the requirements by which the general license for GLROs would cease to be applicable on an individual basis.

Section 26.825 Criminal penalties.

The proposed rule would update § 26.825(b) to include a reference to the proposed § 26.601.

Section 53.830 Training and qualification of commercial nuclear plant personnel.

This proposed rule would add § 53.830, which would address training and qualification requirements for supervisors, technicians, and other appropriate operating personnel at commercial nuclear plants.

Section 53.845 Programs.

This proposed rule would add § 53.845, which would require licensees under Framework A to establish programs that include, but are not limited to, radiation protection, emergency preparedness, security, quality assurance, integrity assessment, fire protection, ISI and IST, and facility safety, to ensure that the safety criteria and functions in subpart B are maintained during normal operations and LBEs.

Section 53.850 Radiation protection.

This proposed rule would add § 53.850, which would require licensees under Framework A to implement and maintain programs and processes to limit and monitor radioactive plant effluents and limit the exposure of plant personnel and the public.

Section 53.855 Emergency preparedness.

This proposed rule would add § 53.855, which would require licensees under this part to develop, implement, and maintain an emergency response plan for radiological emergencies.

Section 53.860 Security programs.

This proposed rule would add § 53.860, which would require licensees under Framework A to develop, implement, and maintain programs for physical security, FFD, AA, cyber security, and information security.

Section 53.865 Quality assurance.

This proposed rule would add § 53.865, which would require licensees under Framework A to establish a quality assurance program that includes a written manual to

ensure activities are conducted in accordance with codes and standards found acceptable by the NRC.

Section 53.870 Integrity assessment programs.

This proposed rule would add § 53.870, which would require licensees under Framework A to establish an integrity assessment program to ensure that the plant continues to fulfill safety criteria and functional design criteria as it ages.

Section 53.875 Fire protection.

This proposed rule would add § 53.875, which would require licensees under Framework A to establish a fire protection plan and describe the necessary elements that the plan must incorporate.

Section 53.880 Inservice inspection and inservice testing.

This proposed rule would add § 53.880, which would require licensees under Framework A to develop and implement a program for ISI and IST in accordance with the requirements of this section.

Section 53.890 Facility safety program.

This proposed rule would add § 53.890, which would require licensees under Framework A to establish a risk-informed, performance-based FSP.

Section 53.910 Procedures and guidelines.

This proposed rule would add § 53.910, which would require licensees under Framework A to develop, maintain, and implement procedures and guidelines that address normal plant operations and responses to unplanned events.

10 CFR part 53, subpart G—Decommissioning Requirements

This proposed rule would add subpart G, to establish decommissioning requirements for applicants for or holders of an OL or COL under Framework A of part 53.

Section 53.1000 Scope and purpose.

This proposed rule would add § 53.1000, which would establish the scope of the decommissioning requirements for applicants and licensees under Framework A of part 53 and describe the contents of subpart G of part 53.

Section 53.1010 Financial assurance for decommissioning.

This proposed rule would add § 53.1010, which would establish the requirement that applicants for an OL or COL under Framework A of part 53 provide reasonable assurance that funds will be available for the decommissioning process. This section would describe the requirements associated with the required plan and an associated decommissioning report that ensures and documents that adequate funding for decommissioning will be available.

Section 53.1020 Cost estimates for decommissioning.

This proposed rule would add § 53.1020, which would require site-specific cost estimates for decommissioning and establish the aspects that must be included in the estimate.

Section 53.1030 Annual adjustments to cost estimates for decommissioning.

This proposed rule would add § 53.1030, which would require that holders of an OL or COL under Framework A of part 53 annually adjust their cost estimate for decommissioning to account for escalation in labor, energy, and waste burial costs. This section would allow licensees to elect either a site-specific adjustment factor or a generic adjustment factor.

Section 53.1040 Methods for providing financial assurance for decommissioning.

This proposed rule would add § 53.1040, which would establish suitable methods that holders of an OL or COL under Framework A of part 53 may use to provide financial assurance for decommissioning to the NRC.

Section 53.1045 Limitations on the use of decommissioning trust funds.

This proposed rule would add § 53.1045, which would establish requirements for decommissioning trust funds under Framework A, including criteria for using decommissioning trust funds and required terms.

Section 53.1050 NRC oversight.

This proposed rule would add § 53.1050, which would outline the steps the NRC may take to ensure adequate accumulation of decommissioning funds.

Section 53.1060 Reporting and recordkeeping requirements.

This proposed rule would add § 53.1060, which would contain reporting and recordkeeping requirements related to decommissioning for each holder of an OL or COL under Framework A of part 53. This section would outline requirements for documents such as: certification of decommissioning funding, decommissioning cost estimates and copies of financial instruments, licensee records of information important to safe and effective decommissioning, post-shutdown decommissioning activities report (PSDARs), financial assurance reports, and reports on the status of funding for managing irradiated fuel.

Section 53.1070 Termination of license.

This proposed rule would add § 53.1070, which would establish procedures for decommissioning and license termination applicable to licensees under Framework A that have determined to permanently cease operations.

Section 53.1075 Program requirements during decommissioning.

This proposed rule would add § 53.1075, which would require licensees under Framework A to establish and maintain a decommissioning fire protection program to prevent, detect, and control fires, and ensure that the risk of fire induced radiological hazards are minimized through the various stages of facility decommissioning.

Section 53.1080 Release of part of a commercial nuclear plant or site for unrestricted use.

This proposed rule would add § 53.1080, which would establish licensee procedures for requesting and NRC procedures for approving partial release of a commercial nuclear plant or site for unrestricted use prior to receiving approval of a license termination plan from the Commission under Framework A.

10 CFR part 53, subpart H—Licenses, Certifications, and Approvals

This proposed rule would add subpart H, which would govern the process of applying for, amending, renewing, or terminating a LWA, ESP, standard design approval, standard DC, ML, CP, OL, or COL under Framework A.

Section 53.1100 Filling of application for licenses, certifications, or approvals; oath or affirmation.

This proposed rule would add § 53.1100, which would establish requirements for applicants seeking a standard design approval, standard DC, license, or permit under Framework A to submit an application.

Section 53.1101 Requirement for license.

This proposed rule would add § 53.1101, which would prohibit any use of a utilization facility except as authorized by a license issued by the NRC or by an exception as described in § 53.1120.

Section 53.1103 Combining applications and licenses.

This proposed rule would add § 53.1103, which would permit applicants under Framework A seeking multiple licenses to submit a single application, and the Commission to issue a single license for activities that would otherwise be licensed separately.

Section 53.1106 Elimination of repetition.

This proposed rule would add § 53.1106, which would allow applicants under Framework A to reference information contained in previous documents filed with the Commission so long as those references are clear and specific.

Section 53.1109 Contents of applications; general information.

This proposed rule would add § 53.1109, which would establish the general content to be included in applications made under Framework A, including but not limited to the identifying information of the applicant and the radiological emergency response plans of government entities within the plume exposure pathway emergency planning zone.

Section 53.1112 Environmental conditions.

This proposed rule would add § 53.1112, which would allow the Commission to attach conditions to CPs, ESPs, and licenses issued under Framework A to address environmental issues during construction, operation, or decommissioning. These conditions will be derived from the information contained in the environmental report submitted as part of the application for a permit or license.

Section 53.1115 Agreement limiting access to classified information.

This proposed rule would add § 53.1115, which would require applicants to agree in writing, prior to receiving a license or standard design approval under Framework A, to restrict individuals with access to plant facilities from possessing Restricted Data or classified National Security Information until they have received the appropriate authorization.

Section 53.1118 Ineligibility of certain applicants.

This proposed rule would add § 53.1118, which would prevent citizens, nationals, or agents of a foreign country or corporations owned, controlled, or dominated by a foreign entity from applying for or obtaining a license under Framework A.

Section 53.1120 Exceptions and exemptions from licensing requirements.

This proposed rule would add § 53.1120, which would establish the activities that are exempt from licensing requirements.

Section 53.1121 Public inspection of applications.

This proposed rule would add § 53.1121, which would allow applicant submissions to be made publicly available in accordance with part 2.

Section 53.1124 Relationship between sections.

This proposed rule would add § 53.1124, which would outline the relationship between LWAs, ESPs, standard design approvals, standard DCs, MLs, CPs, OLs, and COLs under Framework A.

Section 53.1130 Limited work authorizations.

This proposed rule would add § 53.1130, which would establish requirements for requesting an LWA and grounds for the Commission to issue an LWA. It would also contain details about the effect of an LWA and the implementation of a redress plan.

Section 53.1140 Early site permits.

This proposed rule would add § 53.1140, which would provide an overview of the requirements regarding applications for and the issuance of ESPs under Framework A.

Section 53.1143 Filing of applications.

This proposed rule would add § 53.1143, which would enable an applicant under Framework A to apply for an ESP, regardless of whether they have filed an application for a CP or COL for that site.

Section 53.1144 Contents of applications for early site permits; general information.

This proposed rule would add § 53.1144, which would require applications for ESPs to include the information required by § 53.1109(a) through (d) and (j).

Section 53.1146 Contents of applications for early site permits; technical information.

This proposed rule would add § 53.1146, which would require applicants for ESPs to submit technical information, including but not limited to a Site Safety Analysis Report and emergency plans.

Section 53.1149 Review of applications.

This proposed rule would add § 53.1149, which would establish standards for review of applications for ESPs under Framework A, including requirements for the Commission to prepare an environmental impact statement and assess the adequacy of protective actions in the event of a radiological emergency. It would also require the administrative review of applications and hearings to follow the procedural requirements of part 2.

Section 53.1155 Referral to the Advisory Committee on Reactor Safeguards.

This proposed rule would add § 53.1115, which would require the ACRS to review SR content in the application for an ESP under Framework A.

Section 53.1158 Issuance of early site permit.

This proposed rule would add § 53.1158, which would establish the conditions under which the Commission may issue an ESP under Framework A, as well as the information, terms, and conditions to be included in the permit.

Section 53.1161 Extent of activities permitted.

This proposed rule would add § 53.1161, which would require that a valid ESP only be used for the purpose of site redress, unless the site is referenced in an application for a CP or COL under Framework A.

Section 53.1164 Duration of permit.

This proposed rule would add § 53.1164, which would govern the conditions under which an ESP remains valid following the date of issuance.

Section 53.1167 Limited work authorization after issuance of early site permit.

This proposed rule would add § 53.1167, which would permit the holder of an ESP to request a LWA under § 53.1146(c).

Section 53.1170 Transfer of early site permit.

This proposed rule would add § 53.1170, which would govern the transfer of an ESP in accordance with § 53.1570.

Section 53.1173 Application for renewal.

This proposed rule would add § 53.1173, which would establish the conditions and procedures for renewing an ESP under Framework A.

Section 53.1176 Criteria for renewal.

This proposed rule would add § 53.1176, which would establish the criteria that the Commission may use to grant a renewal of an ESP under Framework A.

Section 53.1179 Duration of renewal.

This proposed rule would add § 53.1179, which would govern the duration of a renewed ESP under Framework A.

Section 53.1182 Use of site for other purposes.

This proposed rule would add § 53.1182, which would govern acceptable uses of the site for purposes other than those described in the permit.

Section 53.1188 Finality of early site permit determinations.

This proposed rule would add § 53.1188, which would address the finality of ESP determinations under Framework A.

Section 53.1200 Standard design approvals.

This proposed rule would add § 53.1200, which would address the procedures for filing an application for a standard design approval under Framework A, the process of review by NRC staff, and referral to the ACRS of standard designs.

Section 53.1203 Filing of applications.

This proposed rule would add § 53.1203, which would enable applicants to submit a final design for the entire facility, or major portions, to the NRC staff for review.

Section 53.1206 Contents of applications for standard design approvals; general information

This proposed rule would add § 53.1206, which would require applications for a standard design approval under Framework A to contain the information required by § 53.1109(a) through (c) and (j).

Section 53.1209 Contents of applications for standard design approvals; technical information.

This proposed rule would add § 53.1209, which would require the inclusion of certain technical information, including a FSAR, site parameters, and design information, when an applicant seeks review of a major portion of a standard design.

Section 53.1210 Contents of applications for standard design approvals; other application content.

This proposed rule would add § 53.1210, which would require applications for standard design approvals under Framework A to include a description of the availability controls used to satisfy the safety criteria of § 53.220, the program to protect Safeguards

Information against unauthorized disclosure, evidence that safety questions associated with SSCs have been resolved, and a description of how design features fulfill design criteria.

Section 53.1212 Standards for review of applications.

This proposed rule would add § 53.1212, which would require applications for standard design approval to be reviewed for compliance with the standards in parts 20, 53, and 73.

Section 53.1215 Referral to the Advisory Committee on Reactor Safeguards.

This proposed rule would add § 53.1215, which would require the ACRS to report on any portions of the application for a standard design approval under Framework A concerning safety.

Section 53.1218 Staff approval of design.

This proposed rule would add § 53.1218, which would require the NRC staff to make a determination on the acceptability of the design, publish its decision in the *Federal Register*, and issue a report analyzing the design that is available at http://nrc.gov. Additionally, the rule would establish the conditions under which a design approval under Framework A remains valid.

Section 53.1221 Finality of standard design approvals; information requests.

This proposed rule would add § 53.1221, which would require NRC staff and the ACRS to rely upon an approved design in their review of any standard DC, ML, or individual facility license application under Framework A that references the standard design approval. The proposed rule would also govern requirements for issuing information requests.

Section 53.1230 Standard design certifications.

This proposed rule would add § 53.1230, which would provide an overview of the requirements and procedures that govern the issuance of standard DCs under Framework A.

Section 53.1233 Filing of applications.

This proposed rule would add § 53.1233, which would enable an application for DC to be filed, regardless of whether an application for a CP, COL, or ML has been filed, provided it complies with the filing requirements in § 53.040 and §§ 2.811 through 2.819.

Section 53.1236 Contents of applications for standard design certifications; general information.

This proposed rule would add § 53.1236, which would require an application for a standard DC under Framework A to contain all of the information required by § 53.1109(a) through (c) and (j).

Section 53.1239 Contents of applications for standard design certifications; technical information.

This proposed rule would add § 53.1239, which would require applicants for a standard DC under Framework A to submit a FSAR that includes technical design information at a level of detail sufficient to enable the Commission to make a safety determination.

Section 53.1241 Contents of applications for standard design certifications; other application content.

This proposed rule would add § 53.1241, which would require applications for standard DCs under Framework A to include an environmental report, as well as a description of the availability controls used to satisfy the safety criteria of § 53.220, proposed ITAAC, the program to protect Safeguards Information against unauthorized

disclosure, evidence that safety questions associated with SSCs have been resolved, and a description of how design features fulfill design criteria.

Section 53.1242 Review of applications.

This proposed rule would add § 53.1242, which would require applications for standard DCs to be reviewed for compliance with the standards in parts 20, 51, 53, and 73. It would also establish procedural requirements for reviewing applications and holding hearings in accordance with subpart H of part 2.

Section 53.1245 Referral to the Advisory Committee on Reactor Safeguards.

This proposed rule would add § 53.1245, which would require the ACRS to report on any portions of the application for a standard DC under Framework A concerning safety.

Section 53.1248 Issuance of standard design certification.

This proposed rule would add § 53.1248, which would establish the conditions under which the Commission may issue a DC rule that specifies the site parameters, design characteristics, and any additional terms and conditions of the DC rule.

Section 53.1251 Duration of certification.

This proposed rule would add § 53.1251, which would set the conditions under which a standard DC remains valid.

Section 53.1254 Application for renewal.

This proposed rule would add § 53.1254, which would establish the conditions and procedures for renewing a standard DC under Framework A.

Section 53.1257 Criteria for renewal.

This proposed rule would add § 53.1257, which would enable the Commission to issue a rule granting the renewal of a standard DC under Framework A, impose additional requirements, and grant amendment requests.

Section 53.1260 Duration of renewal.

This proposed rule would add § 53.1260, which would provide that a renewal of a standard DC under Framework A is valid for not less than 10 years, nor more than 15 years.

Section 53.1263 Finality of standard design certifications.

This proposed rule would add § 53.1263, which would establish limited conditions under which the Commission may initiate a rulemaking to modify, rescind, or impose new requirements on a standard DC rule under Framework A. It would also address requests for an exemption from elements of the certification information, and require that applicants for a CP, COL, or ML that references a DC rule make engineering documents available for audit.

Section 53.1270 Manufacturing licenses.

This proposed rule would add § 53.1270, which would provide an overview of the requirements and procedures for applying for and issuing an ML under Framework A.

Section 53.1273 Filing of applications.

This proposed rule would add § 53.1273, which would establish the requirements to apply for an ML under Framework A.

Section 53.1276 Contents of applications for manufacturing licenses; general information.

This proposed rule would add § 53.1276, which would require applicants for an ML under Framework A to include the information contained in § 53.1109(a) through (e) and (j).

Section 53.1279 Contents of applications for manufacturing licenses; technical information.

This proposed rule would add § 53.1279, which would require an applicant for an ML under Framework A to include certain technical information in a FSAR, including but not limited to information about site parameters, design information, manufacturing information, and information related to the deployment of a completed manufactured reactor.

Section 53.1282 Contents of applications for manufacturing licenses; other application content.

This proposed rule would add § 53.1282, which would require applicants for an ML under Framework A to include in their application the proposed ITAAC, an environmental report, a description of the program to protect Safeguards Information against unauthorized disclosure, and a description of how design features fulfill design criteria. It would also include content requirements for the ITAAC and environmental reports in applications that reference a standard DC.

Section 53.1285 Review of applications.

This proposed rule would add § 53.1285, which would require applications for MLs under Framework A to be reviewed for compliance with applicable standards and establish procedural requirements for reviewing applicants and holding hearings in accordance with part 2.

Section 53.1286 Referral to the Advisory Committee on Reactor Safeguards.

This proposed rule would add § 53.1286, which would require the ACRS to report on any portions of the application for an ML under Framework A concerning safety.

Section 53.1287 Issuance of manufacturing license.

This proposed rule would add § 53.1287, which would establish the conditions under which the Commission may issue an ML under Framework A.

Section 53.1288 Finality of manufacturing licenses.

This proposed rule would add § 53.1288, which would address the limited circumstances in which the Commission may modify, rescind, or impose new requirements following the issuance of an ML under Framework A. It would also address requests for a departure from the specifications of the license.

Section 53.1291 Duration of manufacturing licenses.

This proposed rule would add § 53.1291, which would govern the expiration of an ML, which is valid for no less than 5, nor more than 15 years from the date of issuance.

Section 53.1293 Transfer of manufacturing licenses.

This proposed rule would add § 53.1293, which would provide that an ML under Framework A may be transferred in accordance with § 53.1570.

Section 53.1295 Renewal of manufacturing licenses.

This proposed rule would add § 53.1295, which would establish the procedures for applicants to apply for and the Commission to grant a renewal of an ML under Framework A.

Section 53.1300 Construction permits.

This proposed rule would add § 53.1300, which would provide an overview of the requirements and procedures for applicants to apply for and the Commission to grant a CP under Framework A.

Section 53.1306 Contents of applications for construction permits; general information.

This proposed rule would add § 53.1306, which would require applicants for a CP under Framework A to submit the general information required by § 53.1109, as well as financial information.

Section 53.1309 Contents of applications for construction permits; technical information.

This proposed rule would add § 53.1309, which would require applicants for a CP under Framework A to submit a PSAR and a description of the program to protect Safeguards Information from unauthorized disclosure.

Section 53.1312 Contents of applications for construction permits; other application content.

This proposed rule would add § 53.1312, which would require applicants for a CP under Framework A to submit an environmental report and to provide additional details in the PSAR if the application references an ESP, standard design approval, or standard DC.

Section 53.1215 Review of applications.

This proposed rule would add § 53.1315, which would require applications for CPs under Framework A to be reviewed for compliance with applicable standards and establish procedural requirements for reviewing applications and holding hearings in accordance with part 2.

Section 53.1318 Finality of referenced NRC approvals, permits, and certifications.

This proposed rule would add § 53.1318, which would address the finality of ESPs, standard design approvals, and standard DCs referenced in the CP application.

Section 53.1324 Referral to the Advisory Committee on Reactor Safeguards.

This proposed rule would add § 53.1324, which would require the ACRS to report on any portions of the application for a CP under Framework A concerning safety.

Section 53.1327 Authorization to conduct limited work authorization activities.

This proposed rule would add § 53.1327, which would govern authorization to conduct LWA activities.

Section 53.1330 Exemptions, departures, and variances.

This proposed rule would add § 53.1330, which would govern requests for and issuance of exemptions from the Commission's regulations and exemptions, departures, and variances from NRC approvals, permits, and certifications.

Section 53.1333 Issuance of construction permits.

This proposed rule would add § 53.1333, which would establish the conditions under which the Commission may issue CPs and accompanying terms and conditions under Framework A.

Section 53.1336 Finality of construction permits.

This proposed rule would add § 53.1336, which would address the finality of CPs.

Section 53.1342 Duration of construction permit.

This proposed rule would add § 53.1342, which would establish requirements for the expiration of a CP.

Section 53.1345 Transfer of construction permits.

This proposed rule would add § 53.1345, which would govern the transfer of CPs under Framework A.

Section 53.1348 Termination of construction permits.

This proposed rule would add § 53.1348, which would require the holder of a permit under Framework A to provide written certification to the Commission within 30 days of determining to permanently cease construction.

Section 53.1360 Operating licenses.

This proposed rule would add § 53.1360, which would provide an overview of the requirements and procedures for applicants to apply for and the Commission to issue an OL under Framework A.

Section 53.1366 Contents of applications for operating licenses; general information.

This proposed rule would add § 53.1366, which would require an application for an OL under Framework A to include the information required by § 53.1109 as well as financial information.

Section 53.1369 Contents of applications for operating licenses; technical information.

This proposed rule would add § 53.1369, which would require an application for an OL under Framework A to include certain technical information in an FSAR at a level of detail sufficient for the Commission to reach a final conclusion on all safety matters.

Section 53.1372 Contents of applications for operating licenses; other application content.

This proposed rule would add § 53.1372, which would require an application for an OL under Framework A to include an environmental report and a description of availability controls.

Section 53.1375 Review of applications.

This proposed rule would add § 53.1375, which would establish the standards and procedures for reviewing applications and holding hearings on OLs under Framework A.

Section 53.1381 Referral to the Advisory Committee on Reactor Safeguards.

This proposed rule would add § 53.1381, which would require the ACRS to report on any portions of the application for a CP under Framework A concerning safety.

Section 53.1384 Exemptions, departures, and variances.

This proposed rule would add § 53.1384, which would govern requests for and the issuance of exemptions from the Commission's regulations and exemptions, departures, and variances from NRC approvals, permits, and certifications.

Section 53.1387 Issuance of operating licenses.

This proposed rule would add § 53.1387, which would establish the conditions under which the Commission may issue OLs and accompanying conditions and limitations, including TS, under Framework A.

Section 53.1390 Backfitting of operating licenses.

This proposed rule would add § 53.1390, which would prevent the Commission from modifying, adding, or deleting any terms or conditions of the OL, except in accordance with § 53.1590.

Section 53.1396 Duration of operating license.

This proposed rule would add § 53.1396, which would provide that an OL under Framework A may be valid for up to 40 years.

Section 53.1399 Transfer of an operating license.

This proposed rule would add § 53.1399, which would provide that an OL under Framework A may be transferred in accordance with § 53.1570.

Section 53.1402 Application for renewal.

This proposed rule would add § 53.1402, which would provide that an application for a renewed OL under Framework A must be filed in accordance with § 53.1595.

Section 53.1405 Continuation of an operating license.

This proposed rule would add § 53.1405, which would govern the continuing obligations of the holder of an OL under Framework A following the permanent cessation of operations.

Section 53.1410 Combined licenses.

This proposed rule would add § 53.1410, which would provide an overview of the requirements and procedures for applicants to apply for and the Commission to issue a COL under Framework A.

Section 53.1413 Contents of applications for combined licenses; general information.

This proposed rule would add § 53.1413, which would require an application for a COL under Framework A to include the information required by § 53.1109 as well as financial information.

Section 53.1416 Contents of applications for combined licenses; technical information.

This proposed rule would add § 53.1416, which would require applicants for a COL under Framework A to submit an FSAR with a level of technical information sufficient to reach a final conclusion on all safety matters.

Section 53.1419 Contents of applications for combined licenses; other application content.

This proposed rule would add § 53.1419, which would require applicants for a COL under Framework A to submit an environmental report, a description of availability

controls, the ITAAC that the licensee must perform. It would also include ITAAC requirements for applications that reference an ESP, standard DC, ML, or combination thereof.

Section 53.1422 Review of applications.

This proposed rule would add § 53.1422, which would require applications for COLs under Framework A to be reviewed for compliance with applicable standards and establish procedural requirements for reviewing applications and holding hearings in accordance with part 2.

Section 53.1425 Finality of referenced NRC approvals.

This proposed rule would add § 53.1425 which would address the finality of ESPs, standard DC rules, standard design approvals, or MLs referenced in the application for a COL under Framework A.

Section 53.1431 Referral to the Advisory Committee on Reactor Safeguards.

This proposed rule would add § 53.1431, which would require the ACRS to report on any portions of the application for a COL under Framework A concerning safety.

Section 53.1434 Authorization to conduct limited work authorization activities.

This proposed rule would add § 53.1434, which would address authorization to conduct LWA activities.

Section 53.1437 Exemptions, departures, and variances.

This proposed rule would add § 53.1437, which would govern the conditions in which the Commission may grant an exemption for one or more of its regulations, or an exemption, variance, or departure from a permit, design approval, or license.

Section 53.1440 Issuance of combined licenses.

This proposed rule would add § 53.1440, which would establish the conditions under which the Commission may issue COLs and accompanying conditions and limitations, including TS, under Framework A.

Section 53.1443 Finality of combined licenses.

This proposed rule would add § 53.1443, which would govern permissible modifications or amendments that the Commission may make to a COL, as well as permissible changes that a licensee may make to facilities and procedures as described in the FSAR.

Section 53.1449 Inspection during construction.

This proposed rule would add § 53.1449, which would establish requirements related to inspections, tests, and analyses for the holder of a COL under Framework A.

Section 53.1452 Operation under a combined license.

This proposed rule would add § 53.1452, which would establish requirements describing the notifications, hearings, and findings to be made prior to commencing facility operations.

Section 53.1455 Duration of a combined license.

This proposed rule would add § 53.1455, which would govern the duration of a COL under Framework A.

Section 53.1456 Transfer of a combined license.

This proposed rule would add § 53.1456, which would permit the transfer of a COL under Framework A in accordance with § 53.1570.

Section 53.1458 Application for renewal.

This proposed rule would add § 53.1458, which would provide that an application for renewal of a COL must be filed in accordance with § 53.1595.

Section 53.1461 Continuation of combined license.

This proposed rule would add § 53.1461, which would govern the continuing obligations of the holder of a COL under Framework A following the permanent cessation of operations.

Section 53.1470 Standardization of commercial nuclear plant designs: licenses to construct and operate nuclear power reactors of identical design at multiple sites.

This proposed rule would add § 53.1470, which would govern the requirements and procedures for filing and issuing applications for a CP, OL, or COL under Framework A in which the applicant seeks approval of the same design for multiple sites.

10 CFR part 53, subpart I—Maintaining and Revising Licensing Basis Information

This proposed rule would add subpart I, which would address the maintenance of licensing basis information for Framework A.

Section 53.1500 Licensing basis information.

This proposed rule would add § 53.1500, describing the purpose of subpart I, which would be to provide the requirements for the maintenance of licensing basis information for commercial nuclear plants licensed under Framework A.

Section 53.1502 Specific terms and conditions of licenses.

This proposed rule would add § 53.1502, which would outline the specific terms and conditions for obtaining a license under Framework A.

Section 53.1505 Changes to licensing basis information requiring prior NRC approval.

This proposed rule would add § 53.1505, which would provide an overview of the process for licensees to request, and the Commission to issue, amendments to licensing basis information under Framework A.

Section 53.1510 Application for amendment of license.

This proposed rule would add § 53.1510, which would require licensees under Framework A to file an application to request an amendment to the license. Applicants must assess how their requested changes would impact the safety criteria and analysis requirements in subparts B and C, whether the amendment involves no significant hazards consideration using the standards in § 53.1520, and consider potential impacts on environmental factors.

Section 53.1515 Public notices; State consultation.

This proposed rule would add § 53.1515, which would outline the Commission's procedures for issuing a *Federal Register* notice and consulting with the State in which the commercial nuclear facility is located in connection with its consideration of applications for an amendment to an OL or COL under Framework A.

Section 53.1520 Issuance of amendment.

This proposed rule would add § 53.1520, which would outline criteria for the Commission to consider in issuing license amendments under Framework A.

Section 53.1525 Revising certification information within a design certification rule.

This proposed rule would add § 53.1525, which would address the requirements for applicants to request, and the Commission to grant, an exemption to a DC rule under Framework A.

Section 53.1530 Revising design information within a manufacturing license.

This proposed rule would add § 53.1530, which would require the holder of an ML to request an amendment under § 53.1510 and, as applicable, § 53.1520 to make changes to the design of a manufactured reactor. It would also outline the requirements

for holders of a COL under Framework A to request amendments for changes to the design information of a manufactured reactor.

Section 53.1535 Amendments during construction.

This proposed rule would add § 53.1535, which would outline the process for licensees under Framework A to request amendments to CPs or LWAs during construction.

Section 53.1540 Updating licensing basis information and determining the need for NRC approval.

This proposed rule would add § 53.1540, which would provide an overview of the regulations in subpart I for holders of an OL or COL under Framework A to modify licensing basis information and definitions relevant to §§ 53.1545 through 53.1565.

Section 53.1545 Updating Final Safety Analysis Reports.

This proposed rule would add § 53.1545, which would require licensees under Framework A to regularly update FSARs in accordance with the requirements of this section to reflect changes to licensing basis information.

Section 53.1550 Evaluating changes to facility as described in Final Safety Analysis Reports.

This proposed rule would add § 53.1550, which would require licensees under Framework A to follow the guidelines outlined in this section in determining whether changes to licensing basis information described in the UFSAR require them to obtain a license amendment.

Section 53.1560 Updating program documents included in licensing basis information.

This proposed rule would add § 53.1560, which would require the holders of an OL or COL under Framework A to regularly update the program documents that they submitted in their application for a license.

Section 53.1565 Evaluating changes to programs included in licensing basis information.

This proposed rule would add § 53.1565, which would enable licensees under Framework A to make changes to the facility, procedures, or organization, or address changes to site environs as described in program documents without NRC approval if these changes satisfy the criteria outlined in this section.

Section 53.1570 Transfer of licenses.

This proposed rule would add § 53.1570, which would outline the requirements for an application for transfer of a license issued under Framework A.

Section 53.1575 Termination of license.

This proposed rule would add § 53.1575, which would outline the process for terminating an OL or COL issued under Framework A.

Section 53.1580 Information requests.

This proposed rule would add § 53.1580, which would address the process and circumstances under which the NRC may send information requests to the various types of licensees within Framework A.

Section 53.1585 Revocation, suspension, modification of licenses and approvals for cause.

This proposed rule would add § 53.1585, which would address grounds for the revocation, suspension, or modification of a license or standard design approval issued under Framework A.

Section 53.1590 Backfitting.

This proposed rule would add § 53.1590, which would define backfitting and establish requirements to be met by the NRC when it takes backfitting actions under Framework A.

Section 53.1595 Renewal.

This proposed rule would add § 53.1595, which would provide for the renewal of a license under Framework A upon expiration.

10 CFR part 53, subpart J—Reporting and Other Administrative Requirements

This proposed rule would add subpart J, to establish various reporting and other administrative requirements for licensees under Framework A.

Section 53.1600 General information.

This proposed rule would add § 53.1600, which provides an overview of the sections that would require applicants and licensees under Framework A to provide NRC inspectors with unfettered access to sites and facilities, maintain records and make reports, demonstrate compliance with financial qualification and reporting requirements, and maintain required financial protection for accidents.

Section 53.1610 Unfettered access for inspections.

This proposed rule would add § 53.1610, which would require applicants and licensees under Framework A to provide unfettered access to NRC inspectors, including

~~access to records, premises, activities, and licensed materials, in addition to providing office space to accommodate temporary or resident inspectors.~~

~~Section 53.1620 Maintenance of records, making of reports.~~

~~This proposed rule would add § 53.1620, which would require part 53 licensees to maintain all records and make reports as required by the conditions of the license or by the regulations in Framework A.~~

~~Section 53.1630 Immediate notification requirements for operating commercial nuclear plants.~~

~~This proposed rule would add § 53.1630, which would impose immediate notification requirements on part 53 licensees following the declaration of an Emergency Class or the discovery of certain non-emergency events.~~

~~Section 53.1640 Licensee event report system.~~

~~This proposed rule would add § 53.1640, which would require any commercial plant licensee holding an OL under Framework A to submit a Licensee Event Report in accordance with the specifications outlined in this section.~~

~~Section 53.1645 Reports of radiation exposure to members of the public.~~

~~The proposed rule would add § 53.1645, which would require reports to the Commission of the quantity of radionuclides released to unrestricted areas in liquid and gaseous effluents at least annually.~~

~~Section 53.1650 Facility information and verification.~~

~~The proposed rule would add § 53.1650, which would include a reporting requirement for applicants and holders of a CP or license under Framework A to support safeguards agreements between the United States and the IAEA.~~

Section 53.1660 Financial requirements.

This proposed rule would add § 53.1660, which would introduce requirements and procedures related to financial qualifications and reporting requirements for applicants, licensees, and CP holders under Framework A.

Section 53.1670 Financial qualifications.

This proposed rule would add § 53.1670, which would require an applicant for a CP, OL, or COL under Framework A to must demonstrate possession or ability to obtain funds necessary for the activities for which the permit or license is sought.

Section 53.1680 Annual financial reports.

This proposed rule would add § 53.1680, which would require licensees and holders of a CP under Framework A to submit annual financial reports to the Commission, with exceptions for those that submit financial forms to the Securities and Exchange Commission or the Federal Energy Regulatory Commission.

Section 53.1690 Licensee's change of status; financial qualifications.

This proposed rule would add § 53.1690, which would require electric utility licensees that hold an OL or COL for a commercial nuclear plant under Framework A to provide the NRC with the financial qualifications information outlined in this section within seventy-five days of ceasing to be an electric utility.

Section 53.1700 Creditor regulations.

This proposed rule would add § 53.1700, which would establish regulations with respect to the creditors of any facility under Framework A.

Section 53.1710 Financial protection.

This proposed rule would add § 53.1710, which would establish requirements for licenses under Framework A to obtain and maintain insurance to cover the costs of an accident.

Section 53.1720 Insurance required to stabilize and decontaminate plant following an accident.

This proposed rule would add § 53.1720, which would require commercial nuclear plant licensees under Framework A to obtain insurance sufficient to cover the costs of stabilizing and decontaminating the plant in the event of an accident.

Section 53.1730 Financial protection requirements.

This proposed rule would add § 53.1730, which would require commercial nuclear plant licensees under Framework A to satisfy the provisions of part 140.

10 CFR part 53, subpart K—Quality Assurance Criteria for Commercial Nuclear Plants.

This proposed rule would add subpart K, which would establish quality assurance requirements applicable to the design, manufacture, construction, and operation of SR SSCs under Framework A.

Section 53.1800 General provisions.

This proposed rule would add § 53.1800, which would establish quality assurance requirements for the design, manufacture, construction, and operation of SR SSCs under Framework A and all activities affecting their SR functions. It would also define "quality assurance" for the purposes of subpart K.

Section 53.1805 Organization.

This proposed rule would add § 53.1805, which would establish requirements for establishing and executing a quality assurance program under Framework A.

Section 53.1810 Quality assurance program.

This proposed rule would add § 53.1810, which would detail requirements for an applicant's quality assurance programs under Framework A, including requirements for

~~documentation, scope, review, indoctrination and training, and management of the program.~~

~~Section 53.1815 Design control.~~

~~This proposed rule would add § 53.1815, which would detail required design control measures for applicants under Framework A.~~

~~Section 53.1820 Procurement document control.~~

~~This proposed rule would add § 53.1820, which would establish requirements under Framework A for procurement document control related to quality assurance.~~

~~Section 53.1825 Instructions, procedures, and drawings.~~

~~This proposed rule would add § 53.1825, which would establish requirements under Framework A for documenting activities affecting quality.~~

~~Section 53.1830 Document control.~~

~~This proposed rule would add § 53.1830, which would require that applicants under Framework A establish measures to control the issuance of documents that govern activities affecting quality.~~

~~Section 53.1835 Control of purchased material, equipment, and services~~~~.~~

~~This proposed rule would add § 53.1835, which would establish requirements under Framework A for assuring that purchased material, equipment, and services conform to procurement documents.~~

~~Section 53.1840 Identification and control of materials, parts, and components~~~~.~~

~~This proposed rule would add § 53.1840, which would establish requirements under Framework A for measures to identify and control materials, parts, and components including partially fabricated assemblies.~~

Section 53.1845 Control of special processes.

This proposed rule would add § 53.1845, which would address requirements under Framework A for special processes, such as welding, heat treating, and nondestructive testing.

Section 53.1850 Inspection.

This proposed rule would add § 53.1850, which would establish requirements for inspection of activities affecting quality under Framework A.

Section 53.1855 Test control.

This proposed rule would add § 53.1855, which would establish requirements under Framework A for a test program for demonstrating SSCs will perform satisfactorily in service.

Section 53.1860 Control of measuring and test equipment.

This proposed rule would add § 53.1860, which would require that measures are established to assure that measuring or testing devices under Framework A are properly controlled, calibrated, and adjusted to maintain accuracy within necessary limits.

Section 53.1865 Handling, storage, and shipping.

This proposed rule would add § 53.1865, which would establish requirements under Framework A for handling, storage, shipping, cleaning, and preservation of materials and equipment.

Section 53.1870 Inspections, test, and operating status.

This proposed rule would add § 53.1870, which would establish requirements under Framework A for indicating inspection and test status of individual items and for including operating status of SSCs of a commercial nuclear power plant.

Section 53.1875 Nonconforming materials, parts, or components.

This proposed rule would add § 53.1875, which would establish requirements under Framework A for measures to control materials, parts, or components, which do not conform to requirements.

Section 53.1880 Corrective action.

This proposed rule would add § 53.1880, which would establish requirements for corrective action of conditions adverse to quality under Framework A.

Section 53.1885 Quality assurance records.

This proposed rule would add § 53.1885, which would establish requirements for records of activities affecting quality under Framework A.

Section 53.1890 Audits.

This proposed rule would add § 53.1890, which would establish requirements for auditing of the quality assurance program under Framework A.

10 CFR part 53, subpart N—Siting Requirements.

The proposed rule would add subpart N, which would address requirements associated with the siting of commercial nuclear facilities under Framework B, including considerations of external hazards and potential adverse impacts on the surrounding population.

Section 53.3505 Scope.

This proposed rule would add § 53.3505, which would apply the siting requirements of this subpart to applicants seeking a permit or license under Framework B.

Section 53.3510 Definitions.

This proposed rule would add § 53.3510, which would define terms relevant to this subpart.

Section 53.3515 Factors to be considered when evaluating sites.

This proposed rule would add § 53.3515, which would require the Commission to consider certain factors, including population density, the nature and proximity of constructed hazards, and the physical characteristics of the site, when determining the suitability of a site for a commercial nuclear plant licensed under Framework B.

Section 53.3520 Non-seismic siting criteria.

This proposed rule would add § 53.3520, which would require applicants to demonstrate that the proposed site fulfills certain siting criteria.

Section 53.3525 Geologic and seismic siting criteria.

This proposed rule would add § 53.3525, which would establish geologic and seismic siting criteria for the Commission to evaluate in considering whether the proposed site and the design bases present undue risk to the public health and safety.

10 CFR part 53, subpart O—Construction and Manufacturing Requirements

The proposed rule would add subpart O, which would establish requirements for the construction and manufacturing of an advanced nuclear plant under Framework B.

Section 53.4100 Construction and manufacturing – scope and purpose.

The proposed rule would add § 53.4100, which would describe the applicability of subpart O.

Section 53.4105 Reporting of defects and noncompliance.

The proposed rule would add § 53.4105, which would stipulate that each CP, ML, and COL under Framework B is subject to procedures, notification requirements, record retention requirements under this section with respect to reporting of defects and noncompliance and further describes the requirements and procedures for reporting defects.

Section 53.4110 Construction.

The proposed rule would add § 53.4110 to address the management and control of the construction of a commercial nuclear plant under Framework B through the development and implementation of certain plans, programs, and organizational units.

Section 53.4120 Manufacturing.

This proposed rule would add § 53.4120, which would require holders of an ML to ensure that compliance with the requirements of an ML issued under Framework B is fulfilled through the development of plans, programs, and organizational units to manage and control manufacturing activities.

10 CFR part 53, subpart P—Requirements for Operation

This proposed rule would add subpart P, which would require licensees under Framework B to develop and implement certain programs to maintain the safety and reliability of commercial nuclear plant functions.

Section 53.4200 Operational objectives.

This proposed rule would add § 53.4200, which would require each holder of an OL or COL under Framework B to ensure that the proper controls are in place to ensure that SSCs, as well as plant personnel, have the capability to maintain plant safety during normal operations and DBEs.

Section 53.4210 Maintenance, repair, and inspection programs.

This proposed rule would add § 53.4210, which would establish performance monitoring and maintenance requirements to ensure that SSCs under Framework B operate as intended, in accordance with licensee-established performance goals that account for safety and industry-wide operating experience.

Section 53.4213 Technical specifications.

This proposed rule would add § 53.4213, which would require the holders of an OL or COL under Framework B to establish TS including, but not limited to: (1) safety limits, limiting safety system settings, and limiting control settings, (2) LCO, (3) surveillance requirements, (4) design features, (5) administrative controls, (6) decommissioning, (7) initial notification, and (8) written reports.

Section 53.4215 Response to seismic events.

This proposed rule would add § 53.4215, which would require a licensee to shut down the commercial nuclear plant if a vibratory ground motion exceeds the OBE Ground Motion or causes significant plant damage until the licensee can demonstrate that no functional damage has occurred or the damage has since been repaired.

Section 53.4220 General staffing, training, personnel qualifications, and human factors requirements.

This proposed rule would add § 53.4220, which would apply the rules of §§ 53.725 through 53.830 to Framework B.

Section 53.4300 Programs.

This proposed rule would add § 53.4300, which would require licensees under Framework B to implement the programs described in the remaining sections of subpart P to maintain plant safety during normal operations and DBEs.

Section 53.4310 Radiation protection.

This proposed rule would add § 53.4310, which would require licensees under Framework B to implement a Radiation Protection Program to control radioactive effluents and keep public exposure as low as is reasonably achievable.

Section 53.4320 Emergency preparedness.

This proposed rule would add § 53.4320, which would apply the proposed rules in § 53.855 to Framework B.

Section 53.4330 Security programs.

This proposed rule would add § 53.4330, which would require licensees under Framework B to develop, implement, and maintain programs for physical security, FFD, AA, cyber security, and information security.

Section 53.4340 Quality assurance.

This proposed rule would add § 53.4340, which would require licensees under Framework B to develop, implement, and maintain a quality assurance program, including a written quality assurance program manual, in accordance with subpart U.

Section 53.4350 Fire protection.

This proposed rule would add § 53.4350, which would require licensees under Framework B to develop and implement a fire protection program.

Section 53.4360 Inservice inspection and inservice testing.

This proposed rule would add § 53.4360, which would require licensees under Framework B to demonstrate compliance with the ISI and IST specifications under § 50.55a for boiling or pressurized water-cooled commercial nuclear plants and § 53.880 for non-light-water-cooled commercial nuclear plants.

Section 53.4380 Environmental qualification of electric equipment important to safety for commercial nuclear plants.

This proposed rule would add § 53.4380, which would require licensees under Framework B to maintain a program for qualifying electric equipment important to safety.

Section 53.4390 Procedures and guidelines.

This proposed rule would add § 53.4390, which would require licensees under Framework B to develop, implement, and maintain a set of procedures, guidelines, and supporting activities to support normal operations and response to unplanned events.

Section 53.4400 Integrity assessment program.

This proposed rule would add § 53.4400, which would require licensees under Framework B to establish an integrity assessment program to ensure that certain SSCs continue to operate as intended.

Section 53.4410 Primary containment leakage rate testing program.

This proposed rule would add § 53.4410, which would apply the requirements of appendix J to part 50 to primary reactor containments for water-cooled commercial nuclear plants.

Section 53.4420 Mitigation of beyond-design-basis events.

This proposed rule would add § 53.4420, which would require certain licensees under Framework B to develop, implement, and maintain mitigation strategies for beyond-design basis external events and extensive damage mitigation guidelines in accordance with the requirements of this section.

10 CFR part 53, subpart Q—Decommissioning

This proposed rule would add subpart Q, to establish decommissioning requirements for applicants for or holders of an OL or COL under Framework B.

Section 53.4600 Scope and purpose.

This proposed rule would add § 53.4600, which would establish the scope of the decommissioning requirements for applicants and licensees under Framework B of part 53 and describe the contents of subpart Q of part 53.

~~Section 53.4610 Financial assurance for decommissioning.~~

~~This proposed rule would add § 53.4610, which would establish the need for financial assurance for decommissioning and require that applicants for an OL or COL under Framework B prepare a plan and an associated decommissioning report that reasonably assures and documents that adequate funding for decommissioning will be available.~~

~~Section 53.4620 Cost estimates for decommissioning.~~

~~This proposed rule would add § 53.4620, which would require site-specific cost estimates for decommissioning and establish the aspects that must be included in the estimate.~~

~~Section 53.4630 Annual adjustments to cost estimates for decommissioning.~~

~~This proposed rule would add § 53.4630, which would require that holders of an OL or COL under Framework B annually adjust their cost estimate for decommissioning to account for escalation in labor, energy, and waste burial costs. This section would allow licensees to elect either a site-specific adjustment factor or a generic adjustment factor.~~

~~Section 53.4640 Methods for providing financial assurance for decommissioning.~~

~~This proposed rule would add § 53.4640, which would establish suitable methods that holders of an OL or COL under Framework B may use to provide financial assurance for decommissioning to the NRC.~~

~~Section 53.4645 Limitations on the use of decommissioning trust funds.~~

~~This proposed rule would add § 53.4645, which would establish requirements for decommissioning trust funds under Framework B, including criteria for using decommissioning trust funds and required terms.~~

Section 53.4650 NRC oversight.

This proposed rule would add § 53.4650, which would outline the steps the NRC may take to ensure adequate accumulation of decommissioning funds.

Section 53.4660 Reporting and recordkeeping requirements.

This proposed rule would add § 53.4660, which would contain reporting and recordkeeping requirements related to decommissioning for each holder of an OL or COL under Framework B. This section would outline requirements for documents such as: certification of decommissioning funding, decommissioning cost estimates and copies of financial instruments, licensee records of information important to safe and effective decommissioning, PSDARs, financial assurance reports, and reports on the status of funding for managing irradiated fuel.

Section 53.4670 Termination of license.

This proposed rule would add § 53.4670, which would establish procedures for decommissioning and license termination applicable to licensees under Framework B that have determined to permanently cease operations.

Section 53.4675 Program requirements during decommissioning.

This proposed rule would add § 53.4675, which would require licensees under Framework B to establish and maintain a decommissioning fire protection program to prevent, detect, and control fires, and ensure that the risk of fire-induced radiological hazards are minimized through the various stages of facility decommissioning.

Section 53.4680 Release of part of a commercial nuclear plant or site for unrestricted use.

This proposed rule would add § 53.4680, which would establish licensee procedures for requesting and NRC procedures for approving partial release of a

commercial nuclear plant or site for unrestricted use prior to receiving approval of a license termination plan from the Commission under Framework B.

10 CFR part 53, subpart R—Licenses, Certifications, and Approvals

This proposed rule would add subpart R, which would govern the process of applying for, amending, renewing, or terminating a LWA, ESP, standard design approval, standard DC, ML, CP, OL, or COL under Framework B.

Section 53.4700 Filling of application for licenses, certifications, or approvals; oath or affirmation.

This proposed rule would add § 53.4700, which would establish requirements for applicants seeking a standard design approval, standard DC, license, or permit under Framework B to submit an application.

Section 53.4701 Requirement for license.

This proposed rule would add § 53.4701, which would prohibit any use of a utilization facility except as authorized by a license issued by the NRC.

Section 53.4703 Combining applications and licenses.

This proposed rule would add § 53.4703, which would permit applicants under Framework B seeking multiple licenses to submit a single application and the Commission to issue a single license for activities that would otherwise be licensed separately.

Section 53.4706 Elimination of repetition.

This proposed rule would add § 53.4706, which would allow applicants under Framework B to reference information contained in previous documents filed with the Commission so long as those references are clear and specific.

Section 53.4709 Contents of applications; general information.

This proposed rule would add § 53.4709, which would establish the general content to be included in applications under Framework B, including but not limited to the identifying information of the applicant and the radiological emergency response plans of government entities within the plume exposure pathway emergency planning zone.

Section 53.4712 Environmental conditions.

This proposed rule would add § 53.4712, which would allow the Commission to attach conditions to CPs, ESPs, and licenses issued under Framework B to address environmental issues during construction, operation, or decommissioning. These conditions may be derived from the information contained in the environmental report submitted as part of the application for a permit or license.

Section 53.4715 Agreement limiting access to classified information.

This proposed rule would add § 53.4715, which would require applicants to agree in writing, prior to receiving a license or standard design approval under Framework B, to restrict individuals with access to plant facilities from possessing Restricted Data or classified National Security Information until they have received the appropriate authorization.

Section 53.4718 Ineligibility of certain applicants.

This proposed rule would add § 53.4718, which would prevent citizens, nationals, or agents of a foreign country, or corporations owned, controlled, or dominated by a foreign entity from applying for or obtaining a license under Framework B.

Section 53.4720 Exceptions and exemptions from licensing requirements.

This proposed rule would add § 53.4720, which would establish the activities that are exempt from licensing requirements.

Section 53.4721 Public inspection of applications.

~~This proposed rule would add § 53.4721, which would allow applicant submissions to be made publicly available in accordance with part 2.~~

~~Section 53.4724 Relationship between sections.~~

~~This proposed rule would add § 53.4724, which would outline the relationship between LWAs, ESPs, standard design approvals, standard DCs, MLs, CPs, OLs, and COLs under Framework B.~~

~~Section 53.4730 General technical requirements.~~

~~This proposed rule would add § 53.4730, which would contain the primary safety requirements for Framework B licensees and outline the general technical information to be included in the Safety Analysis Report in an application for a CP, OL, ESP, COL, standard design approval, standard DC, or ML.~~

~~Section 53.4731 Risk-informed classification of structures, systems, and components.~~

~~This proposed rule would add § 53.4731, which would define four levels of Risk-Informed Safety Class SSCs and describe alternative requirements for the SSCs of a commercial nuclear plant.~~

~~Section 53.4733 Seismic design alternatives.~~

~~This proposed rule would add § 53.4733, which would define relevant terms and outline an alternative set of seismic design requirements that can be met in place of the requirements in appendix S to part 50.~~

~~Section 53.4740 Limited work authorizations.~~

~~This proposed rule would add § 53.4740, which would establish requirements for requesting an LWA and grounds for the Commission to issue an LWA. It would also contain details about the effect of an LWA and the implementation of a redress plan.~~

~~Section 53.4750 Early site permits.~~

~~This proposed rule would add § 53.4750, which would provide an overview of the requirements regarding applications for and the issuance of ESPs under Framework B.~~

~~Section 53.4753 Filing of applications.~~

~~This proposed rule would add § 53.4753, which would enable an applicant under Framework B to apply for an ESP, regardless of whether they have filed an application for a CP or COL for that site.~~

~~Section 53.4754 Contents of applications for early site permits; general information.~~

~~This proposed rule would add § 53.4754, which would require applications for ESPs to include the information required by § 53.4709(a) through (d) and (j).~~

~~Section 53.4756 Contents of applications for early site permits; technical information.~~

~~This proposed rule would add § 53.4756, which would require applicants for ESPs to submit technical information, including but not limited to a Site Safety Analysis Report and emergency plans.~~

~~Section 53.4759 Review of applications.~~

~~This proposed rule would add § 53.4759, which would establish standards for review of applications for ESPs under Framework B, including requirements for the Commission to prepare an environmental impact statement and assess the adequacy of protective actions in the event of a radiological emergency. It would also require the administrative review of applications and hearings to follow the procedural requirements of part 2.~~

~~Section 53.4765 Referral to the Advisory Committee on Reactor Safeguards.~~

~~This proposed rule would add § 53.4765, which would require the ACRS to review SR content in the application for an ESP under Framework B.~~

Section 53.4768 Issuance of early site permit.

This proposed rule would add § 53.4768, which would establish the conditions under which the Commission may issue an ESP under Framework B, as well as the information, terms, and conditions to be included in the permit.

Section 53.4771 Extent of activities permitted.

This proposed rule would add § 53.4771, which would require that a valid ESP only be used for the purpose of site redress, unless the site is referenced in an application for a CP or COL under Framework B.

Section 53.4774 Duration of permit.

This proposed rule would add § 53.4774, which would govern the conditions under which an ESP remains valid following the date of issuance under Framework B.

Section 53.4777 Limited work authorization after issuance of early site permit.

This proposed rule would add § 53.4777, which would permit the holder of an ESP under Framework B to request an LWA under § 53.4756(c).

Section 53.4780 Transfer of early site permit.

This proposed rule would add § 53.4780, which would govern the transfer of an ESP that was issued under Framework B in accordance with § 53.6070.

Section 53.4783 Application for renewal.

This proposed rule would add § 53.4783, which would establish the conditions and procedures for renewing an ESP under Framework B.

Section 53.4786 Criteria for renewal.

This proposed rule would add § 53.4786, which would establish the criteria that the Commission may use to grant a renewal of an ESP under Framework B.

Section 53.4789 Duration of renewal.

~~This proposed rule would add § 53.4789, which would govern the duration of a renewed ESP under Framework B.~~

~~Section 53.4792 Use of site for other purposes.~~

~~This proposed rule would add § 53.4792, which would govern acceptable uses of the site for purposes other than those described in the permit issued under Framework B.~~

~~Section 53.4798 Finality of early site permit determinations.~~

~~This proposed rule would add § 53.4798, which would address the finality of ESP determinations under Framework B.~~

~~Section 53.4800 Standard design approvals.~~

~~This proposed rule would add § 53.4800, which would provide an overview of the procedures for filing an application for a standard design approval under Framework B, review by NRC staff, and referral to the ACRS of standard designs.~~

~~Section 53.4803 Filing of applications.~~

~~This proposed rule would add § 53.4803, which would enable applicants to submit a final design for the entire facility, or major portions, to the NRC staff for review.~~

~~Section 53.4806 Contents of applications for standard design approvals; general information~~

~~This proposed rule would add § 53.4806, which would require applications for a standard design approval under Framework B to contain the information required by § 53.4709(a) through (c) and (j).~~

~~Section 53.4809 Contents of applications for standard design approvals; technical information.~~

~~This proposed rule would add § 53.4809, which would require the inclusion of certain technical information, including an FSAR, site parameters, and design~~

information, when an applicant seeks review of a standard design under Framework B. The requirements may be scaled back when the applicant seeks approval of a major portion of a standard design.

Section 53.4812 Review of applications.

This proposed rule would add § 53.4812, which would require applications for standard design approval under Framework B to be reviewed for compliance with the standards in parts 20, 53, and 73.

Section 53.4815 Referral to the Advisory Committee on Reactor Safeguards.

This proposed rule would add § 53.4815, which would require the ACRS to report on any portions of the application for a standard design approval under Framework B concerning safety.

Section 53.4818 Staff approval of design.

This proposed rule would add § 53.4818, which would require the NRC to make a determination on the acceptability of the design, publish its decision in the *Federal Register*, and issue a report analyzing the design that is available at http://nrc.gov Additionally, the rule would establish the conditions under which a design approval under Framework B remains valid.

Section 53.4821 Finality of standard design approvals; information requests.

This proposed rule would add § 53.4821, which would require NRC staff and the ACRS to rely upon an approved design in their review of any standard DC or individual facility license application under Framework B that references the standard design approval. The proposed rule would also govern requirements for issuing information requests.

Section 53.4830 Standard design certifications.

This proposed rule would add § 53.4830, which would provide an overview of the requirements and procedures that govern the issuance of standard DCs under Framework B.

Section 53.4833 Filing of applications.

This proposed rule would add § 53.4833, which would enable an application for DC to be filed, regardless of whether an application for a CP, COL, or ML has been filed, provided it complies with the filing requirements in § 53.040 and §§ 2.811 through 2.819.

Section 53.4836 Contents of applications for standard design certifications; general information.

This proposed rule would add § 53.4836, which would require an application for a standard DC under Framework B to contain all of the information required by § 53.4709(a) through (c) and (j).

Section 53.4839 Contents of applications for standard design certifications; technical information.

This proposed rule would add § 53.4839, which would require applicants for a standard DC under Framework B to submit a FSAR that includes technical design information at a level of detail sufficient to enable the Commission to make a safety determination.

Section 53.4841 Contents of applications for standard design certifications; other application content.

This proposed rule would add § 53.4841, which would require applications for standard DCs under Framework B to include an environmental report, proposed ITAAC, and a description of the program to protect Safeguards Information against unauthorized disclosure. It would also require applications for certification of a modular nuclear power reactor design to describe and analyze the possible operating configurations of the

reactor units with common systems, interface requirements, and system interactions and to account for differences among the configurations.

Section 53.4842 Review of applications.

This proposed rule would add § 53.4842, which would require applications for standard DCs to be reviewed for compliance with the standards in parts 20, 51, 53, and 73. It would also establish procedural requirements for reviewing applications and holding hearings in accordance with subpart H of part 2.

Section 53.4845 Referral to the Advisory Committee on Reactor Safeguards.

This proposed rule would add § 53.4845, which would require the ACRS to report on any portions of the application for a standard design approval under Framework B concerning safety.

Section 53.4848 Issuance of standard design certification.

This proposed rule would add § 53.4848, which would establish the conditions under which the Commission may issue a DC rule under Framework B that specifies the site parameters, design characteristics, and any additional terms and conditions of the DC rule.

Section 53.4851 Duration of certification.

This proposed rule would add § 53.4851, which would set the conditions under which a standard DC under Framework B remains valid.

Section 53.4854 Application for renewal.

This proposed rule would add § 53.4854, which would establish the conditions and procedures for an application to renew a standard DC under Framework B.

Section 53.4857 Criteria for renewal.

This proposed rule would add § 53.4857, which would enable the Commission to issue a rule granting the renewal of a standard DC under Framework B, impose additional requirements, and grant amendment requests.

Section 53.4860 Duration of renewal.

This proposed rule would add § 53.4860, which would provide that a renewal of a standard DC under Framework B is valid for not less than 10 years, nor more than 15 years.

Section 53.4863 Finality of standard design certifications.

This proposed rule would add § 53.4863, which would establish conditions under which the Commission may initiate a rulemaking to modify, rescind, or impose new requirements on a standard DC rule under Framework B. It would also address requests for an exemption from elements of the certification information, and require that applicants for a CP, OL, COL, or ML that references a DC rule make information available for audit.

Section 53.4870 Manufacturing licenses.

This proposed rule would add § 53.4870, which would provide an overview of the requirements and procedures for applying for and issuing an ML under Framework B.

Section 53.4873 Filing of applications.

This proposed rule would add § 53.4873, which would establish the requirements to apply for an ML under Framework B.

Section 53.4876 Contents of applications for manufacturing licenses; general information.

This proposed rule would add § 53.4876, which would require applicants for an ML under Framework B to include the information contained in § 53.4709(a) through (e) and (j).

Section 53.4879 Contents of applications for manufacturing licenses; technical information.

This proposed rule would add § 53.4879, which would require an applicant for an ML under Framework B to include certain technical information in a FSAR, including but not limited to information about the PDCs and design bases of the manufactured reactor and a description of the SSCs of the reactor to be manufactured.

Section 53.4882 Contents of applications for manufacturing licenses; other application content.

This proposed rule would add § 53.4882, which would require applicants for an ML under Framework B to include in their application ITAAC, an environmental report, a description of actions taken to protect Safeguards Information against unauthorized disclosure, and a description of how design features fulfill design criteria. It would also include content requirements for the ITAAC and environmental reports in applications that reference a standard DC.

Section 53.4885 Review of applications.

This proposed rule would add § 53.4885, which would require applications for MLs under Framework B to be reviewed for compliance with applicable standards and establish procedural requirements for reviewing applicants and holding hearings in accordance with part 2.

Section 53.4886 Referral to the Advisory Committee on Reactor Safeguards.

This proposed rule would add § 53.4886, which would require the ACRS to report on any portions of the application for an ML under Framework B concerning safety.

Section 53.4887 Issuance of manufacturing license.

This proposed rule would add § 53.4887, which would establish the conditions under which the Commission may issue an ML under Framework B.

Section 53.4888 Finality of manufacturing licenses.

This proposed rule would add § 53.4888, which would address the circumstances in which the Commission may modify, rescind, or impose new requirements following the issuance of an ML under Framework B. It would also address requests for a departure from the specifications of the license.

Section 53.4891 Duration of manufacturing licenses.

This proposed rule would add § 53.4891, which would govern the expiration of an ML under Framework B.

Section 53.4893 Transfer of manufacturing licenses.

This proposed rule would add § 53.4893, which would provide that an ML under Framework B may be transferred in accordance with § 53.6070.

Section 53.4895 Renewal of manufacturing licenses.

This proposed rule would add § 53.4895, which would establish the procedures for applicants to apply for and the Commission to grant a renewal of an ML under Framework B.

Section 53.4900 Construction permits.

This proposed rule would add § 53.4900, which would provide an overview of the requirements and procedures for applicants to apply for and the Commission to grant a CP under Framework B.

Section 53.4906 Contents of applications for construction permits; general information.

This proposed rule would add § 53.4906, which would require applicants for a CP under Framework B to submit the general information required by § 53.4709, as well as financial information.

Section 53.4909 Contents of applications for construction permits; technical information.

This proposed rule would add § 53.4909, which would require applicants for a CP under Framework B to submit a PSAR.

Section 53.4912 Contents of applications for construction permits; other application content.

This proposed rule would add § 53.4912, which would require applicants for a CP under Framework B to submit an environmental report and to provide additional details in the PSAR if the application references an ESP, standard design approval, or standard DC.

Section 53.4915 Review of applications.

This proposed rule would add § 53.4915, which would require applications for CPs under Framework B to be reviewed for compliance with applicable standards and establish procedural requirements for reviewing applications and holding hearings in accordance with part 2.

Section 53.4918 Finality of referenced NRC approvals, permits, and certifications.

This proposed rule would add § 53.4918, which would address the finality of ESPs, standard design approvals, and standard DCs referenced in the CP application.

Section 53.4924 Referral to the Advisory Committee on Reactor Safeguards.

This proposed rule would add § 53.4924, which would require the ACRS to report on any portions of the application for a CP under Framework B concerning safety.

Section 53.4927 Authorization to conduct limited work authorization activities.

This proposed rule would add § 53.4927, which would govern authorization to conduct LWA activities.

Section 53.4930 Exemptions, departures, and variances.

~~This proposed rule would add § 53.4930, which would govern requests for and the issuance of exemptions from the Commission's regulations, and exemptions, departures, and variances from NRC approvals, permits, and certifications.~~

~~Section 53.4933 Issuance of construction permits.~~

~~This proposed rule would add § 53.4933, which would establish the conditions under which the Commission may issue CPs and accompanying terms and conditions under Framework B.~~

~~Section 53.4936 Finality of construction permits.~~

~~This proposed rule would add § 53.4936, which would address the finality of CPs under Framework B.~~

~~Section 53.4942 Duration of construction permit.~~

~~This proposed rule would add § 53.4942, which would establish requirements for the expiration of a CP under Framework B.~~

~~Section 53.4945 Transfer of construction permits.~~

~~This proposed rule would add § 53.4945, which would govern the transfer of CPs under Framework B in accordance with § 53.6070.~~

~~Section 53.4948 Termination of construction permits.~~

~~This proposed rule would add § 53.4948, which would require the holder of a permit under Framework B to provide written certification to the Commission within 30 days of permanently ceasing construction.~~

~~Section 53.4960 Operating licenses.~~

~~This proposed rule would add § 53.4960, which would provide an overview of the requirements and procedures for applicants to apply for and the Commission to issue an OL under Framework B.~~

Section 53.4966 Contents of applications for operating licenses; general information.

This proposed rule would add § 53.4966, which would require an application for an OL under Framework B to include the information required by § 53.4709 as well as financial information.

Section 53.4969 Contents of applications for operating licenses; technical information.

This proposed rule would add § 53.4969, which would require an application for an OL under Framework B to include certain technical information in a FSAR describing the facility, design bases, and limits on the facility's operations, and providing a safety analysis of the SSCs and facility.

Section 53.4972 Contents of applications for operating licenses; other application content.

This proposed rule would add § 53.4972, which would require an application for an OL under Framework B to include an environmental report. Applicants for an OL under Framework B that do not demonstrate compliance with the criteria of § 53.4730(a)(34)(ii)(A) and (B) must submit a plan for achieving compliance with § 53.4420 to mitigate beyond-design-basis events.

Section 53.4975 Review of applications.

This proposed rule would add § 53.4975, which would establish the standards and procedures for reviewing applications and holding hearings on OLs under Framework B.

Section 53.4981 Referral to the Advisory Committee on Reactor Safeguards.

This proposed rule would add § 53.4981, which would require the ACRS to report on any portions of the application for a CP under Framework B concerning safety.

Section 53.4984 Exemptions, departures, and variances.

This proposed rule would add § 53.4984, which would govern requests for and the issuance of exemptions from the Commission's regulations, and exemptions, departures, and variances from NRC approvals, permits, and certifications.

Section 53.4987 Issuance of operating licenses.

This proposed rule would add § 53.4987, which would establish the conditions under which the Commission may issue OLs and accompanying conditions and limitations, including TS, under Framework B.

Section 53.4990 Backfitting of operating licenses.

This proposed rule would add § 53.4990, which would prevent the Commission from modifying, adding, or deleting any terms or conditions of the OL issued under Framework B, except in accordance with § 53.6090.

Section 53.4996 Duration of operating license.

This proposed rule would add § 53.4996, which would provide that an OL under Framework B may be valid for up to 40 years.

Section 53.4999 Transfer of an operating license.

This proposed rule would add § 53.4999, which would provide that an OL under Framework B may be transferred in accordance with § 53.6070.

Section 53.5002 Application for renewal.

This proposed rule would add § 53.5002, which would provide that an application for a renewed OL under Framework B must be filed in accordance with § 53.6095.

Section 53.5005 Continuation of an operating license.

This proposed rule would add § 53.5005, which would govern the continuing obligations of the holder of an OL under Framework B following the permanent cessation of operations.

Section 53.5010 Combined licenses.

This proposed rule would add § 53.5010, which would provide an overview of the requirements and procedures for applicants to apply for and the Commission to issue a COL under Framework B.

Section 53.5013 Contents of applications for combined licenses; general information.

This proposed rule would add § 53.5013, which would require an application for a COL under Framework B to include the information required by § 53.4709 as well as financial information.

Section 53.5016 Contents of applications for combined licenses; technical information.

This proposed rule would add § 53.5016, which would require applicants for a COL under Framework B to submit a FSAR describing the facility, design basis, limits on facility operation, and a safety analysis of the SSCs and facility.

Section 53.5019 Contents of applications for combined licenses; other application content.

This proposed rule would add § 53.5019, which would require applicants for a COL under Framework B to submit an environmental report, a description of the ITAAC that the licensee must perform, and, for Framework B application that do not demonstrate compliance with the criteria in § 53.4730(a)(34)(ii)(A) and (B), a plan for mitigation of beyond-design-basis events in accordance with § 53.4420. It would also include ITAAC requirements for applications that reference an ESP with ITAAC, standard DC, ML, or combination thereof.

Section 53.5022 Review of applications.

This proposed rule would add § 53.5022, which would require applications for COLs under Framework B to be reviewed for compliance with applicable standards and establish procedural requirements for reviewing applicants and holding hearings in accordance with part 2.

Section 53.5025 Finality of referenced NRC approvals.

This proposed rule would add § 53.5025 which would address the finality of ESPs, standard DC rules, standard design approvals, or MLs referenced in the application for a COL under Framework B.

Section 53.5031 Referral to the Advisory Committee on Reactor Safeguards.

This proposed rule would add § 53.5031, which would require the ACRS to report on any portions of the application for a COL under Framework B concerning safety.

Section 53.5034 Authorization to conduct limited work authorization activities.

This proposed rule would add § 53.5034, which would address authorization to conduct LWA activities.

Section 53.5037 Exemptions, departures, and variances.

This proposed rule would add § 53.5037, which would govern the conditions in which the Commission may grant an exemption for one or more of its regulations, or an exemption, variance, or departure from a permit, design approval, or license.

Section 53.5040 Issuance of combined licenses.

This proposed rule would add § 53.5040, which would establish the conditions under which the Commission may issue COLs and accompanying conditions and limitations, including TS, under Framework B.

Section 53.5043 Finality of combined licenses.

This proposed rule would add § 53.5043, which would govern permissible modifications or amendments that the Commission may make to a COL, as well as

permissible changes that a licensee may make to facilities and procedures as described in the FSAR.

Section 53.5049 Inspection during construction.

This proposed rule would add § 53.5049, which would establish requirements related to inspections, tests, and analyses for the holder of a COL under Framework B.

Section 53.5052 Operation under a combined license.

This proposed rule would add § 53.5052, which would establish requirements describing the notifications, hearings, and findings to be made prior to commencing facility operations.

Section 53.5055 Duration of a combined license.

This proposed rule would add § 53.5055, which would govern the validity of a COL under Framework B.

Section 53.5056 Transfer of a combined license.

This proposed rule would add § 53.5056, which would permit the transfer of a COL under Framework B in accordance with § 53.6070.

Section 53.5058 Application for renewal.

This proposed rule would add § 53.5058, which would provide that an application for renewal of a COL must be filed in accordance with § 53.6095.

Section 53.5061 Continuation of combined license.

This proposed rule would add § 53.5061, which would govern the continuing obligations of the holder of a COL under Framework B following the permanent cessation of operations.

Section 53.5070 Standardization of commercial nuclear plant designs: licenses to construct and operate nuclear power reactors of identical design at multiple sites.

This proposed rule would add § 53.5070, which would govern the requirements and procedures for filing and issuing applications for a CP, OL, or COL under Framework B which seek approval of the same design for multiple sites.

10 CFR part 53, subpart S—Maintaining and Revising Licensing Basis Information

This proposed rule would add subpart S, which would address the maintenance of licensing basis information for Framework B.

Section 53.6000 Licensing basis information.

This proposed rule would add § 53.6000, describing the purpose of subpart S, which would be to provide the requirements for the maintenance of licensing basis information for commercial nuclear plants licensed under Framework B.

Section 53.6002 Specific terms and conditions of licenses.

This proposed rule would add § 53.6002, which would outline the specific terms and conditions in a license under Framework B.

Section 53.6005 Changes to licensing basis information requiring prior NRC approval.

This proposed rule would add § 53.6005, which would provide an overview of the process for licensees to request and the Commission to issue amendments to licensing basis information under Framework B.

Section 53.6010 Application for amendment of license.

This proposed rule would add § 53.6010, which would require licensees under Framework B to file an application to request an amendment to the license. Applicants must assess whether the requested amendment involves no significant hazards consideration using the standards in § 53.6020 and evaluate the potential impact on environmental factors.

Commented [A36]: Note that there is no mention of the potential impact on environmental factors in the draft proposed 53.6010.

Section 53.6015 Public notices; State consultation.

This proposed rule would add § 53.6015, which would outline the Commission's procedures for issuing a *Federal Register* notice and consulting with the State in which the commercial nuclear facility is located, in connection with the NRC's consideration of applications for an amendment to an OL or COL under Framework B.

Section 53.6020 Issuance of amendment.

This proposed rule would add § 53.6020, which would outline criteria for the Commission to consider when issuing license amendments under Framework B.

Section 53.6025 Revising certification information within a design certification rule.

This proposed rule would add § 53.6025, which would address the requirements for applicants to request, and the Commission to grant, an exemption to a DC rule under Framework B.

Section 53.6030 Revising design information within a manufacturing license.

This proposed rule would add § 53.6030, which would require ML holders to request an amendment under §§ 53.6010 and 53.6020 to make changes to the design of a manufactured reactor. It would also outline the requirements for holders of a COL under Framework B to request amendments for changes to the design information of a manufactured reactor.

Section 53.6035 Amendments during construction.

This proposed rule would add § 53.6035, which would outline the process for licensees under Framework B to request amendments to CPs, COLs, or LWAs during construction.

Section 53.6040 Updating licensing basis information and determining the need for NRC approval.

This proposed rule would add § 53.6040, which would provide an overview of the regulations in subpart S for holders of an OL or COL under Framework B to modify licensing basis information, the circumstances in which NRC approval would be required to implement modifications, and definitions relevant to §§ 53.6045 through 53.6065.

Section 53.6045 Updating Final Safety Analysis Reports.

This proposed rule would add § 53.6045, which would require licensees under Framework B to regularly update FSARs in accordance with the requirements of this section to reflect changes to licensing basis information.

Section 53.6050 Evaluating changes to facility as described in Final Safety Analysis Reports.

This proposed rule would add § 53.6050, which would require licensees under Framework B to follow the guidelines outlined in this section in determining whether the changes to licensing basis information described in the UFSAR require them to obtain a license amendment.

Section 53.6052 Maintenance of risk evaluations.

This proposed rule would add § 53.6052, which would require that certain applicants and licensees submit, update, and maintain a risk evaluation.

Section 53.6054 Control of aircraft impact assessments.

This proposed rule would add § 53.6054, which would require licensees under Framework B to evaluate plant changes to ensure the protections against aircraft impacts would be maintained.

Section 53.6060 Updating program documents included in licensing basis information.

This proposed rule would add § 53.6060, which would require the holders of an OL or COL under Framework B to regularly update the program documents that they submitted in their application for a license in accordance with the requirements of this section.

Section 53.6065 Evaluating changes to programs included in licensing basis information.

This proposed rule would add § 53.6065, which would enable licensees under Framework B to make changes to the facility, procedures, or organization, or address changes to site environs as described in program documents without NRC approval if these changes satisfy the criteria outlined in this section.

Section 53.6070 Transfer of licenses.

This proposed rule would add § 53.6070, which would outline the requirements for an application for transfer of a license issued under Framework B.

Section 53.6075 Termination of license.

This proposed rule would add § 53.6075, which would outline the process for terminating an OL or COL issued under Framework B.

Section 53.6080 Information requests.

This proposed rule would add § 53.6080, which would provide the process and circumstances under which the NRC may send information requests to the various types of licensees within Framework B.

Section 53.6085 Revocation, suspension, modification of licenses and approvals for cause.

This proposed rule would add § 53.6085, which would provide grounds for the revocation, suspension, or modification of a license or standard design approval issued under Framework B.

Section 53.6090 Backfitting.

This proposed rule would add § 53.6090, which would define backfitting and establish requirements to be met by the NRC when it takes backfitting actions under Framework B.

Section 53.6095 Renewal.

This proposed rule would add § 53.6095, which would provide for the renewal of a license under Framework B upon expiration.

10 CFR part 53, subpart T—Reporting and Other Administrative Requirements

This proposed rule would add subpart T, to establish various reporting and other administrative requirements for licensees under Framework B.

Section 53.6300 General Information.

This proposed rule would add § 53.6300, which would describe requirements that applicants and licensees under Framework B to provide NRC inspectors with unfettered access to sites and facilities, maintain records and make reports, demonstrate compliance with financial qualification and reporting requirements, and maintain required financial protection for accidents.

Section 53.6310 Unfettered access for inspections.

This proposed rule would add § 53.6310, which would require applicants and licensees under Framework B to provide unfettered access to NRC inspectors, including

access to records, premises, activities, and licensed materials, in addition to providing office space to accommodate temporary or resident inspectors.

Section 53.6320 Maintenance of records, making of reports.

This proposed rule would add § 53.6320, which would require part 53 licensees under Framework B to retain all records and make reports as required by the conditions of the license or by the regulations.

Section 53.6330 Immediate notification requirements for operating commercial nuclear plants.

This proposed rule would add § 53.6330, which would impose immediate notification requirements on part 53 licensees under Framework B following the declaration of an emergency class or the discovery of certain non-emergency events.

Section 53.6340 Licensee event report system.

This proposed rule would add § 53.6340, which would require any commercial plant licensee holding an OL under Framework B to submit a Licensee Event Report in accordance with the specifications outlined in this section.

Section 53.6345 Reports of radiation exposure to members of the public.

The proposed rule would add § 53.6345, which would require periodic reports under Framework B to the Commission of the quantity of radionuclides released to unrestricted areas in liquid and gaseous effluents.

Section 53.6350 Facility information and verification.

The proposed rule would add § 53.6350, which would include a reporting requirement for applicants and holders of a CP or license under part 53 Framework B to support safeguards agreements between the United States and the IAEA.

Section 53.6360 Financial requirements.

This proposed rule would add § 53.6360, which would introduce requirements and procedures related to financial qualifications and reporting requirements under Framework B.

Section 53.6370 Financial qualifications.

This proposed rule would add § 53.6370, which would require an applicant for a CP, OL, or COL under Framework B to demonstrate possession or ability to obtain funds necessary for the activities for which the permit or license is sought.

Section 53.6380 Annual financial reports.

This proposed rule would add § 53.6380, which would require licensees and holders of a CP under Framework B to submit annual financial reports to the Commission, with exceptions for those that submit financial forms to the Securities and Exchange Commission or the Federal Energy Regulatory Commission.

Section 53.6390 Licensee's change of status; financial qualifications.

This proposed rule would add § 53.6390, which would require electric utility licensees that hold an operating or COL for a commercial nuclear plant under Framework B to provide the NRC with the financial qualifications information outlined in this section within seventy-five days of ceasing to be an electric utility.

Section 53.6400 Creditor regulations.

This proposed rule would add § 53.6400, which would establish regulations with respect to the creditors of any facility under Framework B.

Section 53.6410 Financial protection.

This proposed rule would add § 53.6410, which would establish requirements for licenses under Framework B to obtain and maintain insurance to cover the costs of an accident.

Section 53.6420 Insurance required to stabilize and decontaminate plant following an accident.

This proposed rule would add § 53.6420, which would require commercial nuclear plant licensees under Framework B to obtain insurance sufficient to cover the costs of stabilizing and decontaminating the plant in the event of an accident.

Section 53.6430 Financial protection requirements.

This proposed rule would add § 53.6430, which would require commercial nuclear plant licensees under Framework B to satisfy the provisions of part 140.

10 CFR part 53, subpart U—Quality Assurance Criteria for Commercial Nuclear Plants.

This proposed rule would add subpart U, which would establish quality assurance requirements for applicants for or holders of an OL or COL under Framework B applicable to the design, manufacture, construction, and operation of SR SSCs.

Section 53.6600 General provisions.

This proposed rule would add § 53.6600, which would define the applicability of subpart U of Framework B.

Section 53.6605 Organization.

This proposed rule would add § 53.6605, which would govern the requirements for establishing and executing a quality assurance program.

Section 53.6610 Quality assurance program.

This proposed rule would add § 53.6610, which would detail requirements for a Framework B applicant's quality assurance programs, including requirements for documentation, scope, review, indoctrination and training, and management of the program.

Section 53.6615 Design control.

This proposed rule would add § 53.6615, which would detail required design control measures for applicants under Framework B.

Section 53.6620 Procurement document control.

This proposed rule would add § 53.6620, which would establish requirements under Framework B for procurement document control related to quality assurance.

Section 53.6625 Instructions, procedures, and drawings.

This proposed rule would add § 53.6625, which would establish requirements under Framework B for documenting activities affecting quality.

Section 53.6630 Document control.

This proposed rule would add § 53.6630, which would require that applicants under Framework B establish measures to control the issuance of documents that govern activities affecting quality.

Section 53.6635 Control of purchased material, equipment, and services.

This proposed rule would add § 53.6635, which would establish requirements under Framework B for ensuring that purchased material, equipment, and services conform to procurement documents.

Section 53.6640 Identification and control of materials, parts, and components.

This proposed rule would add § 53.6640, which would establish requirements under Framework B for measures to identify and control materials, parts, and components including partially fabricated assemblies.

Section 53.6645 Control of special processes.

This proposed rule would add § 53.6645, which would establish requirements for special processes, such as welding, heat treating, and nondestructive testing, under Framework B.

Section 53.6650 Inspection.

This proposed rule would add § 53.6650, which would establish requirements under Framework B for inspection of activities affecting quality.

Section 53.6655 Test control.

This proposed rule would add § 53.6655, which would establish requirements under Framework B for a test program for demonstrating SSCs will perform satisfactorily in service.

Section 53.6660 Control of measuring and test equipment.

This proposed rule would add § 53.6660, which would require that measures are established to ensure that measuring or testing devices under Framework B are properly controlled, calibrated, and adjusted to maintain accuracy within necessary limits.

Section 53.6665 Handling, storage, and shipping.

This proposed rule would add § 53.6665, which would establish requirements under Framework B for handling, storage, shipping, and cleaning and preservation of materials and equipment.

Section 53.6670 Inspection, test, and operating status.

This proposed rule would add § 53.6670, which would establish requirements for indicating inspection and test status of individual items and for including operating status of SSCs of a commercial nuclear power plant under Framework B.

Section 53.6675 Nonconforming materials, parts, or components.

This proposed rule would add § 53.6675, which would establish requirements under Framework B for measures to control materials, parts, or components which do not conform to requirements.

~~**Section 53.6680 Corrective action.**~~

~~This proposed rule would add § 53.6680, which would establish requirements under Framework B for corrective action of conditions adverse to quality.~~

~~**Section 53.6685 Quality assurance records.**~~

~~This proposed rule would add § 53.6685, which would establish requirements under Framework B for records of activities affecting quality.~~

~~**Section 53.6690 Audits.**~~

~~This proposed rule would add § 53.6690, which would establish requirements under Framework B for auditing of the quality assurance program.~~

- ~~**10 CFR part 53, subpart X—Enforcement**~~

~~This proposed rule would add subpart X, which would address certain violations and penalties associated with violations of part 53 regulations.~~

~~**Section 53.9000 Violations.**~~

~~This proposed rule would add § 53.9000, providing notice of the Commission's authority to obtain injunctions or other court orders for the violations enumerated in this section.~~

~~**Section 53.9010 Criminal penalties.**~~

~~This proposed rule would add § 53.9010, providing notice to all persons and entities subject to part 53 that they are subject to criminal sanctions for willful violations, attempted violations, or conspiracy to violate certain regulations under part 53.~~

10 CFR part 55

Section 55.1 Purpose.

This proposed rule would revise § 55.1 to include a reference to part 53.

Section 55.2 Scope.

This proposed rule would revise § 55.2 to include references to part 53.

Section 55.5 Communications.

This proposed rule would revise § 55.1 to include references to part 53.

10 CFR part 70

Section 70.20a General license to possess special nuclear material for transport.

This proposed rule would revise § 70.20a(b) to include a reference to part 53.

Section 70.22 Contents of applications.

This proposed rule would revise § 70.22, paragraphs (b), (h)(1), (j)(1), and (k) to include the appropriate references to part 53.

Section 70.24 Criticality accident requirements.

This proposed rule would revise § 70.24, paragraphs (d)(1) and (2) to include the appropriate references to part 53.

Section 70.32 Conditions of licenses.

This proposed rule would revise § 70.32(c)(1) and (d) to incorporate the appropriate references to part 53.

Section 70.50 Reporting requirements.

This proposed rule would revise § 70.50(d) to clarify the applicability of the reporting requirements of this section to part 53 licensees.

10 CFR part 72

Section 72.3 Definitions.

This proposed rule would revise the definition of “Independent spent fuel storage installation or ISFSI” in § 72.3 to include a reference to facilities licensed under part 53.

Section 72.30 Financial assurance and recordkeeping for decommissioning.

This proposed rule would revise § 72.30(e)(5) to include the appropriate references to part 53.

Section 72.32 Emergency plan.

This proposed rule would revise § 72.32 to include a reference to the exclusion area as defined in part 53.

Section 72.40 Issuance of license.

This proposed rule would revise § 72.40(c) regarding the issuance of a license under part 72 to include a reference to previous licensing actions, including the issuance of a CP under part 53.

Section 72.75 Reporting requirements for specific events and conditions.

This proposed rule would revise § 72.75(i)(1)(ii) regarding reporting requirements for specific events and conditions with references to reactors licensed under part 53.

Section 72.184 Safeguards contingency plan.

This proposed rule would revise § 72.184 regarding the requirements of a licensee's safeguarding contingency plan with a reference to nuclear facilities licensed under part 53.

Section 72.210 General license issued.

This proposed rule would revise § 72.210 to issue a general license for the storage of spent fuel in an independent spent storage installation at power to persons authorized to possess or operate nuclear power reactors under part 53.

Section 72.212 Conditions of general license issued under § 72.210.

This proposed rule would revise § 72.212 regarding the conditions of a general license issued under § 72.210 to include a reference to license amendments for a facility made pursuant to part 53.

Section 72.218 Termination of licenses.

This proposed rule would revise § 72.218(a) to include a reference to the notification required under part 53 regarding the plan for managing spent fuel prior to

decommissioning. It would also extend the provisions of § 72.218(b) to a reactor operating or COL under part 53.

10 CFR part 73

Section 73.1 Purpose and scope.

This proposed rule would revise § 73.1 to extend the scope of part 73 to production and utilization facilities licensed under part 53, in addition to parts 50 and 52.

Section 73.2 Definitions.

This proposed rule would revise § 73.2(a) such that terms defined in part 53 have the same meaning in part 73.

Section 73.8 Information collection requirements: OMB approval.

This proposed rule would revise § 73.8 with the new information collection requirements contained in proposed §§ 73.77, 73.100, 73.110, and 73.120.

Section 73.50 Requirements for physical protection of licensed activities.

This proposed rule would revise § 73.50 to exempt nuclear reactor facilities licensed under part 53, in addition to parts 50 and 52, from the requirements of this section.

Section 73.55 Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage.

This proposed rule would revise § 73.55, paragraphs (a)(4), (i)(4)(iii), (l)(1), (l)(7)(ii), (p)(1)(i), (r)(2), and (r)(4)(iii) to incorporate the appropriate references to part 53 regarding requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage.

Section 73.56 Personnel access authorization requirements for nuclear power plants.

This proposed rule would revise § 73.56(a)(3) to apply this section's personnel AA requirements to applicants for an OL or holders of a COL under part 53 who do not demonstrate compliance with certain requirements under part 53.

Section 73.57 Requirements for criminal history records checks of individuals granted unescorted access to a nuclear power facility, a non-power reactor, or access to Safeguards Information.

This proposed rule would revise § 73.57(a)(3) to incorporate the appropriate references to OLs granted under part 53 and Commission findings under ~~§~~§§ 53.1452(g) ~~and 53.5052(g)~~ regarding the requirement for license applicants to submit fingerprints for all personnel with unescorted access.

Section 73.58 Safety/security interface requirements for nuclear power reactors.

This proposed rule would revise § 73.58(a) to extend the requirements of this section to part 53 licensees.

Section 73.67 Licensee fixed site and in-transit requirements for the physical protection of special nuclear material of moderate and low strategic significance.

This proposed rule would revise § 73.67(d) and (f) to include a reference to licensees authorized who are licensed to operate a nuclear power plant reactor pursuant to part 53.

~~Section 73.71 Reporting of safeguards events.~~

~~This proposed rule would revise § 73.71(d) and (e) to include references to part 53 regarding the reporting of safeguards events.~~

Commented [A37]: Edited to match the text of 73.67(d) and (f) and include COL holders prior to the finding that authorizes operation.

Commented [A38]: Staff should confirm that the exceptions of 73.67(d) and (f) are not applicable to holders of construction permits for nuclear power reactors (commercial nuclear plants).

Commented [A39]: Staff should explain somewhere within this document that it is not necessary to address licensees authorized to operate a nuclear power plant pursuant to part 52 (e.g., Vogtle 3 and 4) because they are also considered to be authorized to operate a nuclear power plant pursuant to part 50. This is appropriate because the current text of 73.67(d) and (f) only provides exceptions to the requirements of those paragraphs to "licensee(s) … who are licensed to operate a nuclear power reactor pursuant to part 50."

Section 73.77 Cyber security event notifications.

This proposed rule would revise § 73.77, paragraphs (a), (b), (c)(6) and (7) regarding the notification process for cyber security events to include notifications for the declaration of an emergency class made in accordance with part 53.

Section 73.100 Technology-inclusive requirements for physical protection of licensed activities at commercial nuclear plants against radiological sabotage.

This proposed rule would add § 73.100, which would establish a performance-based regulatory framework for physical protection as an alternative to the prescriptive requirements of § 73.55, which also governs physical protection programs for part 50 and 52 licensees.

Section 73.110 Technology-inclusive requirements for protection of digital computer and communication systems and networks.

This proposed rule would add § 73.110, which would establish a consequence-based approach to cyber security and would require that part 53 licensees under Frameworks A and B demonstrate reasonable assurance that digital computer and communication systems and networks are adequately protected against cyberattacks in a manner that is commensurate with the potential consequences of those attacks.

Section 73.120 Access authorization program for commercial nuclear plants.

This proposed rule would add § 73.120, which would establish performance objectives as an alternative to compliance with the AA provisions of §§ 73.55, 73.56, and 73.57. This proposed rule would afford part 53 licensees additional flexibility in establishing an AA program that demonstrates compliance with the performance objectives and requirements of this section.

Section 73.1200 Notification of physical security events.

This proposed rule would revise § 73.1200, to add appropriate references to part 53 in paragraphs (o)(5)(i) and (o)(6)(i).

Section 73.1205 Written follow-up reports of physical security events.

This proposed rule would revise § 73.1205, to add appropriate references to part 53.

Appendix B to part 73 – General Criteria for Security Personnel

This proposed rule would revise appendix B to part 73 to state that terms defined in part 53 have the same meaning when used in this appendix.

10 CFR part 74

Section 74.31 Nuclear material control and accounting for special nuclear material of low strategic significance.

This proposed rule would revise § 74.31(a) to include a reference to production or utilization facilities licensed under part 53, in addition to parts 50 and 70.

Section 74.41 Nuclear material control and accounting for special nuclear material of moderate strategic significance.

This proposed rule would revise § 74.41(a) to include a reference to nuclear reactors licensed under part 53.

Section 74.51 Nuclear material control and accounting for strategic special nuclear material.

This proposed rule would revise § 74.51(a) to include a reference to nuclear reactors licensed under part 53.

10 CFR part 75

Section 75.4 Definitions.

This proposed rule would revise § 75.4 such that terms defined in § 53.020 have the same meaning when used in this part. The definition of “Facility” would also be revised to include any plant or location where more than 1 effective kilogram of nuclear material is licensed pursuant to part 53.

10 CFR part 95

Section 95.5 Definitions.

This proposed rule would revise the definition of “License” in § 95.5 to include those issued under part 53.

Section 95.39 External transmission of documents and material.

This proposed rule would revise § 95.39(a) to apply restrictions to the external transmission of documents and material containing classified information in connection with NRC licenses, certificates, standard design approvals, or standard DCs issued under part 53.

10 CFR part 140

Section 140.2 Scope.

This proposed rule would revise § 140.2(a)(1) and (2) to include part 53 applicants and licensees within the scope of part 140 regulations.

Section 140.10 Scope.

This proposed rule would revise § 140.10 to apply the provisions of subpart B to applicants or holders of a license to operate a nuclear reactor under part 53, as well as applicants and holders of a COL under part 53.

Section 140.11 Amounts of financial protection for certain reactors.

This proposed rule would revise § 140.11 to require the licensee's primary financial protection to cover all reactors in any case where a person is authorized under part 53 to operate two or more nuclear reactors at the same location.

Section 140.12 Amount of financial protection required for other reactors.

This proposed rule would revise § 140.12 to require the licensee's primary financial protection to cover all reactors in any case where a person is authorized under part 53 to operate two or more nuclear reactors at the same location.

Section 140.13 Amount of financial protection required of certain holders of construction permits and combined licenses under 10 CFR part 52.

This proposed rule would revise § 140.13 with the appropriate references to part 53 regarding the requirement for holders of a CP or COL under part 53 to obtain financial protection.

Section 140.20 Indemnity agreements and liens.

This proposed rule would revise § 140.20(a)(1)(i) and (ii) with appropriate references to part 53.

10 CFR part 150

Section 150.15 Persons not exempt.

The proposed rule would revise § 150.15, paragraphs (a)(7)(iii) and (a)(8) to add a reference to facilities licensed under parts 53 and 52.

10 CFR part 170

Section 170.3 Definitions.

The proposed rule would revise § 170.3 to incorporate references to part 53 into the definitions of "Manufacturing license," "Part 55 Reviews," "Power reactor," and "Special projects."

Section 170.12 Payment of fees.

The proposed rule would revise § 170.12(d)(1)(v) regarding special project fees in connection with Final Safety Analysis Reports to include part 53.

Section 170.21 Schedule of fees for production and utilization facilities, review of standard referenced design approvals, special projects, inspections, and import and export licenses.

The proposed rule would revise § 170.21, footnote 1 to include fees charged for approvals issued under the exemption provision in § 53.080.

Section 170.41 Failure by applicant or licensee to pay prescribed fees.

The proposed rule would revise § 170.41 to include a general reference to part 53 in connection with remedial actions that the Commission might take when an applicant or licensee fails to pay a prescribed fee required by this part.

10 CFR part 171

Section 171.3 Scope.

The proposed rule would revise § 171.3 to apply the provisions of this part to any person holding an OL for a power reactor licensed under part 53 or a COL issued under part 53.

Section 171.5 Definitions.

This proposed rule would revise the definitions of “Operating license” and “Power reactor” in § 171.5 to incorporate the appropriate references to part 53.

Section 171.15 Annual fees: Non-power production or utilization licenses, reactor licenses, and independent spent fuel storage licenses.

This proposed rule would revise § 171.15, paragraphs (a), (b)(2)(iii), (c)(1), and (d)(1) regarding annual fees that are applicable to part 53 licensees.

Section 171.17 Proration.

This proposed rule would revise § 171.17, paragraphs (a), (a)(1)(ii) and (a)(2) with references to part 53 licenses.

VIII~~IX~~. Regulatory Flexibility Certification

The Regulatory Flexibility Act of 1980 (RFA), as amended at 5 U.S.C. 601 *et seq*, requires that agencies consider the impact of their rulemakings on small entities and, consistent with applicable statutes, consider alternatives to minimize these impacts on the businesses, organizations, and government jurisdictions to which they apply.

In accordance with the Small Business Administration's (SBA's) regulation at 13 CFR 121.903(c), the NRC has developed its own size standards for performing an RFA analysis and has verified with the SBA Office of Advocacy that its size standards are appropriate for NRC analyses. The NRC size standards at § 2.810, "NRC size standards," are used to determine whether an applicant or licensee qualifies as a small entity in the NRC's regulatory programs. Section 2.810 defines the following types of small entities:

Small business is a for-profit concern and is a— (1) Concern that provides a service or a concern not engaged in manufacturing with average gross receipts of $8.0 million or less over its last 5 completed fiscal years; or (2) Manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months.

Small organization is a not-for-profit organization which is independently owned and operated and has annual gross receipts of $8.0 million or less.

Small governmental jurisdiction is a government of a city, county, town, township, village, school district, or special district with a population of less than 50,000.

Small educational institution is one that is—_(1) Supported by a qualifying small governmental jurisdiction; or (2) Not Sstate or publicly supported and has 500 or fewer employees.

Number of Small Entities Affected

The NRC is currently not aware of any known small entities as defined in § 2.810 that are planning to apply for a commercial nuclear plant ESP, CP, OL, ML, or COL under part 53 that would be impacted by this proposed rule. Based on this finding, the NRC has preliminarily determined that the proposed rule would not have a significant economic impact on a substantial number of small entities.

Economic Impact on Small Entities

Depending on how the ownership and/or operating responsibilities for such an enterprise were structured, applicants for a commercial nuclear plant rated 8 Megawatts electric (MWe) or less could conceivably ~~demonstrate compliance with the definition of~~qualify small entities as defined by § 2.810. Owners that operate power reactors rated greater than 8 MWe could generate sufficient electricity revenue that exceeds the gross annual receipts limit of $8 million, assuming a 90 percent capacity factor and the June 2021 DOE's Energy Information Administration U.S. average price of electricity to the ultimate customer for all sectors of 11.3 cents per kilowatt-hour.

Although the NRC is not aware of any small entities that would be affected by the proposed rule, there is a possibility that future applications for a commercial nuclear plant permit or license could be submitted by small entities who plan to own and operate a commercial nuclear plant rated 8 MWe or less. Commercial nuclear plants that are rated 8 MWe or less would most likely be used to support electrical demand for military bases or small remote towns and would provide process heat, so they would not directly compete with a larger commercial nuclear plant that would typically produce electricity

Commented [A40]: There is a typographic error in 2.810(d)(2) in which the word "State" is not capitalized as would be necessary for conformance with the NRC practice of capitalizing "State" and "Federal" when referring to governmental organizations as described in NUREG-1379, Revision 2, Section 3.4. Staff should correct this in an administrative rulemaking.

for the grid. As a result of these differing purposes, the NRC would expect that small and large entities would not be in direct competition with each other.

Therefore, the NRC preliminarily concludes that this proposed rule would not have a significant economic impact on a substantial number of small entities.

Request for Comments

The NRC is seeking comments on both its initial RFA analysis and on its preliminary conclusion that this proposed rule would not have a significant economic impact on a substantial number of small entities because of the likelihood that most expected applicants would not qualify as a small entity. Additionally, the NRC is seeking comments on its preliminary conclusion that if a small entity were to submit a commercial nuclear plant application, the small entity would not incur a significant economic impact as it would most likely not be in competition with a large entity.

Any small entity that could be subject to this regulation that determines, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this opinion in a comment that indicates—

1. The applicant's size and how the proposed regulation would impose a significant economic burden on the applicant as compared to the economic burden on a larger applicant;

2. How the proposed regulations could be modified to take into account the applicant's differing needs or capabilities;

3. The benefits that would accrue or the detriments that would be avoided if the proposed regulations were modified as suggested by the applicant;

4. How the proposed regulation, as modified, would more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individual or group; and

5. How the proposed regulation, as modified, would still adequately demonstrate compliance with the NRC's obligations under the AEA.

IX. Regulatory Analysis

The NRC has prepared a draft regulatory analysis for this proposed rule. The analysis examines the costs and benefits of the alternatives considered by the NRC. The conclusion from the analysis is that this proposed rule and associated guidance would result in net averted costs to the industry and the NRC of $ 5326.16 million using a 7-percent discount rate and $ 3168.92 million using a 3-percent discount rate due to reductions in exemption requests. The analysis also assumes one applicant under Framework A, and one applicant under Framework Bpart 53. As the number of applicants increases, so do the estimated averted costs. The NRC requests public comment on the draft regulatory analysis, which is available as indicated in the "Availability of Documents" section of this document. Comments on the draft regulatory analysis may be submitted to the NRC as indicated under the ADDRESSES caption of this document.

XI. Backfitting and Issue Finality

This section describes the backfitting and issue finality implications of this proposed rule and the draft guidance documents described in section XVIII, "Availability of Guidance," in this document, as applied to pertinent NRC approvals and certain applicants that reference NRC approvals in their applications. The NRC's current backfitting provisions associated with nuclear power plants appear in § 50.109, "Backfitting," and apply to CPs and OLs under part 50 as well as design approvals, MLs and COLs under part 52. Issue finality provisions (analogous to the backfitting provisions in § 50.109) for approvals under part 52 are located in various provisions of part 52. NRC Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue

Finality, and Information Requests," describes the Commission's policies on backfitting and issue finality.

This proposed rule would provide a regulatory scheme for entities to apply for approvals under part 53. The part 50 backfitting provisions and part 52 issue finality provisions apply to actions taken by the NRC under part 50 or part 52, respectively, or actions taken by the NRC under other parts of 10 CFR chapter I that, for holders of certain approvals under part 50 or part 52, inextricably affect their activities regulated under part 50 or part 52. Issuance and implementation of proposed part 53 would not constitute actions taken under part 50 or part 52. Also, proposed part 53 would not allow an applicant to reference approvals issued under part 50 or part 52. Therefore, the issuance and implementation of proposed part 53 would not affect part 50 or part 52 entities' activities regulated under part 50 or part 52. Therefore, the addition of part 53 through this proposed rule would not be within the scope of the part 50 backfitting and part 52 issue finality provisions.

The NRC also proposes conforming changes to parts 1, 2, 10, 11, 19, 20, 21, 25, 26, 30, 40, 50, 51, 55, 70, 72, 73, 74, 75, 95, 140, 150, 170, and 171 to reflect the addition of part 53. These changes would not meet the definition of "backfitting" in § 50.109 or § 70.76, "Backfitting," because the proposed changes would not modify or add to the systems, structures, components, or design of a facility or to the procedures or organization required to operate a facility under part 50 or 70. These changes would not meet the definition of "backfitting" in § 72.62, "Backfitting," because the proposed changes would not add, eliminate, or modify the SSCs of an ISFSI or the procedures or organization required to operate an ISFSI. These proposed changes would not inextricably affect activities regulated under parts 50, 52, 70, or 72. Therefore, the proposed changes to parts 1, 2, 10, 11, 19, 20, 21, 25, 26, 30, 40, 50, 51, 55, 70, 72, 73,

74, 75, 95, 140, 150, 170, and 171 would not constitute backfitting under parts 50, 70, or 72 or affect the issue finality of an approval under part 52.

The NRC is issuing 10 draft guidance documents that, if issued as final guidance documents, would provide guidance on the methods acceptable to the NRC for complying with aspects of this proposed rule. These documents would not apply to holders of approvals issued under part 50 or part 52. Further, as discussed in the guidance documents, applicants and licensees would not be required to comply with the positions set forth in the guidance. Therefore, issuance of the guidance documents as final guidance would not constitute backfitting under part 50 or affect the issue finality of any approval issued under part 52.

XII. Cumulative Effects of Regulation

The NRC seeks to minimize any potential negative consequences resulting from the cumulative effects of regulation (CER). The CER describes the challenges that licensees, or other impacted entities such as State partners, may face while implementing new regulatory positions, programs, or requirements (e.g., rules, generic letters, backfits, inspections). The CER is an organizational effectiveness challenge that may result from a licensee or impacted entity implementing a number of complex regulatory actions, programs, or requirements within limited available resources. The NRC's CER process involved engaging with external stakeholders throughout this proposed rule and related regulatory activities. Public involvement has included numerous public meetings to examine the part 53 risk-informed, technology-inclusive requirements for commercial nuclear plants and the publication of numerous versions of preliminary proposed rule language. The NRC is considering holding additional public meetings during the remainder of the rulemaking process.

In parallel with this proposed rule, the NRC is issuing 10 draft implementing guidance documents for comment to support informed external stakeholder feedback. Section XVIII, “Availability of Guidance,” of this document describes how the public can access the draft implementing guidance.

In addition to the questions in the “Specific Requests for Comments” section of this document, the NRC is requesting CER feedback on the following questions:

1. In light of any current or projected CER challenges, does the proposed rule’s effective date provide sufficient time to implement the new proposed requirements, including changes to programs, procedures, and the facility?

2. If CER challenges currently exist or are expected, what should be done to address them? For example, if more time is required for implementation of the new requirements, what period of time is sufficient?

3. Do other (NRC or other agency) regulatory actions (e.g., orders, generic communications, license amendment requests, inspection findings of a generic nature) influence the implementation of the proposed rule’s requirements?

4. Are there unintended consequences? Does the proposed rule create conditions that would be contrary to the proposed rule’s purpose and objectives? If so, what are the unintended consequences, and how should they be addressed?

5. Please comment on the NRC’s cost and benefit estimates in the regulatory analysis that supports this proposed rule. The draft regulatory analysis is available as indicated under the “Availability of Documents” section of this document.

XIII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential

Memorandum, “Plain Language in Government Writing,” published June 10, 1998 (63 FR 31885). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

XIII~~V~~. Environmental Assessment and Proposed Finding of No Significant Environmental Impact

The Commission has preliminarily determined under the National Environmental Policy Act of 1969, as amended, and the Commission’s regulations in subpart A of part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and an environmental impact statement is not required. The implementation of the proposed rule requirements does not have a significant impact on the environment. The proposed rulemaking would either have requirements that are administrative in application, matters of procedure, or provide an equivalent level of safety as existing requirements; therefore, there would be similar environmental impacts from the implementation of the part 53 regulations as there are for existing requirements.

The preliminary determination of this environmental assessment is that there will be no significant effect on the quality of the human environment from this action. Public stakeholders should note, however, that comments on any aspect of this environmental assessment may be submitted to the NRC as indicated under the ADDRESSES caption. The environmental assessment is available as indicated under the “Availability of Documents” section.

The NRC has sent a copy of the environmental assessment, and this proposed rule to every State Liaison Officer and has requested comments.

XIV. Paperwork Reduction Act

This proposed rule contains new collections of information contained in parts 26, 53, and 73 and NRC Forms 361S, 366, 366A, 366B, 893, and 894 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). The collections of information have been submitted to the OMB for review and approval. The proposed changes to parts 2, 10, 11, 19, 20, 21, 25, 30, 40, 50, 51, 55, 70, 72, 74, 75, 95, 140, ~~and~~ 150, 170, and 171 do not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995. Existing collections of information were approved by the OMB, approval numbers 3150-0062 (part 11), 3150-0044 (part 19), 3150-0014 (part 20), 3150-0035 (part 21), 3150-0046 (part 25), 3150-0017 (part 30), 3150–0020 (part 40), 3150–0011 (part 50), 3150-0021 (part 51), 3150-0024 (part 55), 3150-0090 (part 55), 3150-0009 (part 70), 3150–0132 (part 72), 3150-0123 (part 74), 3150–0055 (part 75), 3150-0047 (part 95), 3150-0039 (part 140), and 3150-0032 (part 150).

Type of submission, new or revision: Revision and new.

The title of the information collection: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors.

The form number if applicable: NRC Forms 361S, 366, 366A, 366B, 893, and 894.

How often the collection is required or requested: Once, on occasion, every 30 days, biannually, annually, biennially, every four years, every five years, every ten years.

Who will be required or asked to respond: Part 53 commercial nuclear plant licensees and license applicants for commercial nuclear plants to be licensed under part 53.

An estimate of the number of annual responses: 30. (3 responses for Part 26, 27 responses for Part 53, and 0 responses for Part 73 and NRC Forms 361S, 366, 366A, 366B, 893, and 894)

The estimated number of annual respondents: 6 (3 respondents for Part 26, 6 respondents for Part 53, and 0 respondents for Part 73 and NRC Forms 361S, 366, 366A, 366B, 893, and 894)

An estimate of the total number of hours needed annually to comply with the information collection requirement or request: 377,059 hours. (984 hours for Part 26, 376,075 hours for Part 53, and 0 hours for Part 73 and NRC Forms 361S, 366, 366A, 366B, 893, and 894)

Abstract: The NRC is proposing to establish an optional technology-inclusive regulatory framework for use by applicants for new commercial nuclear plant designs. The regulatory requirements developed in this rulemaking would use methods of evaluation, including risk-informed and performance-based methods, that are flexible and practicable for application to a variety of new reactor technologies. The NRC's goals in amending these regulations are to continue to provide reasonable assurance of adequate protection of public health and safety and the common defense and security at reactor sites at which new nuclear reactor designs are deployed to at least the same degree of protection as required for current-generation LWRs; protect health and minimize danger to life or property to at least the same degree of protection as required for current-generation LWRs; provide greater operational flexibilities where supported by enhanced margins of safety that may be provided in new nuclear designs; and promote regulatory stability, predictability, and clarity.

The proposed rule covers diverse topics across ~~two~~ one alternative licensing frameworks ~~(Framework A and Framework B) which~~that result in recordkeeping and reporting requirements related to contents of applications, plant design and analysis, siting, construction and manufacturing, licensing basis information, facility operations,

programs, staffing, FFD, physical security, cyber security, AA, decommissioning, and quality assurance.

In addition to the new information collections in the proposed regulations, part 53 would result in new collections via NRC Forms 361S, 366, 366A, 366B, 893, and 894. NRC Forms 366, 366A, and 366B would be modified to include part 53 reportable events covering an equivalent scope as the requirements in 10 CFR 50.73, but without LWR-specific terminology to ensure technology-inclusiveness. The proposed rule also would require part 53 licensees to use NRC Forms 893 and 894 to report on positive drug and alcohol test results (NRC Form 893) and annual fitness-for-duty program performance (NRC Form 894). Finally, a new version of NRC Form 361 (NRC Form 361S) would be created for use by Part 53 licensees, covering an equivalent scope as the requirements in 10 CFR 50.72, but without LWR-specific terminology to ensure technology-inclusiveness.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility? Please explain your response.

2. Is the estimate of the burden of the proposed information collection accurate? Please explain your response.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected? Please explain your response.

4. How can the burden of the proposed information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology? Please explain your response.

The OMB clearance documents and proposed rule is available as indicated under the "Availability of Documents" section in this document or may be viewed free of charge by contacting the NRC's PDR reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.resource@nrc.gov. You may obtain information and comment submissions related to the OMB clearance package by searching on http://www.regulations.gov under Docket ID NRC-2019-0062.

You may submit comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by the following methods:

- **Federal rulemaking website:** Go to http://www.regulations.gov and search for Docket ID NRC-2019-0062.
- **Mail comments to:** FOIA, Library, and Information Collections Branch, Office of the Chief Information Officer, Mail Stop: T6-A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or by e-mail to Infocollects.Resource@nrc.gov or to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-XXXX, 3150-0002, -0104, -0146, -0238), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: oira_submission@omb.eop.gov.

Submit comments by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XV~~I~~. Criminal Penalties

For the purposes of Section 223 of the AEA, the NRC is issuing this proposed rule that would add a new part 53 and amend parts 26 and 73 under one or more of Sections 161b, 161i, or 161o of the AEA, except as noted in proposed § 53.9010(b) and § 26.825(b). Willful violations of the part 53 and part 26 regulations not listed in proposed § 53.9010(b) and § 26.825(b) would be subject to criminal enforcement. Criminal penalties as they apply to regulations in part 53 would be discussed in § 53.9010.

XVI~~I~~. Voluntary Consensus Standards

The NTTAA requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC would revise regulations by adding a risk-informed, technology-inclusive regulatory framework for commercial advanced nuclear reactors. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XVII~~I~~. Availability of Guidance

As discussed in the section II, Background, the NRC's development of proposed part 53 built upon recent and ongoing activities such as those described in SECY-19-0117. Because a number of those activities are ongoing to support new reactor applications under the existing regulatory framework of 10 CFR parts 50 and 52, the NRC staff identified in its response to SRM-SECY-20-0032 that the timing of guidance document development to support the part 53 rulemaking was a key risk and

uncertainty to publishing the final part 53 rule. To mitigate this risk, the NRC engaged external stakeholders to ensure a common prioritization of the development of these guidance documents and to work diligently on those that would be needed to support this rulemaking, forthcoming applications, or broader efforts such as the Advanced Reactor Demonstration Program being sponsored by the DOE. The NRC also recognizes that guidance development to support part 53 and advanced reactors will continue as the industry and NRC learn lessons from licensing reviews and operating experience. Therefore, the NRC categorized guidance supporting the part 53 rulemaking into four categories: (1) guidance issued to support applications under the existing regulatory framework; (2) guidance under development to support applications under the existing regulatory framework; (3) implementing guidance for part 53-specific proposed rule language; and (4) future guidance activities that would need to be completed after the part 53 proposed rule is published for public comment.

(1) Hundreds of guidance documents exist for the current fleet of operating reactors. While some of the guidance is specific to LWR technologies, other guidance is technology-inclusive in nature and should be considered, as appropriate, in the development of all licensing applications and NRC reviews. In addition, the NRC has undertaken efforts to incorporate or reference the most relevant guidance in its efforts to develop additional guidance for future advanced reactors. The NRC has issued the following guidance to support licensing reviews of advanced reactors under the existing regulatory framework that will continue to inform applicant development and NRC reviews under parts 50 and 52. Conforming changes to these guidance documents would be needed to ensure they are applicable under part 53. The NRC will issue revisions to these guidance documents for public comment after the publication of this

proposed rule and then finalize and issue the guidance documents with or after the final part 53 rule.

- RG 1.233, “Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light Water Reactors”
- RG 1.232, “Guidance for Developing Principal Design Criteria for Non-Light Water Reactors”
- RG 1.247 for trial use, “Acceptability of Probabilistic Risk Assessment Results for Non-Light-Water Reactor Risk-Informed Activities”
- NUREG-2246, “Fuel Qualification for Advanced Reactors”
- RG 1.87, Revision 2, “Acceptability of ASME Code, Section III, Division 5, “High Temperature Reactors”
- RG 1.246, “Acceptability of ASME Code, Section XI, Division 2, ‘Requirements for Reliability And Integrity Management (RIM) Programs for Nuclear Power Plants,’ for Non-Light Water Reactors”

(2) The NRC is developing additional guidance to support licensing reviews of advanced reactors under the existing regulatory framework. These guidance documents will be issued before the finalization of part 53 to support near-term applicants and NRC reviews. Conforming changes to these documents would be needed to ensure they are applicable under part 53, and these revisions would occur between publication of the proposed rule and the final rule. The NRC is currently engaged with the DOE and industry to develop content of application guidance for advanced reactors, initially developed to support applications under the existing regulatory framework. These guidance documents, the industry-led Technology-Inclusive Content of Application

Project (TICAP) guidance found in NEI 21-07 and the NRC-led Advanced Reactor Content of Application Project (ARCAP) interim staff guidance (ISG) documents, will support developers in preparing advanced reactor applications and facilitate the NRC's review of applications for CPs, OLs, COLs, MLs, standard design approval, and DCs under ~~Framework A of~~ part 53. These guidance documents provide an overview of the information that should be included in an advanced reactor application, a review roadmap for the NRC with the principal purpose of ensuring consistency, quality, and uniformity of NRC reviews, and a well-defined base from which the NRC can evaluate proposed changes in the scope and requirements of reviews. While specific sections of the information are primarily aligned with the LMP methodology, as endorsed in RG 1.233, as one acceptable process for applicants to use when developing portions of an application, the concepts and general information may be used to inform the review of an application submitted using other traditional licensing approach methodologies (as applicable). Other sections of the information are generally applicable and independent of the methodology used to develop an advanced reactor application. The ARCAP ISGs provide references to numerous regulatory guidance documents that should be considered by both applicants and the NRC in developing and reviewing, respectively, advanced reactor applications. The NRC will issue the following documents for public comment separately from this proposed rule and then finalize and issue the guidance documents with or after the final part 53 rule.

- DG-1404, "Guidance for a Technology Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors"

- DANU-ISG-2022-01, “Advanced Reactor Content of Application Project, ‘Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications – Roadmap’”
- DANU-ISG-2022-02, “Advanced Reactor Content of Application Project Chapter 2, ‘Site Information’”
- DANU-ISG-2022-03, “Advanced Reactor Content of Application Project Chapter 9, ‘Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste’”
- DANU-ISG-2022-04, “Advanced Reactor Content of Application Project Chapter 10, ‘Control of Occupational Dose’”
- DANU-ISG-2022-05, “Advanced Reactor Content of Application Project Chapter 11, ‘Organization and Human-System Considerations’”
- DANU-ISG-2022-06, “Advanced Reactor Content of Application Project Chapter 12, ‘Post-Construction Inspection, Testing, and Analysis Program’”
- DANU-ISG-2022-07, “Advanced Reactor Content of Application Project, ‘Risk-Informed Inservice Inspection/Inservice Testing’”
- DANU-ISG-2022-08, “Advanced Reactor Content of Application Project, ‘Risk-Informed Technical Specifications’”
- DANU-ISG-2022-09, “Advanced Reactor Content of Application Project, ‘Risk-Informed, Performance-Based Fire Protection Program (for Operations)’”
- DG-1350 (RG 1.242), “Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities”
- RG 4.7, “General Site Suitability Criteria for Nuclear Power Stations”

(3) The NRC is issuing for comment ten draft guidance documents for the implementation of the proposed requirements in this rulemaking. The guidance is available in ADAMS under the Accession Numbers as indicated under the "Availability of Documents" section in this document. Comments on this draft regulatory guidance may be submitted by the methods outlined in the ADDRESSES section of this document. Interested persons may obtain information and comment submissions related to the draft guidance by searching on http://www.regulations.gov under Docket ID NRC-2019-0062.

- DG-1413, "Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants"

This DG describes an acceptable approach for identifying licensing events that can be used to inform the design basis, licensing basis, and content of applications for commercial nuclear plants, including large LWRs and non-LWRs. It applies to nuclear power reactor designers, applicants, and licensees of commercial nuclear plants applying for permits, licenses, certifications, and approvals under parts 50, 52, and 53. In this DG, the term "licensing events" is used in a generic sense to refer to collections of designated event categories such as, but not limited to AOOs, DBAs, DBEs, and postulated accidents. Specifically, this DG provides an acceptable approach for: (1) conducting a comprehensive and systematic search for initiating events; (2) using a systematic process to delineate a comprehensive set of event sequences; (3) grouping initiating events and event sequences into designated licensing event categories; and (4) providing assurance that the set of licensing events is complete.

- DG-1414, "Alternative Evaluation for Risk Insights Methodology"

Commented [A41]: Staff should work with stakeholders to adapt the AERI guidance as an acceptable form of risk evaluation for use under part 53.

This DG describes an acceptable approach for performing an AERI. Applicants for permits, licenses, certifications, and approvals under ~~Framework B~~part 53 may elect to develop an AERI in lieu of a PRA when the AERI entry conditions ~~in~~

~~§ 53.4730(a)(34)(ii)~~ are met. Specifically, this DG provides an acceptable approach to: (1) identifying and characterizing a bounding event or events; (2) confirming that the commercial nuclear plant design demonstrate compliance with the AERI entry conditions ~~specified in § 53.4730(a)(34)(ii)~~ by determining a dose estimate for the bounding event or events; (3) developing a demonstrably conservative risk estimate for the bounding event to show that the Commission's safety goals and associated QHOs as stated in "Safety Goals for the Operation of Nuclear Power Plants," (51 FR 28044; August 4, 1986 as corrected and republished at 51 FR 30028; August 21, 1986) are met; (4) searching for severe accident vulnerabilities for the entire set of licensing events; (5) identifying risk insights for the entire set of licensing events; (6) assessing defense in depth adequacy for the entire set of licensing events; (7) maintaining and upgrading the AERI; (8) considering application-specific aspects such as developing an AERI to support a CP application when an applicant may have a conceptual design that does not include sufficient information to demonstrate that AERI entry conditions are met at the time of application; and (9) addressing procedural and other non-technical aspects such as independent review and the use of expert opinion.

- DG-5073, "Fitness For Duty Programs for Commercial Nuclear Plants And Manufacturing Facilities Licensed Under 10 CFR Part 53"

This DG describes guidance for applicants under part 53 and licensees and other entities described in § 26.3(f) who would elect to or be required to implement FFD programs for facilities licensed under part 53. The FFD program requirements would be detailed in subpart M of part 26 and involve, in part, policies, procedures, drug and alcohol testing, laboratory requirements, behavioral observation, MRO responsibilities, fitness determinations, reporting, and recordkeeping. The FFD program for facilities licensed under part 53 subject to part 26 would also include requirements for a PMRP

and FFD program change control that licensees or other entities must implement to maintain an effective FFD program.

- DG-5074, “Access Authorization Program for Commercial Nuclear Plants”

This DG describes a method that the staff considers acceptable to comply with requirements in proposed § 73.120, “Access authorization program for commercial nuclear plants,” related to an AA program. This document provides guidance and would be one NRC-approved method (not the only method) for meeting regulatory requirements for part 53. The proposed language in § 73.120 would provide flexibility through availability of the use of an alternate approach, commensurate with risk and consequence to public health and safety, for part 53 applicants who demonstrate in an analysis that the offsite consequences satisfy the criterion defined in proposed § 53.860(a)(2)(i).

- DG-5075, “Establishing Cyber ~~s~~Security Programs for Commercial Nuclear Plants Licensed Under 10 CFR Part 53”

This DG describes an approach the NRC staff deems acceptable for complying with the Commission’s proposed regulations for establishing, implementing, and maintaining a cyber security program at commercial nuclear plants that would be licensed under part 53. This guidance provides an approach for meeting the requirements of proposed § 73.110, “Technology-inclusive requirements for protection of digital computer and communication systems and networks.”

- DG-5076, “Guidance ~~f~~For Technology Inclusive Requirements For Physical Protection Of Licensed Activities At Commercial Nuclear Plants”

This DG describes methods and approaches that the NRC staff considers acceptable for meeting the proposed physical security requirements of part 53 and § 73.100. The guidance is intended to provide methods and considerations for

complying with § 53.440(f) safety and security design process considerations, determining eligibility for meeting the performance criterion in § 53.860 ~~or § 53.4330~~ to relieve the applicant from the applicable requirements to defend against radiological sabotage outlined in § 73.55 or § 73.100, and (if the required analysis for eligibility is not satisfied) applying the physical security requirements of § 73.100 as an alternative pathway from § 73.55 for protection against radiological sabotage.

- DG-5078, "Fatigue Management For Nuclear Power Plant Personnel At Commercial Nuclear Plants Licensed Under 10 CFR Part 53"

This DG describes proposed methods that the NRC staff considers acceptable for addressing certain aspects of FFD programs that would be established at commercial nuclear facilities licensed under part 53. This guidance, in conjunction with the existing RG 5.73, "Fatigue Management for Nuclear Plant Personnel," would provide comprehensive guidance regarding acceptable methods for the development and implementation of licensee fatigue-management programs.

The NRC is issuing for public comment the following draft ISG documents for the implementation of NRC staff review of applications under the proposed requirements in this rulemaking:

- DRO-ISG-2023-01, "Operator Licensing Programs"

This draft ISG provides guidance for the review of tailored operator licensing programs that are submitted for review consistent with the technical requirements of proposed § 53.730(g). This guidance primarily addresses the review of operator licensing examination processes to facilitate the ability of reviewers to assess whether a proposed approach to the testing of licensed operators and trainees reflects sound assessment testing practices that are suitable for the screening of competent licensed

operators. Additionally, this ISG provides further review guidance in other areas such as licensed operator continuing training and proficiency programs.

- DRO-ISG-2023-02, "Interim Staff Guidance Augmenting NUREG-1791, 'Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m),' for Licensing Commercial Nuclear Plants under 10 CFR Part 53"

This draft ISG provides guidance for the review of customized facility operator staffing plans that are submitted for review consistent with the technical requirements of proposed § 53.730(f). This ISG is structured as a companion document to the existing NUREG-1791 and adapts the existing HFE-based methodologies of that document for use in the evaluation of staffing plans that would be submitted within the context of part 53 facilities. Additionally, this ISG provides further guidance to address other staffing-related considerations, such as provisions for engineering expertise.

- DRO-ISG-2023-03, "Development of Scalable Human Factors Engineering Review Plans"

This draft ISG applies to the HFE review of applications for OLs, COLs, DCs, and standard design approvals for commercial nuclear plants submitted under proposed part 53. The purpose of this ISG is to facilitate NRC understanding of an acceptable method for developing a scalable (i.e., application-specific) plan for the review of these applications for compliance with applicable HFE requirements. The ISG describes a process and provides implementation guidance for the NRC to tailor HFE review plans to each application to achieve an effective and efficient review.

(4) The NRC has identified future guidance activities that would need to be completed after the part 53 proposed rule is published for public comment to support advanced reactor applications and NRC reviews. ~~For example, the NRC recognizes that~~

~~a standardized content of application for applications under Framework B of proposed part 53 would ensure review consistency and predictability from the NRC.~~

Accordingly, the NRC has prioritized development of content of application guidance that would serve the same purpose as the TICAP and ARCAP efforts underway to support applications under ~~Framework A of~~ part 53. The NRC has not yet initiated the development of these guidance documents but will engage stakeholders during the development of these documents to ensure common prioritization. In addition, the NRC works with standards development organizations, advanced reactor developers, DOE, and other stakeholders to identify and facilitate new consensus codes and standards needed for advanced reactor development. The NRC will continue its membership and participation on standards development committees and working groups to support standards for advanced reactor technologies, where appropriate.

XVIII~~X~~. Public Meeting

The NRC will conduct a public meeting on this proposed rule for the purpose of describing the proposed rule and implementation guidance to the public and answering questions from the public on the proposed rule and implementation guidance.

The NRC will publish a notice of the public meeting's location, time, and agenda on the NRC's public meeting Web site at least 10 calendar days before the meeting. Stakeholders should monitor the NRC's public meeting Web site for information about the public meeting at: http://www.nrc.gov/public-involve/public-meetings/index.cfm.

XIX. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS Accession No. / Web link / *Federal Register* Citation
Proposed Rule Documents	

SECY-23-XXXX, “Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31),” <INSERT DATE>	ML21162A095
SECY-23-XXXX, Enclosure 2, “Draft Environmental Assessment for the Proposed Rule—Risk Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors,” <INSERT DATE>	ML21162A104
SECY-23-XXXX, Enclosure 3, “Draft Regulatory Analysis for the Proposed Rule: Risk Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors,” <INSERT DATE>	ML21165A112
SECY-23-XXXX, Enclosure 4, “Alternative Approaches Considered for Selected Topics During the Development of 10 CFR Part 53”	ML22244A001
SECY-23-XXXX, Enclosure 5, “Estimated Resources For The Risk-Informed, Technology-Inclusive Regulatory Framework For Advanced Reactors Rulemaking”	ML22304A099 (non-public)
Information Collection Documents	
Draft Supporting Statement for Information Collection Analysis – 10 CFR Part 53	ML21162A109
Draft Supporting Statement for Information Collection Analysis – 10 CFR Part 26	ML23030A400
Draft Supporting Statement for Information Collection Analysis – 10 CFR Part 73	ML23030A576
Draft NRC Form 361S, “Part 53 Plant Event Notification Worksheet”	ML23032A443
Draft NRC Form 366, “Licensee Event Report (LER)”	ML23032A445
Draft NRC Form 366A, “Licensee Event Report (LER) Continuation Sheet”	ML23032A447
Draft NRC Form 366B, “Licensee Event Report (LER) (Failure Continuation)”	ML23032A454
Draft NRC Form 893, “10 CFR Part 26, Subpart M, Single FFD Policy Violation Form”	ML23032A435
Draft NRC Form 894, “10 CFR Part 26, Subpart M, Annual Reporting Form for FFD Performance Information”	ML23032A439
Draft Regulatory Guidance Documents	
DG-1413, “Technology-Inclusive Identification Of Licensing Events For Commercial Nuclear Plants,” <INSERT DATE>	ML22257A173
DG-1414, "Alternative Evaluation for Risk Insights Methodology," <INSERT DATE>	ML22257A248

DG-5073, “Fitness-For-Duty Programs For Commercial Nuclear Plants And Manufacturing Facilities Licensed Under 10 CFR Part 53,” <INSERT DATE>	ML22200A037
DG-5074, “Access Authorization Program for Commercial Nuclear Plants,” <INSERT DATE>	ML22199A246
DG-5075, “Establishing Cyber ~~s~~Security Programs For Commercial Nuclear Plants Licensed Under 10 CFR Part 53,” <INSERT DATE>	ML22199A257
DG-5076, “Guidance for Technology Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants,” <INSERT DATE>	ML22203A131
DG-5078, “Fatigue Management For Nuclear Power Plant Personnel At Commercial Nuclear Plants Licensed Under 10 CFR Part 53,” <INSERT DATE>	ML22264A109
Draft ISG Documents	
Draft ISG DRO-ISG-2023-01, “Operator Licensing Programs,” <INSERT DATE>	ML22266A066
Draft ISG DRO-ISG-2023-02, “Interim Staff Guidance Augmenting NUREG-1791, ‘Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m),’ for Licensing Commercial Nuclear Plants under 10 CFR Part 53,” <INSERT DATE>	ML22266A068
Draft ISG DRO-ISG-2023-03, “Development of Scalable Human Factors Engineering Review Plans,” <INSERT DATE>	ML22266A072
Other References	
American National Standards Institute/ANS-3.4-2013, “Medical Certification And Monitoring Of Personnel Requiring Operator Licenses For Nuclear Power Plants”	https://webstore.ansi.org/Standards/ANSI/ansians2013
ASME/ANS RA-S-1.4-2021, “Probabilistic Risk Assessment Standard for Advanced Non-Light Water Reactor Nuclear Power Plants”	https://www.asme.org/codes-standards/find-codes-standards/ra-s-1-4-probabilistic-risk-assessment-standard-advanced-non-light-water-reactor-nuclear-power-plants/2021/drm-enabled-pdf
ASCE/SEI 43-19, “Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities”	https://doi.org/10.1061/9780784415405

Federal Register notice—Final policy statement, "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement," dated August 16, 1995	60 FR 42622
Federal Register notice—Final rule, "Fitness-for-Duty Programs," dated June 7,1989	54 FR 24473
Federal Register notice—Final rule, "Fitness for Duty Programs," dated March 31, 2008	84 FR 16970
Federal Register notice—Final rule, "Licenses, Certifications, and Approvals for Nuclear Power Plants," dated August 28, 2007	72 FR 49351
Federal Register notice—Final rule, "Loss of all alternating current power," dated June 21, 1988	52 FR 23203
Federal Register notice—Final rule, "Technical Specifications," dated July 19,1995	60 FR 36953, 36955
Federal Register notice—Guidance, "Mandatory Guidelines for Federal Workplace Drug Testing Programs," dated January 23, 2017	82 FR 7920
Federal Register notice—Guidance, "Mandatory Guidelines for Federal Workplace Drug Testing Programs – Oral/Fluid," dated October 25, 2019	84 FR 57554
Federal Register notice—Policy Statement, "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants," dated August 8, 1985	50 FR 32138
Federal Register notice—Policy Statement, "Safety Goals for the Operation of Nuclear Power Plants; Policy Statement; Correction and Republication," dated August 21, 1986	51 FR 30028
Federal Register notice—Policy Statement, "Tribal Policy Statement," dated January 9, 2017	82 FR 2402
Federal Register notice—Policy Statement, "Policy Statement on the Regulation of Advanced Reactors," dated October 14, 2008	73 FR 60612
Federal Register notice—Policy Statement, "Final Safety Culture Policy Statement," dated June 14, 2011	76 FR 34773
Federal Register notice—Proposed rule, "Emergency Preparedness for Small Modular Reactors and Other New Technologies," dated May 12, 2020	85 FR 28436

Federal Register notice—Proposed rule, "Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning," dated March 3, 2022	87 FR 12254
Federal Register notice—Public meeting, "Reporting Requirements for Nonemergency Events at Nuclear Power Plants," dated November 29, 2021	86 FR 67669
ICRP, Publication 2 "Permissible dose for internal radiation," dated 1960	https://www.icrp.org/publication.asp?id=icrp%20publication%202
ICRP, Publication 26 "Recommendations of the ICRP," dated 1977	https://www.icrp.org/publication.asp?id=ICRP%20Publication%2026
ICRP, Publication 30 "Limits for Intakes of Radionuclides by Workers," dated 1979	https://www.icrp.org/publication.asp?id=ICRP%20Publication%2030%20(Index)
Letter to Chairman Hanson, NRC, "Final Letter on Draft 10 CFR Part 53 Rulemaking Language," dated November 22, 2022	ML22319A104
Letter to Chairman Hanson, NRC, "Fourth Interim Letter on 10 CFR Part 53 Rulemaking Language," dated August 2, 2022	ML22196A292
Letter to Chairman Hanson, NRC, "Preliminary Proposed Rule Language For 10 CFR Part 53, Regulation of Advanced Nuclear Reactors, Interim Report," dated May 30, 2021	ML21140A354
Letter to Chairman Hanson, NRC, "Preliminary Rule Language For 10 CFR Part 53, Subpart F, 'Requirements for Operations,' Interim Report.," dated February 17, 2022	ML22040A361
Letter to Chairman Rempe, ACRS, "Response to the Advisory Committee on Reactor Safeguards, 'Fourth Interim Letter on 10 CFR Part 53 Rulemaking Language,'" dated September 30, 2022	ML22249A073
Letter to Chairman Rempe, ACRS, "Response to the Advisory Committee on Reactor Safeguards Letter on Preliminary Rule Language for 10 CFR Part 53, Subpart F, 'Requirements for Operations,' Interim Report," dated March 30, 2022	ML22063A012
Letter to Chairman Sunseri, ACRS, "Part 53, Licensing and Regulation of Advanced Nuclear Reactors," dated November 24, 2020	ML20311A006
Letter to Chairman Svinicki, NRC, "10 CFR Part 53, Licensing and Regulation of Advanced Nuclear Reactors," dated October 21, 2020	ML20295A647

Michigan v. EPA, 135 S. Ct. 2699 (2015)	
National Laboratory of Medicine, National Institutes of Health, Workshop Summary, "The Evolution of Telehealth: Where Have We Been and Where Are We Going?," dated November 2012	https://www.ncbi.nlm.nih.gov/books/NBK207141/
NEI 18-04, Rev. 1, "Risk-Informed Performance-Based Technology-Inclusive Guidance for Non-Light Water Reactors," dated August 2019	ML19241A472
NIA, "Clarifying 'Major Portions' of a Reactor Design in Support of a Standard Design Approval," dated April 2017	https://www.nuclearinnovationalliance.org/clarifying-major-portions-reactor-design-support-standard-design-approval
NRC, "A Regulatory Review Roadmap for Non-Light Water Reactors," dated December 2017	ML17312B567
NRC, "Manufacturing License ML-1 for Production of Up to Eight Floating Nuclear Plants," dated September 30, 1982	ML20070J215
NRC, "Risk-Informed and Performance-Based Human-System Considerations for Advanced Reactors," dated March 2021	ML21069A003
NRC Form 890, "Single Positive Test Form"	ML22013B187
NRC Form 891, "Annual Reporting for Drug and Alcohol Tests"	ML22013B240
NRC From 892, "Annual Fatigue Reporting Form"	ML220138250
NUREG-0654/FEMA-REP-1, Revision 2, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," dated December 2019	ML19347D139
NUREG-0880, "Safety Goals for Nuclear Power Plant Operation," dated May 1983	ML071770230
NUREG-1530, Revision 1, "Reassessment of NRC's Dollar Per Person-Rem Conversion Factor Policy, Final Report," dated February 2022	ML22053A025
NUREG/BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," dated April 2017	ML17100A480
NUREG/CR-5884, "Revised Analyses of Decommissioning for the Reference Pressurized Water Reactor Power Station," dated November 1995	ML14008A187

NUREG/CR-6187, Volume 1, “Revised Analyses of Decommissioning for the Reference Boiling Water Reactor Power Station,” dated July 1996	ML14008A186
OMB Circular No. A-119, “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,” dated February 19, 1998	https://obamawhitehouse.archives.gov/omb/circulars_a119_a119fr
PNNL, Technical Letter Report, “The Use of Electronic Communications to Perform Determinations of Fitness,” dated August 2017	ML18081A607
Pre-decisional DG, “Technology-Inclusive, Risk-Informed, and Performance-Based Methodology for Seismic Design of Commercial Nuclear Plants,” dated October 3, 2022	ML22276A149
Research Information Letter 2021-04, “Feasibility Study on a Potential Consequence-Based Seismic Design Approach for Nuclear Facilities,” dated April 2021	ML21113A066
RG 1.110, Revision 1, “Cost-Benefit Analysis for Radwaste Systems for Light-Water-Cooled Nuclear Power Reactors,” dated October 2013	ML13241A052
RG 1.134, Revision 4, “Medical Assessment Of Licensed Operators Or Applicants For Operator Licenses At Nuclear Power Plants,” dated September 2014	ML14189A385
RG 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” Revision 3, dated January 2018	ML17317A256
RG 1.208, “A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion,” dated March 2007	ML070310619
RG 1.232, “Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors,” Revision 0, dated April 2018	ML17325A611
RG 1.233, Revision 0, “Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light Water Reactors,” dated June 2020	ML20091L698

RG 1.247, “Acceptability of Probabilistic Risk Assessment Results for Non-Light-Water Reactor Risk-Informed Activities,” issued March 2022 for trial use	ML21235A008
RG 5.73, “Fatigue Management for Nuclear Power Plant Personnel,” dated March 20, 2009	ML083450028
RG 5.77, “Insider Mitigation Program,” Revision 1, dated September 08, 2022.	ML16342B024
RG 5.81, “Target Set Identification and Development for Nuclear Power Reactors,” Revision 1, dated December 2019	ML13151A355
SECY-18-0096, “Functional Containment Performance Criteria For Non-Light-Water-Reactors,” dated September 28, 2018	ML18115A157
SECY-19-0117, “Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,” dated December 2019	ML18311A264
SECY-20-0032, “Rulemaking Plan on ‘Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062,’” dated April 13, 2020	ML19340A056
SECY-20-0070, “(Redacted) Technical Evaluation of the Security Bounding Time Concept for Operating Nuclear Power Plants,” dated November 8, 2021	ML20126G265
SECY-22-0052, “Proposed Rule: Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150-AI66),” dated June 6, 2022	ML21159A057
SECY-22-0072, “Proposed Rule: Alternative Physical Security Requirements for Advanced Reactors (RIN 3150-AK19),” dated August 2, 2022	ML21334A003
SECY-83-293, “Amendments to 10 CFR 50 Related to Anticipated Transients Without Scram (ATWS) Events," dated July 19, 1983	ML21278A823 (non-public) ML21278A994 (non-public)
SECY-93-092, “Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and their Relationship to Current Regulatory Requirements,” dated April 8, 1993	ML040210725
SRM-SECY-10-0121, “Modifying the Risk-Informed Regulatory Guidance for New Reactors,” dated March 2, 2011	ML110610166

SRM-SECY-17-0100, “Security Baseline Inspection Program Assessment Results and Recommendations for Program Efficiencies,” dated October 8, 2018	ML18283A072
SRM-SECY-20-0032, “Rulemaking Plan on ‘Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062),’” dated October 2, 2020	ML20276A293
SRM-SECY-20-0045, “Population Related Siting Considerations for Advanced Reactors,” dated July 30, 2022	ML22194A885
SRM-SECY-98-144, “Staff Requirements—SECY-98-144—White Paper on Risk-Informed and Performance-Based Regulations,” dated February 24, 1999	ML003753593

Throughout the development of this rule, the NRC may post documents related to this rule, including public comments, on the Federal rulemaking website at https://www.regulations.gov under Docket ID NRC-2019-0062. The Federal rulemaking website allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder (NRC-2019-0062-0012); (2) click the “Sign up for E-mail Alerts” link; and (3) enter your e-mail address and select how frequently you would like to receive e-mails (daily, weekly, or monthly).

Commented [A42]: Staff should replace the docket folder her with the appropriate one as NRC-2019-0062-0012 is the docket folder for the preliminary proposed rule language and would not seem to be the appropriate location for the posting of additional information after the proposed rule is finalized and published.

List of Subjects

10 CFR Part 1

Flags, Organization and functions (Government Agencies), Seals and insignia.

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Confidential business information, Freedom of information, Environmental protection, Hazardous waste, Nuclear energy, Nuclear materials, Nuclear power plants

and reactors, Penalties, Reporting and recordkeeping requirements, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 10

Administrative practice and procedure, Classified information, Government employees, Security measures.

10 CFR Part 11

Hazardous materials transportation, Investigations, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Security measures, Special nuclear material.

10 CFR Part 19

Criminal penalties, Environmental protection, Nuclear Energy, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements, Sex discrimination.

10 CFR Part 20

Byproduct material, Criminal penalties, Hazardous waste, Licensed material, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 21

Nuclear power plants and reactors, Penalties, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 25

Classified information, Criminal penalties, Investigations, Penalties, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 26

Administrative practice and procedure, Alcohol abuse, Alcohol testing, Appeals, Chemical testing, Drug abuse, Drug testing, Employee assistance programs, Fitness for duty, Management actions, Nuclear power plants and reactors, Privacy, Protection of information, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear energy, Nuclear materials, Penalties, Radiation protection, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR Part 40

Criminal penalties, Exports, Government contracts, Hazardous materials transportation, Hazardous waste, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Source material, Uranium, Whistleblowing.

10 CFR Part 50

Administrative practice and procedure, Antitrust, Backfitting, Classified information, Criminal penalties, Education, Emergency planning, Fire prevention, Fire protection, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Penalties, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statements, Hazardous waste, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 53

Administrative practice and procedure, Antitrust, Backfitting, Construction permit, Combined license, Classified information, Criminal penalties, Early site permit, Emergency planning, Fees, Fire prevention, Fire protection, ~~Incorporation by reference,~~ Inspection, Intergovernmental relations, Limited work authorization, Manufacturing license, Nuclear power plants and reactors, Operating license, Penalties, Prototype, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Standard design, Standard design certification, Training programs.

10 CFR Part 55

Criminal penalties, Manpower training programs, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements.

10 CFR Part 70

Classified information, Criminal penalties, Emergency medical services, Hazardous materials transportation, Material control and accounting, Nuclear energy, Nuclear materials, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material, Whistleblowing.

10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

10 CFR Part 73

Criminal penalties, Exports, Hazardous materials transportation, Imports, Incorporation by reference, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 74

Accounting, Criminal penalties, Hazardous materials transportation, Material control and accounting, Nuclear energy, Nuclear materials, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Special nuclear material.

10 CFR Part 75

Criminal penalties, Intergovernmental relations, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Security measures, Treaties.

10 CFR Part 95

Classified information, Criminal penalties, Penalties, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 140

Criminal penalties, Extraordinary nuclear occurrence, Insurance, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements.

10 CFR Part 150

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Security measures, Source material, Special nuclear material.

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Non-payment penalties, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Annual charges, Approvals, Byproduct material, Holders of certificates, Intergovernmental relations, Nonpayment penalties, Nuclear materials, Nuclear power plants and reactors, Registrations, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 1, 2, 10, 11, 19, 20, 21, 25, 26, 30, 40, 50, 51, 70, 72, 73, 74, 75, 95, 140, 150, 170, and 171 and adding 10 CFR part 53:

PART 1 – STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

1. The authority citation for part 1 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 23, 25, 29, 161, 191 (42 U.S.C. 2033, 2035, 2039, 2201, 2241); Energy Reorganization Act of 1974, secs. 201, 203, 204, 205, 209 (42 U.S.C. 5841, 5843, 5844, 5845, 5849); Administrative Procedure Act (5 U.S.C. 552, 553); Reorganization Plan No. 1 of 1980, 5 U.S.C. Appendix (Reorganization Plans).

§ 1.43 [Amended]

2. In § 1.43, add “53,” after “52,”.

PART 2 – AGENCY RULES OF PRACTICE AND PROCEDURE

3. The authority citation for part 2 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 29, 53, 62, 63, 81, 102, 103, 104, 105, 161, 181, 182, 183, 184, 186, 189, 191, 234 (42 U.S.C. 2039, 2073, 2092, 2093, 2111, 2132, 2133, 2134, 2135, 2201, 2231, 2232,2233, 2234, 2236, 2239, 2241, 2282); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); Nuclear Waste Policy Act of 1982, secs. 114(f), 134, 135, 141 (42 U.S.C. 10134(f), 10154, 10155, 10161); Administrative Procedure Act (5 U.S.C. 552, 553, 554, 557, 558); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note. Section 2.205(j) also issued under 28 U.S.C. 2461 note.

§ 2.1 [Amended]

4. In § 2.1(e), remove “part 52” and add in its place “parts 52 or 53”.

5. In § 2.4, revise the definitions for “*Contested proceeding*” and “*Facility*” to read as follows:

§ 2.4 Definitions.

* * * * *

Contested proceeding means –

(1) A proceeding in which there is a controversy between the NRC staff and the applicant for a license or permit concerning the issuance of the license or permit or any of the terms or conditions thereof;

(2) A proceeding in which the NRC is imposing a civil penalty or other enforcement action, and the subject of the civil penalty or enforcement action is an applicant for or holder of a license or permit, or is or was an applicant for or holder of a license or permit, or is or was an applicant for a standard design certification under parts 52 or 53 of this chapter; and

(3) A proceeding in which a petition for leave to intervene in opposition to an application for a license or permit has been granted or is pending before the Commission.

* * * * *

Facility means production facility or a utilization facility as defined in §§ 50.2 and 53.020 of this chapter.

* * * * *

§ 2.100 [Amended]

6. In § 2.100, add “or under subpart~~s~~ H ~~or R~~ of part 53” after “part 52”.

7. In § 2.101, revise paragraphs (a)(3)(i), (a)(5), (a)(9) introductory text and paragraph (a)(9)(i) to read as follows:

§ 2.101 Filing of application.

(a)* * *

(3)* * *

(i) Submit to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, such additional copies as the regulations in part 50, part 53, and subpart A of part 51 of this chapter require;

* * * * *

(5) An applicant for a construction permit under part 50 or part 53 of this chapter or a combined license under part 52 or part 53 of this chapter for a production or utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in § 50.21(b)(2) or (b)(3)~~;~~ or § 50.22~~;~~ or part 53~~, as applicable,~~ of this chapter, or is a testing facility, may submit the information required of applicants by parts 50, 52, or 53 of this chapter in two parts. One part shall be accompanied by the information required by § 50.30(f) of this chapter, § 52.80(b) of this chapter, or § 53.1100(f)~~, or § 53.4700(f) of this chapter~~, as applicable. The other part shall include any information required by § 50.34(a) and, if applicable, § 50.34a of this chapter; or §§ 52.79 and 52.80(a); or §§ ~~53.1109,~~ 53.1306~~, 53.1309,~~ and 53.1312; or §§ ~~53.1109,~~ ~~53.1413,~~ 53.1416, and 53.1419~~; or §§ 53.4709, 53.4906, 53.4909, and 53.4912; or §§ 53.4709, 53.5013, 53.5016, and 53.5019 of this chapter~~, as applicable. One part may precede or follow other parts by no longer than 6 months. If it is determined that either of the parts as described above is incomplete and not acceptable for processing, the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, will inform the applicant of this determination and the respects in which the document is deficient. Such a determination of completeness will generally be made within a period of 30 days. Whichever part is filed first shall also include the fee required by § 50.30(e)~~,~~ or § 53.1100(e)~~, or § 53.4700(e)~~ and § 170.21 of this chapter and the information required by §§ 50.33~~,~~ and 50.34(a)(1)~~;~~, or §§ 50.33 and 52.79(a)(1); or §§ 53.1109, 53.1306, and 53.1309~~, and 53.1369~~; or §§ ~~53.1413~~ and

Commented [A43]: Deleted to reflect the inclusion of this information in the first filed part in the remainder of this paragraph.

Commented [A44]: Deleted to reflect the inclusion of this information in the first filed part in the remainder of this paragraph.

Commented [A45]: Deleted to reflect that 53.1369 is an information submittal requirement for an OL application rather than a CP application.

53.1416(a)(1)~~53.4709, 53.4909, and 53.4969~~, as applicable, and § 50.37~~,~~ or § 53.1115, ~~or § 53.4715,~~ as applicable, of this chapter. The Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, will accept for docketing an application for a construction permit under part 50 or part 53 of this chapter or a combined license under part 52 or part 53 of this chapter for a production or utilization facility that~~which~~ is subject to § 51.20(b) of this chapter, and is of the type specified in § 50.21(b)(2) or (b)(3), or § 50.22, or part 53, as applicable, of this chapter or is a testing facility where one part of the application as described above is complete and conforms to the requirements of part 50 of this chapter. The additional parts will be docketed upon a determination by the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, that it is complete.

Commented [A46]: Inserted to reflect the part 53 equivalent of 50.33 and 52.79(a).

* * * * *

(9) An applicant for a construction permit for a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specified in § 50.21(b)(2) or (b)(3), or § 50.22, or part 53 of this chapter, an applicant for or holder of an early site permit under part 52 or part 53 of this chapter, or an applicant for a combined license under part 52 or part 53 of this chapter, who seeks to conduct the activities authorized under § 50.10(d)~~,~~ or § 53.1130~~, or § 53.4740~~ of this chapter may submit a complete application under paragraphs (a)(1) through (a)(4) of this section which includes the information required by § 50.10(d)~~,~~ or § 53.1130~~, or § 53.4740~~ of this chapter. Alternatively, the applicant (other than an applicant for or holder of an early site permit) may submit its application in two parts:

(i) Part one must include the information required by § 50.33(a) through (f), § 53.1109(a) through (e), and § 53.1306~~or § 53.4709~~ of this chapter, as applicable, and

the information required by § 50.10(d)(2) and (d)(3)~~,~~ or § 53.1130(b)(2) and (b)(3)~~, or § 53.4740(b)(2) and (b)(3)~~ of this chapter, as applicable.

* * * * *

8. In § 2.104, revise paragraph (a) to read as follows:

§ 2.104 Notice of hearing.

(a) In the case of an application on which a hearing is required by the Act or this chapter, or in which the Commission finds that a hearing is required in the public interest, the Secretary will issue a notice of hearing to be published in the *Federal Register*. The notice must be published at least 15 days, and in the case of an application concerning a limited work authorization, construction permit, early site permit, or combined license for a facility of the type described in § 50.21(b) or 50.22, or ~~subparts H or R of~~ part 53 of this chapter, as applicable, or a testing facility, at least 30 days, before the date set for hearing in the notice.[1] In addition, in the case of an application for a limited work authorization, construction permit, early site permit, or combined license for a facility of the type described in § 50.22 or ~~subparts H or R of~~ part 53 of this chapter, as applicable, or a testing facility, the notice must be issued as soon as practicable after the NRC has docketed the application. If the Commission decides, under § 2.101(a)(2), to determine the acceptability of the application based on its technical adequacy as well as completeness, the notice must be issued as soon as practicable after the application has been tendered.

[1] If the notice of hearing concerning an application for a limited work authorization, construction permit, early site permit, or combined license for a facility of the type described in § 50.21(b) or § 50.22, or ~~subparts H or R of~~ part 53 of this chapter, as applicable, or a testing facility, does not specify the time and place of initial hearing, a subsequent notice will be published in the *Federal Register* which will provide at least 30-day notice of the time and place of that hearing. After this notice is given, the presiding officer may reschedule the commencement of the initial hearing for a later date or reconvene a recessed hearing without again providing at least 30-day notice.

* * * * *

9. In § 2.105:

a. Revise paragraph (a) introductory text and paragraphs (a)(4), (a)(10), (a)(12), (a)(13); and

b. Revise paragraph (b)(3) introductory text and (b)(3)(i), (ii), and (iv).

The revisions read as follows:

§ 2.105 Notice of proposed action.

(a) If a hearing is not required by the Act or this chapter, and if the Commission has not found that a hearing is in the public interest, it will, before acting thereon, publish in the *Federal Register*, as applicable, or on the NRC's Web site, http://www.nrc.gov, or both, at the Commission's discretion, either a notice of intended operation under § 52.103(a)~~,~~ or § 53.1452(a)~~, or § 53.5052(a)~~ of this chapter, as applicable, and a proposed finding that inspections, tests, analyses, and acceptance criteria for a combined license under subpart C of part 52 or under subpart~~s~~ H ~~or R~~ of part 53, have been or will be met, or a notice of proposed action with respect to an application for:

* * * * *

(4) An amendment to an operating license, combined license, or manufacturing license for a facility licensed under §§ 50.21(b) or 50.22 or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter, as applicable, or for a testing facility, as follows:

(i) If the Commission determines under § 50.58~~,~~ or § 53.1515~~, or § 53.6015~~ of this chapter that the amendment involves no significant hazards consideration, though it will provide notice of opportunity for a hearing pursuant to this section, it may make the amendment immediately effective and grant a hearing thereafter; or

(ii) If the Commission determines under §§ 50.58 and 50.91~~;~~ or § 53.1515~~; or § 53.6015~~ of this chapter, as applicable, that an emergency situation exists or that exigent circumstances exist and that the amendment involves no significant hazards

consideration, it will provide notice of opportunity for a hearing pursuant to § 2.106 (if a hearing is requested, it will be held after issuance of the amendment);

* * * * *

(10) In the case of an application for an operating license for a facility of a type described in § 50.21(b) or § 50.22, or part 53 of this chapter or a testing facility, a notice of opportunity for hearing shall be issued as soon as practicable after the application has been docketed; or

* * * * *

(12) An amendment to an early site permit issued under subpart A of part 52, or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter, as follows:

(i) If the early site permit does not provide authority to conduct the activities allowed under § 50.10(e)(1)~~,~~ or § 53.1130(b)(1)~~, or § 53.4740(b)(1)~~ of this chapter, the amendment will involve no significant hazards consideration, and though the NRC will provide notice of opportunity for a hearing under this section, it may make the amendment immediately effective and grant a hearing thereafter; and

(ii) If the early site permit provides authority to conduct the activities allowed under § 50.10(e)(1)~~,~~ or § 53.1130(b)(1), ~~or § 53.4740(b)(1),~~ and the Commission determines under §§ 50.58 and 50.91~~;~~ or § 53.1515~~; or § 53.6015~~ of this chapter that an emergency situation exists or that exigent circumstances exist and that the amendment involves no significant hazards consideration, it will provide notice of opportunity for a hearing under § 2.106 of this chapter (if a hearing is requested, which will be held after issuance of the amendment).

(13) A manufacturing license under subpart F of part 52 or subpart~~s~~ H ~~or R~~ of part 53 of this chapter.

(b) * * *

(3) For a notice of intended operation under § 52.103(a)~~,~~ or § 53.1452(a)~~, or § 53.5052(a)~~ of this chapter, the following information:

(i) The identification of the NRC action as making the finding required under § 52.103(g)~~,~~ or § 53.1452(g)~~, or § 53.5052(g)~~ of this chapter;

(ii) The manner in which the licensee notifications under 10 CFR 52.99(c)~~,~~ or 10 CFR 53.1449(c)~~, or 10 CFR 53.5049(c) which~~ that are required to be made available by 10 CFR 52.99(e)(2)~~,~~ or 10 CFR 53.1449(e)(2)~~, or 10 CFR 53.5049(e)(2)~~ may be obtained and examined;

* * * * *

(iv) Any conditions, limitations, or restrictions to be placed on the license in connection with the finding under § 52.103(g)~~,~~ or § 53.1452(g)~~, or § 53.5052(g)~~ of this chapter, and the expiration date or circumstances (if any) under which the conditions, limitations or restrictions will no longer apply.

* * * * *

10. In § 2.106, revise paragraphs (a)(2), (a)(3), and (b)(2) introductory text to read as follows:

§ 2.106 Notice of issuance.

(a) * * *

(2) An amendment of a license for a facility of the type described in § 50.21(b) or § 50.22, or part 53 of this chapter, as applicable, or a testing facility, whether or not a notice of proposed action has been previously published; and

(3) The finding under § 52.103(g)~~,~~ or § 53.1452(g)~~, or § 53.5052(g)~~ of this chapter.

(b) * * *

(2) In the case of a finding under § 52.103(g)~~,~~ or § 53.1452(g)~~, or § 53.5052(g)~~ of this chapter:

* * * * *

11. In § 2.109, revise paragraphs (b), (c), and (d) to read as follows:

§ 2.109 Effect of timely renewal application.

* * * * *

(b) If the licensee of a nuclear power plant licensed under 10 CFR 50.21(b) or 10 CFR 50.22 or under ~~subparts H or R of~~ 10 CFR part 53 files a sufficient application for renewal of either an operating license or a combined license at least 5 years before the expiration of the existing license, the existing license will not be deemed to have expired until the application has been finally determined.

(c) If the holder of an early site permit licensed under subpart A of part 52 or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter, as applicable, files a sufficient application for renewal under § 52.29~~,~~ or § 53.1173~~, or § 53.4783~~ of this chapter, as applicable, at least 12 months before the expiration of the existing early site permit, the existing permit will not be deemed to have expired until the application has been finally determined.

(d) If the licensee of a manufacturing license under subpart F of part 52~~,~~ or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter files a sufficient application for renewal under § 52.177~~,~~ or § 53.1295~~, or § 53.4895~~ of this chapter at least 12 months before the expiration of the existing license, the existing license will not be deemed to have expired until the application has been finally determined.

* * * * *

12. In § 2.110, revise paragraphs (a)(1) and (b) to read as follows:

§ 2.110 Filing and administrative action on submittals for standard design approval or early review of site suitability issues.

(a)(1) A submittal for a standard design approval under subpart E of part 52 or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter shall be subject to §§ 2.101(a) and 2.390 to the same extent as if it were an application for a permit or license.

* * * * *

(b) Upon initiation of review by the NRC staff of a submittal for an early review of site suitability issues under Appendix Q of part 50 of this chapter, or for a standard design approval under subpart E of part 52~~,~~ or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter, the Director, Office of Nuclear Reactor Regulation, shall publish in the *Federal Register* a notice of receipt of the submittal, inviting comments from interested persons within 60 days of publication or other time as may be specified, for consideration by the NRC staff and ACRS in their review.

* * * * *

13. In § 2.202, revise paragraph (e) to read as follows:

§ 2.202 Orders.

* * * * *

(e)(1) If the order involves the modification of a part 5~~3~~0 license, except for a combined license, early site permit, manufacturing license, or general license under § 53.810 of this chapter, or a part 5~~0~~3 license and is a backfit, the requirements of § 50.109~~,~~ or § 53.1590~~, or § 53.6090~~ of this chapter, as applicable, shall be followed, unless the licensee has consented to the action required.

(2) If the order involves the modification of combined license under subpart C of part 52, or subpart~~s~~ H ~~or R~~ of part 53 of this chapter, the requirements of § 52.98~~,~~ or

Commented [A47]: These exceptions are inserted to reflect the broad definition of "license" in 53.020 and acknowledge that the listed exceptions are covered elsewhere in this section as appropriate.

§ 53.1443~~, or § 53.5043~~ of this chapter, as applicable, shall be followed unless the licensee has consented to the action required.

(3) If the order involves a change to an early site permit under subpart A of part 52 or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter, the requirements of § 52.39~~,~~ or § 53.1188~~, or § 53.4798~~ of this chapter, as applicable, must be followed, unless the applicant or licensee has consented to the action required.

(4) If the order involves a change to a standard design certification rule referenced by that plant's application, the requirements, if any, in the referenced design certification rule with respect to changes must be followed, or, in the absence of these requirements, the requirements of § 52.63~~,~~ or § 53.1263~~, or § 53.4863~~ of this chapter, as applicable, must be followed, unless the applicant or licensee has consented to follow the action required.

(5) If the order involves a change to a standard design approval referenced by that plant's application, the requirements of § 52.145~~,~~ or § 53.1221~~, or § 53.4821~~ of this chapter, as applicable, must be followed unless the applicant or licensee has consented to follow the action required.

(6) If the order involves a modification of a manufacturing license under subpart F of part 52 or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter, the requirements of § 52.171~~,~~ or § 53.1288~~, or § 53.4888~~ of this chapter, as applicable, must be followed, unless the applicant or licensee has consented to the action required.

14. In § 2.309, revise paragraphs (a), (f)(1)(i), (f)(1)(vi) and (vii), (g), (h)(2), (i)(2), (j) to read as follows:

§ 2.309 Hearing requests, petitions to intervene, requirements for standing, and contentions.

(a) *General requirements*. Any person whose interest may be affected by a proceeding and who desires to participate as a party must file a written request for hearing and a specification of the contentions which the person seeks to have litigated in the hearing. In a proceeding under § 52.103~~,~~ or § 53.1452~~, or § 53.5052,~~ of this chapter, as applicable, the Commission, acting as the presiding officer, will grant the request if it determines that the requestor has standing under the provisions of paragraph (d) of this section and has proposed at least one admissible contention that meets the requirements of paragraph (f) of this section.

* * * * *

(f) * * *

(1) * * *

(i) Provide a specific statement of the issue of law or fact to be raised or controverted, provided further, that the issue of law or fact to be raised in a request for hearing under § 52.103(b)~~,~~ or § 53.1452(b)~~, or § 53.5052(b),~~ of this chapter~~, as applicable,~~ must be directed at demonstrating that one or more of the acceptance criteria in the combined license have not been, or will not be met, and that the specific operational consequences of nonconformance would be contrary to providing reasonable assurance of adequate protection of the public health and safety;

* * * * *

(vi) In a proceeding other than one under § 52.103~~,~~ or § 53.1452~~, or § 53.5052,~~ of this chapter provide sufficient information to show that a genuine dispute exists with the applicant/licensee on a material issue of law or fact. This information must include references to specific portions of the application (including the applicant's environmental report and safety report) that the petitioner disputes and the supporting reasons for each dispute, or, if the petitioner believes that the application fails to contain information on a

Commented [A48]: Staff should confirm that the amendatory instructions proposed here will not result in the deletion of the remainder of paragraph (a) and make appropriate modifications to prevent that if needed.

relevant matter as required by law, the identification of each failure and the supporting reasons for the petitioner's belief; and

(vii) In a proceeding under § 52.103(b)~~,~~ or § 53.1452(b)~~, or § 53.5052(b),~~ of this chapter~~, as applicable, the~~ provide sufficient information ~~must be sufficient~~, ~~and~~ includinge supporting information showing, prima facie, that one or more of the acceptance criteria in the combined license have not been, or will not be met, and that the specific operational consequences of nonconformance would be contrary to providing reasonable assurance of adequate protection of the public health and safety. This information must include the specific portion of the report required by § 52.99(c)~~,~~ or § 53.1449(c)~~, or § 53.5049(c),~~ of this chapter, as applicable, thatwhich the requestor believes is inaccurate, incorrect, and/or incomplete (i.e., fails to contain the necessary information required by § 52.99(c)~~,~~ or § 53.1449(c)~~, or § 53.5049(c),~~ of this chapter, as applicable). If the requestor identifies a specific portion of the report under § 52.99(c)~~,~~ or § 53.1449(c)~~, or § 53.5049(c),~~ of this chapter, as applicable, ~~report~~ as incomplete and the requestor contends that the incomplete portion prevents the requestor from making the necessary *prima facie* showing, then the requestor must explain why this deficiency prevents the requestor from making the *prima facie* showing.

* * * * *

(g) *Selection of hearing procedures*. A request for hearing and/or petition for leave to intervene may, except in a proceeding under § 52.103~~,~~ or § 53.1452~~, or § 53.5052, as applicable~~, also address the selection of hearing procedures, taking into account the provisions of § 2.310. If a request/petition relies upon § 2.310(d), the request/petition must demonstrate, by reference to the contention and the bases provided and the specific procedures in subpart G of this part, that resolution of the

contention necessitates resolution of material issues of fact which may be best determined through the use of the identified procedures.

(h) * * *

(1) * * *

(2) If the proceeding pertains to a production or utilization facility (as defined in § 50.2 or § 53.020 of this chapter) located within the boundaries of the State, local governmental body, or Federally-recognized Indian Tribe seeking to participate as a party, no further demonstration of standing is required. If the production or utilization facility is not located within the boundaries of the State, local governmental body, or Federally-recognized Indian Tribe seeking to participate as a party, the State, local governmental body, or Federally-recognized Indian Tribe also must demonstrate standing.

* * * * *

(i) * * *

(2) Except in a proceeding under § 52.103~~,~~ or § 53.1452~~, or § 53.5052~~ of this chapter~~, as applicable~~, the participant who filed the hearing request, intervention petition, or motion for leave to file new or amended contentions after the deadline may file a reply to any answer. The reply must be filed within 7 days after service of that answer.

* * * * *

(j) *Decision on request/petition*.

(1) In all proceedings other than a proceeding under § 52.103~~,~~ or § 53.1452~~, or § 53.5052~~ of this chapter~~, as applicable~~, the presiding officer shall issue a decision on each request for hearing or petition to intervene within 45 days of the conclusion of the initial pre-hearing conference or, if no pre-hearing conference is conducted, within 45 days after the filing of answers and replies under paragraph (i) of this section. With

respect to a request to admit amended or new contentions, the presiding officer shall issue a decision on each such request within 45 days of the conclusion of any pre-hearing conference that may be conducted regarding the proposed amended or new contentions or, if no pre-hearing conference is conducted, within 45 days after the filing of answers and replies, if any. In the event the presiding officer cannot issue a decision within 45 days, the presiding officer shall issue a notice advising the Commission and the parties, and the notice shall include the expected date of when the decision will issue.

(2) The Commission, acting as the presiding officer, shall expeditiously grant or deny the request for hearing in a proceeding under § 52.103~~,~~ or § 53.1452~~, or § 53.5052~~ of this chapter~~, as applicable~~. The Commission's decision may not be the subject of any appeal under § 2.311.

15. In § 2.310:

a. Add "53," in sequential order to paragraph (a) and paragraph (h) introductory text; and

b. Revise paragraphs (i) and (j).

The revisions read as follows:

§ 2.310 Selection of hearing procedures.

* * * * *

(i) In design certification rulemaking proceedings under part 52 or part 53 of this chapter, any informal hearing held under § 52.51~~,~~ or § 53.1242~~, or § 53.4842~~ of this chapter, ~~as applicable,~~ must be conducted under the procedures of subpart O of this part.

(j) Proceedings on a Commission finding under § 52.103(c) and (g)~~;~~ or § 53.1452(c) and (g)~~; or § 53.5052(c) and (g)~~ of this chapter, ~~as applicable,~~ shall be

conducted in accordance with the procedures designated by the Commission in each proceeding.

* * * * *

16. In § 2.329, revise paragraph (a) to read as follows:

§ 2.329 Prehearing conference.

(a) *Necessity for prehearing conference; timing*. The Commission or the presiding officer may, and in the case of a proceeding on an application for a construction permit or an operating license for a facility of a type described in § 50.21(b) or § 50.22, or part 53 of this chapter, or a testing facility, must~~shall~~ direct the parties or their counsel to appear at a specified time and place for a conference or conferences before trial. A prehearing conference in a proceeding involving a construction permit or operating license for a facility of a type described in § 50.21(b) or § 50.22 or part 53 of this chapter must be held within sixty (60) days after discovery has been completed or any other time specified by the Commission or the presiding officer.

* * * * *

17. In § 2.339, revise paragraph (d) to read as follows:

§ 2.339 Expedited decision-making procedure.

* * * * *

(d) The provisions of this section do not apply to an initial decision directing the issuance of a limited work authorization under § ~~10 CFR~~ 50.10~~,~~ or ~~10 CFR §~~ 53.1130 of this chapter~~, or 10 CFR 53.4740~~; an early site permit under subpart A of part 52 or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter; a construction permit ~~or construction authorization~~ under part 50 or part 53 of this chapter; a combined license under subpart C of part 52 or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter; or a manufacturing license under subpart F of part 52 or under subpart~~s~~ H ~~or R~~ of part 53.

Commented [A49]: Staff should determine whether there is a continuing need for the undefined term "construction authorization" in this section. If the staff identifies such a need, staff should restore the term here.

18. In § 2.340:

a. In paragraph (b), add the phrase “or part 53” after the phrase “part 52” wherever it appears;

b. Revise paragraph (c);

c. In paragraph (d) introductory text, add the phrase “or part 53” after the phrase “part 52”; in paragraphs (d)(1) and (2), add the phrase “or subpart~~s~~ H ~~or R~~ of part 53” after the phrase “part 52”;

d. Revise paragraph (f) and (i); and

e. Revise paragraph (j) introductory text and paragraph (j)(1).

The revisions read as follows:

§ 2.340 Initial decision in certain contested proceedings; immediate effectiveness of initial decisions; issuance of authorizations, permits and licenses.

* * * * *

(c) *Initial decision on findings under* 10 CFR *52.103~~,~~* or *53.1452~~, or 53.5052~~ with respect to acceptance criteria in nuclear power reactor combined licenses*. In any initial decision under § 52.103(g)~~,~~ or § 53.1452(g)~~, or § 53.5052(g)~~ of this chapter with respect to whether acceptance criteria have been or will be met, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties, and any matter designated by the Commission to be decided by the presiding officer. Matters not put into controversy by the parties but identified by the presiding officer as matters requiring further examination, shall be referred to the Commission for its determination; the Commission may, in its discretion, treat any of these referred matters as a request for action under § 2.206 and process the matter in accordance with § 52.103(f)~~,~~ or § 53.1452(f)~~, or § 53.5052(f)~~ of this chapter.

* * * * *

(f) *Immediate effectiveness of certain presiding officer decisions.* A presiding officer's initial decision directing the issuance or amendment of a limited work authorization under § 50.10~~,~~ or § 53.1130~~, or § 53.4740~~ of this chapter; an early site permit under subpart A of part 52 or under subpart~~s~~ H ~~or R~~ of part 53; a construction permit or construction authorization under part 50 or part 53 of this chapter; an operating license under part 50 or part 53 of this chapter; a combined license under subpart C of part 52 or part 53 of this chapter; a manufacturing license under subpart F of part 52 or part 53 of this chapter; a renewed license under part 53 or part 54 of this chapter; or a license under part 72 of this chapter to store spent fuel in an independent spent fuel storage facility (ISFSI) or a monitored retrievable storage installation (MRS); an initial decision directing issuance of a license under part 61 of this chapter; or an initial decision under § 52.103(g)~~,~~ or § 53.1452(g)~~, or § 53.5052(g)~~ of this chapter that acceptance criteria in a combined license have been met, is immediately effective upon issuance unless the presiding officer finds that good cause has been shown by a party why the initial decision should not become immediately effective.

* * * * *

(i) *Issuance of authorizations, permits, and licenses—production and utilization facilities.* The Commission or the Director, Office of Nuclear Reactor Regulation, as appropriate, shall issue a limited work authorization under § 50.10~~,~~ or § 53.1130~~, or § 53.4740~~ of this chapter; an early site permit under subpart A of part 52 or subpart~~s~~ H ~~or R~~ of part 53 of this chapter; a construction permit ~~or construction authorization~~ under part 50 or part 53 of this chapter; an operating license under part 50 or part 53 of this chapter; a combined license under subpart C of part 52 or part 53 of this chapter; or a manufacturing license under subpart F of part 52 or part 53 of this chapter within 10 days from the date of issuance of the initial decision:

* * * * *

(j) *Issuance of finding on acceptance criteria under 10 CFR 52.103~~,~~ or 10 CFR 53.1452~~, or 10 CFR 53.5052~~*. The Commission or the Director, Office of Nuclear Reactor Regulation, as appropriate, shall make the finding under § ~~-~~52.103(g)~~,~~ or § 53.1452(g)~~, or § 53.5052(g)~~ of this chapter~~,~~ that acceptance criteria in a combined license are met within 10 days from the date of the presiding officer's initial decision:

(1) If the Commission or the Director is otherwise able to make the finding under § ~~-~~52.103(g)~~,~~ or § 53.1452(g)~~, or § 53.5052(g)~~ of this chapter, that the prescribed acceptance criteria are met for those acceptance criteria not within the scope of the initial decision of the presiding officer;

* * * * *

§ 2.341 [Amended]

19. In § 2.341(a)(1), add "or § 53.1452(c)~~, or § 53.5052(c)~~" after "§ 52.103(c),".

§ 2.400 [Amended]

20. In § 2.400, add the phrase ", or § 53.1470 ~~or § 53.5070~~" after the phrase, "appendix N of parts 50 or 52".

21. In § 2.401, revise the section heading and paragraph (a) to read as follows:

§ 2.401 Notice of hearing on construction permit or combined license applications ~~pursuant to appendix N of 10 CFR parts 50 or 52, or part 53~~for nuclear power plants of identical design at multiple sites.

(a) In the case of applications under~~pursuant to~~ appendix N of part 50, or § 53.1470 ~~or § 53.5070~~ of this chapter for construction permits for nuclear power reactors of the type described in § 50.22 or part 53 of this chapter, or applications ~~pursuant to~~ under appendix N of part 52, or § 53.1470 ~~or § 53.5070~~ of this chapter for combined licenses, the Secretary will issue notices of hearing pursuant to § 2.104.

* * * * *

§ 2.402 [Amended]

22. In § 2.402**:**

a. Add the phrase, "~~,~~ or § 53.1470 ~~or § 53.5070~~" after the phrase "appendix N of part 50";

b. Add "or part 53" after "10 CFR 50.22"; and

c. Add "~~,~~ or § 53.1470 ~~or § 53.5070~~" after "appendix N of part 52".

~~**§ 2.403 [Amended]**~~

23. In § 2.403, revise the section heading and the unnumbered paragraph to read as follows:~~add ", or § 53.1470 or § 53.5070" after "appendix N of part 50".~~

§ 2.403 Notice of proposed action on applications for operating licenses for nuclear power plants of identical design at multiple sites.

In the case of applications pursuant to appendix N of part 50 or § 53.1470 of this chapter for operating licenses for nuclear power reactors, if the Commission has not found that a hearing is in the public interest, the Commission or the Director, Office of Nuclear Reactor Regulation, as appropriate, will, prior to acting thereon, cause to be published in the Federal Register, pursuant to § 2.105, a notice of proposed action with respect to each application as soon as practicable after the applications have been docketed.

~~**§ 2.404 [Amended]**~~

24. In § 2.404, revise the section heading and the unnumbered paragraph to read as follows:~~add ", or § 53.1470 or § 53.5070" after "appendix N of part 50".~~

§ 2.404 Hearings on applications for operating licenses for nuclear power plants of identical design at multiple sites.

If a request for a hearing and/or petition for leave to intervene is filed within the time prescribed in the notice of proposed action on an application for an operating license pursuant to appendix N of part 50 or § 53.1470 of this chapter with respect to a specific reactor(s) at a specific site, and the Commission, the Chief Administrative Judge, or a presiding officer has issued a notice of hearing or other appropriate order, then the Commission, the Chief Administrative Judge, or the presiding officer may order separate hearings on particular phases of the proceeding and/or consolidate for hearing two or more proceedings in the manner described in § 2.402.

§ 2.405 [Amended]

25. In § 2.405, add "or part 53" after "part 52".

§ 2.406 [Amended]

26. In § 2.406, add "~~, or~~ § 53.1470 ~~or § 53.5070~~" after "appendix N of parts 50 or 52".

§ 2.500 [Amended]

27. In § 2.500, add "or subpart~~s~~ H ~~or R~~ of part 53" after "of part 52".

28. In § 2.501, revise the section heading and paragraph (a) introductory text to read as follows:

§ 2.501 Notice of hearing on application under 10 CFR parts 52 or 53 for a license to manufacture nuclear power reactors.

(a) In the case of an application under subpart F of part 52, or subpart~~s~~ H ~~or R~~ of part 53 of this chapter for a license to manufacture nuclear power reactors of the type described in § 50.22 or part 53 of this chapter to be operated at sites not identified in the license application, the Secretary will issue a notice of hearing to be published in the *Federal Register* at least 30 days before the date set for hearing in the notice.[1] The

notice shall be issued as soon as practicable after the application has been docketed. The notice will state:

* * * * *

§ 2.643 [Amended]

29. In § 2.643(b):

a. Add "; or part 53" after "or § 50.22"; and

b. Add "~~,~~or § 53.1130(a)(3)~~, or § 53.4740(a)(3)~~" after "§ 50.10(d)(3)".

30. In § 2.645(a), revise paragraph (a) to read as follows:

§ 2.645 Notice of hearing~~[Amended]~~

~~30. In § 2.645(a), add ", § 53.1109, or § 53.4709" after "(a) through (f)".~~

(a) The notice of hearing on part one of the application must set forth the matters of fact and law to be considered, as required by § 2.104, which will be modified to state that the hearing will relate only to the matters related to § 50.33(a) through (f) of this chapter, or § 53.1109 and § 53.1306 or § 53.1413 of this chapter, as applicable, and the limited work authorization.

Commented [A50]: Added to capture the equivalent information to 50.33(f) in part 53 applications for construction permits or combined licenses with limited work authorizations.

§ 2.649 [Amended]

31. In § 2.649, add "~~,~~or 10 CFR 53.1130(b~~a~~)~~, or 10 CFR 53.4740(a)~~" after "10 CFR50.10(d)".

§ 2.800 [Amended]

32. In § 2.800, add "~~,~~or subpart~~s~~ H ~~or R~~ of part 53" after "subpart B of part 52" wherever it may appear.

§ 2.801 [Amended]

33. In § 2.801, add "~~,~~or subpart~~s~~ H ~~or R~~ of part 53" after "subpart B of part 52".

§ 2.813 [Amended]

34. In § 2.813(a), add ", 53~~,~~" after "parts 50, 52".

§ 2.1103 [Amended]

35. In § 2.1103, add “or part 53” after “part 50”.

36. In § 2.1202, revise paragraphs (a)(1) through (3) and (a)(6) to read as follows:

§ 2.1202 Authority and role of NRC staff.

(a) * * *

(1) An application to construct and/or operate a production or utilization facility (including an application for a limited work authorization under § 50.12~~,~~ or § 53.1130~~, or § 53.4740~~ of this chapter, or an application for a combined license under subpart C of 10 CFR part 52, or under subpart~~s~~ H ~~or R~~ of 10 CFR part 53;

(2) An application for an early site permit under subpart A of 10 CFR part 52 or under subpart~~s~~ H ~~or R~~ of 10 CFR part 53;

(3) An application for a manufacturing license under subpart F of 10 CFR part 52 or under subpart~~s~~ H ~~or R~~ of 10 CFR part 53;

* * * * *

(6) Production or utilization facility licensing actions that involve significant hazards considerations as defined in § 50.92~~,~~ or § 53.1520~~, or § 53.6020~~ of this chapter.

* * * * *

§ 2.1301 [Amended]

37. In § 2.1301(b), remove “part 50 and part 52” and add in its place “parts 50, 52, and 53”~~ after “10 CFR.”~~

§ 2.1403 [Amended]

38. In § 2.1403(a)(3), add “or 10 CFR 53.1520~~, or 10 CFR 53.6020~~” after “10 CFR 50.92”.

§ 2.1500 [Amended]

39. In § 2.1500, add “or under subpart~~s~~ H ~~or R~~ of part 53” after “subpart B of part 52”.

§ 2.1502 [Amended]

40. In § 2.1502:

a. In paragraph (a), add “~~,~~or § 53.1242(b)(2)~~, or § 53.4842(b)(2)~~” after “§ 52.51(b)".

b. In paragraph (b)(1), wherever it may appear, add “~~,~~or § 53.1242(b)~~, or § 53.4842(b)~~” after “§ 52.51(a)”.

PART 10 – CRITERIA AND PROCEDURES FOR DETERMINING ELIGIBILITY FOR ACCESS TO RESTRICTED DATA OR NATIONAL SECURITY INFORMATION OR AN EMPLOYMENT CLEARANCE

41. The authority citation for part 10 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 145, 161 (42 U.S.C. 2165, 2201); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); E.O. 10450, 18 FR 2489, 3 CFR, 1949-1953 Comp., p. 936, as amended; E.O. 10865, 25 FR 1583, 3 CFR, 1959-1963 Comp., p. 398, as amended; E.O. 12968, 60 FR 40245, 3 CFR, 1995 Comp., p. 391.

§ 10.1 [Amended]

42. In § 10.1(a)(3), add “or part 53” after “under part 52”.

§ 10.2 [Amended]

43. In § 10.~~3~~2(b), wherever it may appear, add “or part 53” after “under part 52”.

PART 11 – Criteria and Procedures for Determining Eligibility for Access to or Control Over Special Nuclear Material

44. The authority citation for 10 CFR part 11 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 161, 223 (42 U.S.C. 2201, 2273); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 44 U.S.C. 3504 note. Section 11.15(e) also issued under 31 U.S.C. 9701; 42 U.S.C. 2214.

§ 11.7 [Amended]

45. In § 11.7 introductory text, add the number “53” in numerical order.

PART 19 – NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTION AND INVESTIGATIONS

46. The authority citation for part 19 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 63, 81, 103, 104, 161, 223, 234, 1701 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 211, 401 (42 U.S.C. 5841, 5851, 5891); 44 U.S.C. 3504 note.

§ 19.2 [Amended]

47. In § 19.2:

a. In paragraph (a)(1), remove "under parts 50 or 52" and add in its place "under parts 50, 52, or 53" ~~after "utilization facility"~~;

b. In paragraph (a)(2) add "53," after "52,"; and

c. In paragraphs (a)(3) and (4) add "or under subpart~~s~~ H ~~or R~~ of part 53" after "of part 52", wherever it may appear.

48. In § 19.3, revise the definitions for "*License*" and "*Regulated entities*" to read as follows:

§ 19.3 Definitions.

* * * * *

License means a license issued under the regulations in parts 30 through 36, 39, 40, 60, 61, 63, 70, or 72 of this chapter, including licenses to manufacture, construct and/or operate a production or utilization facility under parts 50, 52, 53, or 54 of this chapter.

* * * * *

Regulated entities means any individual, person, organization, or corporation that is subject to the regulatory jurisdiction of the NRC, including (but not limited to) an applicant for or holder of a standard design approval under subpart E of part 52 or under

subpart~~s~~ H ~~or R~~ of part 53 of this chapter or a standard design certification under subpart B of part 52 or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter.

* * * * *

§ 19.11 [Amended]

49. In § 19.11, add “or under subpart~~s~~ H ~~or R~~ of part 53" after “of part 52”, wherever it may appear.

§ 19.14 [Amended]

50. In § 19.14(a), add “or under subpart~~s~~ H ~~or R~~ of part 53" after “of part 52”, wherever it may appear.

§ 19.20 [Amended]

51. In § 19.20, add “53,” after “52,”.

PART 20 – STANDARDS FOR PROTECTION AGAINST RADIATION

52. The authority citation for part 20 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 53, 63, 65, 81, 103, 104, 161, 170H, 182, 186, 223, 234, 274, 1701 (42 U.S.C. 2014, 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2210h, 2232, 2236, 2273, 2282, 2021, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Low-Level Radioactive Waste Policy Amendments Act of 1985, sec. 2 (42 U.S.C. 2021b); 44 U.S.C. 3504 note.

§ 20.1002 [Amended]

53. In § 20.1002, add “53,” after “52,”.

§ 20.1003 [Amended]

54. In § 20.1003, revise the definition for “*License*” by adding “52, 53,” after “502,”.

§ 20.1101 [Amended]

55. In § 20.1101(d), add “or § 53.260(b)~~, or § 53.4730(a)(3)~~ of this chapter” after “subject to § 50.34a”.

§ 20.1401 [Amended]

56. In § 20.1401, in paragraph (a) add “53,” after “52,”; and in paragraphs (a) and (c) add “~~,~~or § 53.1080~~, or § 53.4680~~” after “in accordance with § 50.83”.

§ 20.1403 [Amended]

57. In § 20.1403(d) introductory text, ~~add~~ remove “§~~§~~ 30.36(d), ~~§~~ 40.42(d), ~~§~~ 50.82 (a) and (b), ~~subparts G or Q of part 53,~~ § 70.38(d), or § 72.54” and add in its place “§ 30.36(d), § 40.42(d), § 50.82(a) and (b), subpart G of part 53, § 70.38(d), or § 72.54”~~after “in accordance with”~~.

§ 20.1404 [Amended]

58. In § 20.1404(a)(4) introductory text, remove “§§ 30.36(d), 40.42(d), 50.82 (a) and (b), 70.38(d), or 72.54” and add in its place “§ 30.36(d), § 40.42(d), § 50.82(a) and (b), subpart~~s~~ G ~~or Q~~ of part 53, § 70.38(d), or § 72.54”~~ after “in accordance with”~~.

§ 20.1406 [Amended]

59. In § 20.1406, add “or part 53” after “under part 52” wherever it may appear.

§ 20.1501 [Amended]

60. In § 20.1501(b), remove “§§ 30.35(g), 40.36(f), 50.75(g), 70.25(g), or 72.30(d),” and add in its place “§ 30.35(g), § 40.36(f), § 50.75(g), subpart~~s~~ G ~~or Q of~~ part 53, § 70.25(g), or § 72.30(d) of this chapter,”~~ after “in accordance with”~~.

§ 20.1905 [Amended]

61. In § 20.1905(g) introductory text, remove “Parts 50 or 52” and add in its place “parts 50, 52, or 53”~~ after “facility licensed under”~~.

62. In § 20.2004, revise paragraph (b)(1) to read as follows:

§ 20.2004 Treatment or disposal by incineration.

* * * * *

(b)(1) Waste oils (petroleum derived or synthetic oils used principally as lubricants, coolants, hydraulic or insulating fluids, or metalworking oils) that have been

radioactively contaminated in the course of the operation or maintenance of a nuclear power reactor licensed under parts 50, 52, or ~~part~~ 53 of this chapter may be incinerated on the site where generated provided that the total radioactive effluents from the facility, including the effluents from such incineration, conform to the requirements of appendix I to part 50~~,~~ or § 53.425(d) ~~or § 53.4730(a)(3)~~ of this chapter and the effluent release limits contained in applicable license conditions other than effluent limits specifically related to incineration of waste oil. The licensee shall report any changes or additions to the information supplied under § 50.34, § 50.34a, or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter associated with this incineration pursuant to § 50.71~~,~~ or § 53.1620~~, or § 53.6320~~ of this chapter, as appropriate. The licensee shall also follow the procedures of § 50.59~~,~~ or § 53.1565~~, or § 53.6065~~ of this chapter with respect to such changes to the facility or procedures.

* * * * *

63. In § 20.2201, revise paragraphs (a)(2)(i), (b)(2)(i), and (c) to read as follows:

§ 20.2201 Reports of theft or loss of licensed material.

(a) * * *

(2) * * *

(i) Licensees having an installed Emergency Notification System shall make the reports to the NRC Operations Center under~~in accordance with~~ § 50.72~~,~~ or § 53.1630~~, or § 53.6330~~ of this chapter, and

* * * * *

(b) * * *

(2) * * *

(i) For holders of an operating license for a nuclear power plant, the events included in paragraph (b) of this section must be reported under~~in accordance with~~ the

procedures described in § 50.73(b), (c), (d), (e), and (g)~~,~~ or § 53.1640(b), (c), (d), (e), and (g)~~, or § 53.6340(b), (c), (d), (e), and (g)~~ of this chapter and must include the information required in paragraph (b)(1) of this section, and

* * * * *

(c) A duplicate report is not required under paragraph (b) of this section if the licensee is also required to submit a report pursuant to § 30.55(c), § 37.57, § 37.81, § 40.64(c), § 50.72, § 50.73, § 53.1630, § 53.1640, ~~§ 53.6330, § 53.6340,~~ § 70.52, § 73.27(b), § 73.67(e)(3)(vii), § 73.67(g)(3)(iii), § 73.71, or § 150.19(c) of this chapter.

* * * * *

§ 20.2202 [Amended]

64. In § 20.2202(d)(1), remove "10 CFR 50.72 and add in its place "§ 50.72~~,~~ or § 53.1630~~, or § 53.6330~~ of this chapter;" ~~after "in accordance with"~~.

65. In § 20.2203, revise paragraph (c) to read as follows:

§ 20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

* * * * *

(c) For holders of an operating license or a combined license for a nuclear power plant, the occurrences included in paragraph (a) of this section must be reported under~~in accordance with~~ the procedures described in § 50.73(b), (c), (d), (e), and (g)~~,~~ or § 53.1640(b), (c), (d), (e), and (g)~~, or § 53.6340(b), (c), (d), (e), and (g)~~ of this chapter, and must include the information required by paragraph (b) of this section. Occurrences reported under~~in accordance with~~ § 50.73~~,~~ or § 53.1640~~, or § 53.6340~~ of this chapter need not be reported by a duplicate report under paragraph (a) of this section.

* * * * *

§ 20.2206 [Amended]

66. In § 20.2206(a)(1), remove "or § 50.22" and add in its place ", § 50.22, or part 53" ~~after "pursuant to § 50.21(b)"~~.

PART 21 – REPORTING OF DEFECTS AND NONCOMPLIANCE

67. The authority citation for part 21 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 63, 81, 103, 104, 161, 223, 234, 1701 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

68. In § 21.2:

a. In paragraph (a)(2), remove "or 52" and add in its place ", 52, or 53" ~~after "operation under parts 50",~~ and add "53," after "40, 50, 52,";

b. In paragraphs (a)(3) and (4) add "or part 53" after "under part 52", wherever it may appear; and

c. Revise paragraphs (b) and (c) to read as follows:

§ 21.2 Scope.

* * * * *

(b) For persons licensed to construct a facility under either a construction permit issued under § 50.23~~,~~ or § 53.1333~~, or § 53.4933~~ of this chapter or a combined license under part 52 or part 53 of this chapter (for the period of construction until the date that the Commission makes the finding under § 52.103(g)~~,~~ or § 53.1452(g)~~, or § 53.5052(g)~~ of this chapter), or to manufacture a facility under part 52 or part 53 of this chapter, evaluation of potential defects and failures to comply and reporting of defects and failures to comply under § 50.55(e)~~,~~ or § 53.605~~, or § 53.4105~~ of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects and failures to comply under this part and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.

(c) For persons licensed to operate a nuclear power plant under part 50, part 52, or part 53 of this chapter, evaluation of potential defects and appropriate reporting of defects under § 50.72, § 50.73, § 53.1630, § 53.1640, ~~§ 53.6330, § 53.6340,~~ or §§ 73.1200~~71~~ and 73.1205 of this chapter, satisfies each person's evaluation, notification, and reporting obligation to report defects under this part, and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.

* * * * *

69. In § 21.3, revise the definitions for "*Basic component*", "*Commercial grade item*", "*Critical characteristics*", "*Dedicating entity*", "*Dedication*", "*Defect*", and "*Substantial safety hazard*" to read as follows:

§ 21.3 Definitions.

* * * * *

Basic component. (1)(i) When applied to nuclear power plants licensed under ~~10 CFR~~ part 53 of this chapter, basic component means a safety-related structure, system, or component, or part thereof, and when applied to nuclear power plants licensed under ~~10 CFR~~ part 50~~,~~ or part 52, of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

* * * * *

~~(C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), § 53.210, § 53.4730(a)(1)(vi), or § 100.11 of this chapter, as applicable.~~

Commented [A51]: Deleted to reflect no necessary changes as the accidents referred to by this paragraph are only applicable to nuclear power plants licensed under parts 50 and 52.

~~(ii) Basic components are items designed and manufactured under a quality assurance program complying with appendix B to part 50 of this chapter or subparts K or Q of part 53 of this chapter, or commercial grade items which have successfully completed the dedication process.~~

(2) When applied to standard design certifications and approvals under part 53 of this chapter, basic component means the design or procurement information approved or to be approved within the scope of the design certification or approval for a safety-related structure, system, or component, or part thereof. When applied to standard design certifications under subpart B of part 52~~, or subparts H or R of part 53~~ of this chapter and standard design approvals under part 52 ~~or part 53~~ of this chapter, basic component means the design or procurement information approved or to be approved within the scope of the design certification or approval for a structure, system, or component, or part thereof, that affects its safety function necessary to assure:

* * * * *

~~(iii) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), § 53.210, § 53.4730(a)(1)(vi), or § 100.11 of this chapter, as applicable.~~

* * * * *

(4) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under part 52 or part 53 of this chapter, whether these services are performed by the component supplier or others.

Commercial grade item. (1) When applied to nuclear power plants licensed underpursuant to 10 CFR part 50 or 10 CFR part 53, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

* * * * *

Critical characteristics. When applied to nuclear power plants licensed underpursuant to 10 CFR parts 50, 52, or 10 CFR part 53 of this chapter, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedicating entity. When applied to nuclear power plants licensed underpursuant to 10 CFR parts 50, 52, or 10 CFR part 53 of this chapter, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, underpursuant to § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.

Dedication. (1) When applied to nuclear power plants licensed pursuant to 10 CFR parts 30, 40, 50, 52, or 53 of this chapter, 60, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR part 50,

~~appendix B, or 10 CFR part 53, subparts K or U,~~ quality assurance program under appendix B to part 50 of this chapter. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted under~~in accordance with~~ the applicable provisions of ~~10 CFR part 50,~~ appendix B to part 50 of this chapter~~, or 10 CFR part 53, subparts K or U~~. The process is considered complete when the item is designated for use as a basic component.

* * * * *

Defect means:

(1) * * *

(3) A deviation in a portion of a facility subject to the early site permit, standard design certification, standard design approval, construction permit, combined license or manufacturing licensing requirements of parts 50, ~~part~~ 52, or ~~part~~ 53 of this chapter, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance;

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued under parts 50, ~~part~~ 52, or ~~part~~ 53 of this chapter; or

* * * * *

Substantial safety hazard means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for

any facility or activity licensed or otherwise approved or regulated by the NRC, other than for export, under parts 30, 40, 50, 52, 53, 60, 61, 63, 70, 71, or 72 of this chapter.

* * * * *

§ 21.21 [Amended]

70. In § 21.21:

a. In paragraph (a)(3) add “or part 53” after “under part 52” wherever it may appear; and

b. In paragraph (d)(1) add “53,” after “40, 50, 52” wherever they may appear.

§ 21.51 [Amended]

71. In § 21.51, add “or under subparts H or R of part 53” after “of part 52”, wherever it may appear.

§ 21.61 [Amended]

72. In § 21.61(b), add “or part 53” after “under part 52”, wherever it may appear.

PART 25 – ACCESS AUTHORIZATION

73. The authority citation for part 25 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 145, 161, 223, 234 (42 U.S.C. 2165, 2201, 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 44 U.S.C. 3504 note; E.O. 10865, 25 FR 1583, as amended, 3 CFR, 1959-1963 Comp., p. 398; E.O. 12829, 58 FR 3479, 3 CFR, 1993 Comp., p. 570; E.O. 13526, 75 FR 707, 3 CFR, 2009 Comp., p. 298; E.O. 12968, 60 FR 40245, 3 CFR, 1995 Comp., p. 391. Section 25.17(f) and Appendix A also issued under 31 U.S.C. 9701; 42 U.S.C. 2214.

§ 25.5 [Amended]

74. In § 25.5, in the definition for “*License*”, add “53,” after “50, 52”.

§ 25.17 [Amended]

75. In § 25.17(a), add “53,” after “50, 52”.

§ 25.35 [Amended]

76. In § 25.35(a), add “or part 53” after “under part 52”, wherever it may appear.

PART 26—FITNESS FOR DUTY PROGRAMS.

77. The authority citation for part 26 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 103, 104, 107, 161, 223, 234, 1701 (42 U.S.C. 2073, 2133, 2134, 2137, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

78. In § 26.3, revise paragraphs (a) through (d) and add paragraph (f) to read as follows:

§ 26.3 Scope.

(a) Licensees who are authorized to operate a nuclear power reactor under 10 CFR 50.57, and holders of a combined license under 10 CFR Part 52 after the Commission has made the finding under 10 CFR 52.103(g) shall comply with the requirements of this part, except for subparts K and M of this part. Licensees who receive their authorization to operate a nuclear power reactor under 10 CFR 50.57 after the date of publication of this final rule in the Federal Register and holders of a combined license under 10 CFR Part 52 after the Commission has made the finding under 10 CFR 52.103(g) shall implement the FFD program before the receipt of special nuclear material in the form of fuel assemblies.

(b) Licensees who are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) under Part 70 of this chapter, and any corporation, firm, partnership, limited liability company, association, or other organization who obtains a certificate of compliance or an approved compliance plan under Part 76 of this chapter, only if the entity elects to engage in activities involving formula quantities of SSNM shall comply with the requirements of this part, except for subparts I, K and M of this part.

(c) Before the receipt of special nuclear material in the form of fuel assemblies, the following licensees and other entities shall comply with the requirements of this part, except for subparts I and M of this part; and, no later than the receipt of special nuclear material in the form of fuel assemblies, the following licensees and other entities shall comply with the requirements of this part:

* * * * *

(d) Contractor/vendors (C/Vs) who implement FFD programs or program elements, to the extent that the licensees and other entities specified in paragraphs (a) through (c) and (f) of this section rely on those C/V FFD programs or program elements to meet the requirements of this part, shall comply with the requirements of this part.

* * * * *

(f) No later than the start of construction activities, licensees of commercial nuclear plants and ~~other entities that have applied for or have been issued a license~~ holders of limited work authorizations under part 53 of this chapter~~, other than a manufacturing license~~, must implement the requirements in subpart M of this part or all the requirements of this part except subparts ~~K~~I and M. Holders of a manufacturing license under part 53 of this chapter must implement the requirements in subpart M or all the requirements of this part except subparts K and M, before commencing manufacturing activities ~~that assemble a manufactured reactor~~.

79. In § 26.4, revise paragraphs (a), (b), (c), (e), (f), (g) introductory text, and (h) to read as follows:

§ 26.4 FFD program applicability to categories of individuals.

(a) All persons who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a) and, as applicable, (c) and perform the following duties shall be subject to an FFD program that meets all of the requirements of

Commented [A52]: Edited to eliminate GLROs from the scope of this requirement as persons that must implement an FFD. (N.B., operators and senior operators would also be licensees under the draft proposed part 53 but for the edits provided in this document to move their licensing into part 55.) The insertion of "of commercial nuclear plants" also eliminates the need for the exception for MLs as they are not licenses for commercial nuclear plants.

Commented [A53]: Staff should confirm that the intent is to exempt a licensee constructing but not operating a commercial nuclear power plant under part 53 from the fatigue management rules of subpart I rather than the optional construction provisions of subpart K.

this part, except subpart K of this part, and those persons who are granted unescorted access to either nuclear power reactor protected areas or remote facilities where safety-significant systems or components may be operated within the design basis of a licensed commercial nuclear plant, by the licensees and other entities in § 26.3(f) and perform the following duties must be subject to an FFD program that satisfies the requirements in subpart M of this part, unless the licensee or other entity subjects these individuals to an FFD program that satisfies all of the requirements of this part except for those requirements in subparts K and M:

(1) ~~For persons who are granted unescorted access by the licensees in § 26.3(a) and, as applicable, (c), o~~Operating or onsite directing of the operation of systems and components that a risk-informed evaluation process has shown to be significant to public health and safety (for commercial nuclear plants licensed under part 53 of this chapter, onsite directing of operation includes directing of operations at remote facilities described in paragraph (a) of this section); ~~for those persons who are granted unescorted access by the licensees and other entities in § 26.3(f), operating or directing of the operation of systems and components that a risk-informed evaluation process or alternative method of evaluating safety significance has shown to be significant to public health and safety;~~

Commented [A54]: Edited for simplicity and to limit the FFD requirements to personnel directing operations at a remote facility rather than providing any form of direction anywhere (e.g., members of the Board of Directors of a corporation that is a licensee). Additionally, these edits recognize that the AERI proposal is a form of risk evaluation that would fall under the description of risk-informed evaluation process.

* * * * *

(4) ~~For persons who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a) and, as applicable, (c), p~~Performing maintenance or onsite directing of the maintenance of SSCs that a risk-informed evaluation process has shown to be significant to public health and safety (for commercial nuclear plants licensed under part 53 of this chapter, onsite direction of maintenance includes the directing of maintenance at remote facilities described in

paragraph (a) of this section); for those persons who are granted unescorted access to nuclear power reactor protected areas by the licensees and other entities in § 26.3(f), performing maintenance or directing of the maintenance of SSCs that a risk-informed evaluation process or alternative method of evaluating safety significance has shown to be significant to public health and safety; and

* * * * *

(b) All persons who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a) and, as applicable, (c) and who do not perform the duties described in paragraph (a) of this section shall must be subject to an FFD program that meets all of the requirements of this part, except §§ 26.205 through 26.209 and subpart K of this part. All persons who are granted unescorted access to a facility licensed under part 53 of this chapter, and who do not perform or direct the performance of the duties described in § 26.4paragraph (a) of this section, must be subject to the requirements in subpart M of this part, unless the licensee or other entity implements an FFD program that satisfies all of the requirements of this part, except §§ 26.205 through 26.209 and subparts K and M.

(c) All persons who are required by a licensee in § 26.3(a) and, as applicable, (c) to physically report to the licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF) by licensee emergency plans and procedures shall be subject to an FFD program that meets all of the requirements of this part, except §§ 26.205 through 26.209 and subpart K of this part. Also, for licensees or other entities in § 26.3(f), all persons without unescorted access to the facility who make decisions and/or direct actions regarding plant safety and security, and aAll persons who are required by a licensee in § 26.3(f) to participate remotely in emergency response activities or physically report to the TSC or EOF (or an equivalent facility), must be

Commented [A55]: The phrase "all persons without unescorted access to the facility who make decisions and/or direct actions regarding plant safety and security" is overly broad and can encompass people that are not actually assigned by a licensee to do those things.

subject to an FFD program that satisfies all of the requirements described in subpart M of this part, unless the licensee or other entity implements an FFD program that satisfies all of the requirements of this part, except §§ 26.205 through 26.209 and subparts K and M.

* * * * *

(e) When construction activities, as defined in § 26.5, begin, any individual whose duties for the licensees and other entities in § 26.3(c) require him or her to have the following types of access or perform the following activities at the location where the nuclear power plant will be constructed and operated shall be subject to an FFD program that meets all of the requirements of this part, except subparts I, K, and M of this part, and for any individual whose duties for the licensees and other entities in § 26.3(f) require him or her to have the following types of access, perform construction activities as defined in § 26.5, or perform the following activities must be subject to an FFD program as described in subpart M or an FFD program that satisfies all of the requirements of this part, except subparts I, K, and M:

* * * * *

(4) Witnesses or determines inspections, tests, and analyses certification required under Parts 52 or 53 of this chapter;

* * * * *

(f) Any individual who is constructing, manufacturing or directing the construction or manufacture of safety- or security-related SSCs shall be subject to an FFD program that meets the requirements of subpart K, or, if applicable, subpart M of this part, unless the licensee or other entity subjects these individuals to an FFD program that meets all of the requirements of this part, except for subparts I, K, and M of this part.

(g) All FFD program personnel who are involved in the day-to-day operations of the program, as defined by the procedures of the licensees and other entities in § 26.3(a) through (c), and, as applicable, (d) and whose duties require them to have the following types of access or perform the following activities shall be subject to an FFD program that meets all of the requirements of this part, except subparts I, K, and M of this part, and, at the licensee's or other entity's discretion, subpart C of this part. All personnel whose duties require them to have the following types of access or perform the following activities at facilities licensed under part 53 of this chapter must be subject to the requirements in subpart M or an FFD program that satisfies all of the requirements of this part, except subparts I, K, and M, and, at the licensee's or other entity's discretion, subpart C of this part.

* * * * *

(h) Individuals who have applied for authorization to have the types of access or perform the activities described in paragraphs (a) through (d) of this section shall be subject to §§ 26.31(c)(1), 26.35(b), 26.37, 26.39, and the applicable requirements of subparts C, E through H, and M of this part.

* * * * *

80. In § 26.5:

a. Add the definitions for "*Biological marker*", "*Change*", "*Illicit substance*", ~~"*NRC-licensed operator*",~~ "*Reduction in FFD program effectiveness*", and "*Special nuclear material*", in alphabetical order; and

b. Revise the definitions for "*Constructing or construction activities*", "*Contractor/vendor (C/V)*", "*Other entity*", "*Questionable validity*", "*Reviewing official*", "*Safety-related structures, systems, and components (SSCs)*", "*Security-related SSCs*", and "*Unit outage*".

Commented [A56]: Deleted as unnecessary and to reflect that there is not a draft proposed definition of this term in the amendatory text.

The additions and revisions to read as follows:

§ 26.5 Definitions.

* * * * *

Biological marker means, for a part 53 licensee implementing subpart M of this part, an endogenous substance that is used to validate that the biological specimen collected for testing was produced by the donor.

* * * * *

Change as used in § 26.603(e) means an action that results in a modification of, addition to, or removal from the licensee's or other entity's FFD program.

* * * * *

Constructing or construction activities means, for the purposes of this part, the tasks involved in building a nuclear power plant that are performed at the location where the nuclear power plant will be constructed and operated. These tasks include fabricating, erecting, integrating, and testing safety- and security-related SSCs, and the installation of their foundations, including the placement of concrete. For a licensee or other entity described in § 26.3(f), construction is defined in § 53.0204 ~~or § 53.028~~ of this chapter.

Contractor/vendor (C/V) means any company, or any individual not employed by a licensee or other entity specified in § 26.3(a) through (c) and (f), who is providing work or services to a licensee or other entity covered in § 26.3(a) through (c) and (f), either by contract, purchase order, oral agreement, or other arrangement.

* * * * *

Illicit substance means a substance that causes impairment and possible addiction but is not an illegal drug as defined in § 26.5.

* * * * *

Other entity means any corporation, firm, partnership, limited liability company, association, C/V, or other organization who is subject to this part under § 26.3(a) through (c) and (f) but is not licensed by the NRC.

* * * * *

Questionable validity means the results of validity screening or initial validity tests at a licensee testing facility indicating that a urine specimen may be adulterated, substituted, dilute, or invalid. For a part 53 licensee or other entity, *questionable validity* means the results of validity screening or initial validity tests indicating that a biological specimen obtained from an individual pursuant to subpart M of this part may be adulterated, substituted, dilute, or invalid.

Reduction in FFD program effectiveness means, for a part 53 licensee or other entity implementing subpart M of this part, a change or series of changes to an element of the FFD program that reduces or eliminates the licensee's ability to satisfy or maintain site-specific FFD program performance when compared to historical site-specific performance, the licensee's fleet-level program performance, or industry performance.

Reviewing official means an employee of a licensee or other entity specified in § 26.3(a) through (c), and (f) who is designated by the licensee or other entity to be responsible for reviewing and evaluating any potentially disqualifying FFD information about an individual, including, but not limited to, the results of a determination of fitness, as defined in § 26.189, in order to determine whether the individual may be granted or maintain authorization.

Safety-related structures, systems, and components (SSCs) ~~means, for part 50 or part 52 licensees and other entities described in § 26.3(a) through (d), those SSCs that are relied on to remain functional during and following design basis events to ensure the integrity of the reactor coolant pressure boundary, the capability to shut down the~~

~~reactor and maintain it in a safe shutdown condition, or the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposure comparable to the guidelines in § 50.34(a)(1). For part 53 licensees and other entities described in § 26.3(d) and (f), safety-related~~, for persons described in § 26.3(a) through (d) and (f), has the same meaning as that in § 50.2 or § 53.02~~04 or § 53.028~~ of this chapter, as applicable.

Security-related SSCs means, for the purposes of this part, those structures, systems, and components that the licensee will rely on to implement the licensee's physical security and safeguards contingency plans that either are required under Part 73 of this chapter if the licensee is a construction permit applicant or holder or an early site permit holder, as described in § 26.3(c)(3) through (c)(5), respectively, or are included in the licensee's application if the licensee is a combined license applicant or holder, as described in § 26.3(c)(1) and (c)(2), respectively, or a licensee or other entity described in § 26.3(d) and (f).

* * * * *

Special nuclear material (SNM) has the same meaning as that in § 70.4 of this chapter.

* * * * *

Unit outage means, for the purposes of this part~~, for electricity generation units,~~ that the reactor unit is neither ~~dis~~connected ~~from~~ to the electrical grid, for a reactor that generates electricity~~. *Unit outage* means, for the purposes of this part, for non-electricity generation units, that the reactor unit is disconnected from~~ nor connected to the loads to which its output is supplied under normal operating conditions, for a reactor with non-electric outputs.

Commented [A57]: Edited to address reactors with both electrical and non-electrical outputs.

* * * * *

§ 26.8 [Amended]

81. In § 26.8(b), add “26.202, 26.603, 26.604, 26.605, 26.606, 26.607, 26.608, 26.609, 26.611, 26.613, 26.617, 26.619”, in numerical order.

82. Revise § 26.21 to read as follows:

§ 26.21 Fitness-for-duty program.

The licensees and other entities specified in § 26.3(a) through (c) and (f) (for those licensees and other entities that do not implement the requirements in subparts M and K of this part) shall establish, implement, and maintain FFD programs that, at a minimum, comprise the program elements contained in this subpart. The individuals specified in § 26.4(a) through (e) and (g), and, at the licensee's or other entity's discretion, § 26.4(f), and, if necessary, § 26.4(j) shall be subject to these FFD programs. Licensees and other entities may rely on the FFD program or program elements of a C/V, as defined in § 26.5, if the C/V's FFD program or program elements satisfy the applicable requirements of this part.

83. Revise § 26.51 to read as follows:

§ 26.51 Applicability.

The requirements in this subpart apply to the licensees and other entities identified in § 26.3(a), (b), and, as applicable, (c) for the categories of individuals in § 26.4(a) through (d), and, at the licensee's or other entity's discretion, in § 26.4(g) and, if necessary, § 26.4(j). The requirements in this subpart also apply to the licensees and other entities specified in § 26.3(c), as applicable, for the categories of individuals in § 26.4(e). At the discretion of a licensee or other entity in § 26.3(c), the requirements of this subpart also may be applied to the categories of individuals identified in § 26.4(f). In addition, the requirements in this subpart apply to the entities in § 26.3(d) to the extent that a licensee or other entity relies on the C/V to satisfy the requirements of this

subpart. Certain requirements in this subpart also apply to the individuals specified in § 26.4(h). The requirements in this subpart apply to the FFD programs of licensees and other entities identified in § 26.3(f) that elect not to implement the requirements in subpart M for the categories of individuals in § 26.4 and those licensees and other entities that elect to implement the requirements in § 26.605.

§ 26.53 [Amended]

84. In § 26.53:

a. In paragraph (e), add ", and~~, if applicable,~~ (f)" after "§ 26.3(a) through (c)", wherever it may appear;

b. In paragraphs (g), (h), and (i) add ", (d), and (f)" after "as applicable (c)", wherever it may appear.

§ 26.63 [Amended]

85. In § 26.63(d), add "and (f)" after "§ 26.3(a) through (d)".

86. Revise § 26.73 to read as follows:

§ 26.73 Applicability.

The requirements in this subpart apply to the licensees and other entities identified in § 26.3(a), (b), and, as applicable, (c) for the categories of individuals specified in § 26.4(a) through (d) and (g). The requirements in this subpart also apply to the licensees and other entities specified in § 26.3(c), as applicable, for the categories of individuals in § 26.4(e). At the discretion of a licensee or other entity in § 26.3(c), the requirements of this subpart also may be applied to the categories of individuals identified in § 26.4(f). In addition, the requirements in this subpart apply to the entities in § 26.3(d) to the extent that a licensee or other entity relies on the C/V to satisfy the requirements of this subpart. The regulations in this subpart also apply to the individuals specified in § 26.4(h) and (j), as appropriate. The requirements in this subpart apply to

the FFD programs of licensees and other entities identified in § 26.3(f) that elect not to implement the requirements in subpart M for the categories of individuals in § 26.4 and those licensees and other entities that elect to implement the requirements in § 26.605(b).

87. Revise § 26.81 to read as follows:

§ 26.81 Purpose and applicability.

This subpart contains requirements for collecting specimens for drug testing and conducting alcohol tests by or on behalf of the licensees and other entities in § 26.3(a) through (d) for the categories of individuals specified in § 26.4(a) through (d) and (g). At the discretion of a licensee or other entity in § 26.3(c), specimen collections and alcohol tests must be conducted either under this subpart for the individuals specified in § 26.4(e) and (f) or the licensee or other entity may rely on specimen collections and alcohol tests conducted under the requirements of 49 CFR Part 40 for the individuals specified in § 26.4(e) and (f). The requirements of this subpart do not apply to specimen collections and alcohol tests that are conducted under the requirements of 49 CFR Part 40, as permitted in this paragraph and under §§ 26.4(j) and 26.31(b)(2) and Subpart K. The requirements in this subpart apply to the FFD programs of licensees and other entities identified in § 26.3(f) that elect not to implement the requirements in subpart M for the categories of individuals in § 26.4 and those licensees and other entities that elect to implement the requirements in § 26.605.

88. In § 26.201, redesignate the introductory text as new paragraph (a), revise it and add new paragraph (b) to read as follows:

§ 26.201 Applicability.

(a) The requirements in this subpart, with the exception of § 26.202, apply to the licensees and other entities identified in § 26.3(a); if applicable, (c) and (d); and (f), for

licensees and other entities not implementing the requirements in subparts K and M. For the licensees and other entities to whom the requirements in this subpart, with the exception of § 26.202, apply, the requirements in §§ 26.203 and 26.211 apply to the individuals identified in § 26.4(a) through (c). In addition, the requirements in § 26.205 through § 26.209 apply to the individuals identified in § 26.4(a).

(b) The requirements in this subpart, with the exception of § 26.203, apply to the licensees or other entities identified in § 26.3(f) implementing this subpart under~~in accordance with~~ §§ 26.604 and 26.605. For these licensees and other entities, the requirements in §§ 26.202 and 26.211 apply to the individuals identified in § 26.4(a) through (c) and any NRC-licensed operator; and the requirements in §§ 26.205 through 26.209 apply to the individuals identified in § 26.4(a).

89. Add § 26.202 to read as follows:

§ 26.202 General provisions for facilities ~~licensed under~~ implementing subpart M of this part ~~53~~

(a) *Policy*. Licensees must establish a policy for the management of fatigue for all individuals who are subject to the licensee's FFD program and incorporate it into the written policy required in § 26.606(a).

(b) *Procedures*. In addition to the procedures required in § 26.606(b), licensees must develop, implement, and maintain procedures that—

(1) Describe the process to be followed when any individual identified in § 26.4(a) through (c) makes a self-declaration that he or she is not fit to safely and competently perform his or her duties for any part of a working tour as a result of fatigue. The procedure must—

(i) Describe the individual's and licensee's rights and responsibilities related to self-declaration;

(ii) Describe requirements for establishing controls and conditions under which an individual may be permitted or required to perform work after that individual declares that he or she is not fit due to fatigue; and

(iii) Describe the process to be followed if the individual disagrees with the results of a fatigue assessment that is required under § 26.211(a)(2);

(2) Describe the process for implementing the controls required under § 26.205 for the individuals who are performing the duties listed in § 26.4(a);

(3) Describe the process to be followed in conducting fatigue assessments under § 26.211; and

(4) Describe the disciplinary actions that the licensee may impose on an individual following a fatigue assessment, and the conditions and considerations for taking those disciplinary actions.

(c) *Training and assessments*. Licensees must include the following KAs in the content of the training and trainee assessments required in § 26.608:

(1) Knowledge of the contributors to worker fatigue, circadian variations in alertness and performance, indications and risk factors for common sleep disorders, shiftwork strategies for obtaining adequate rest, and the effective use of fatigue countermeasures; and

(2) Ability to identify symptoms of worker fatigue and contributors to decreased alertness in the workplace.

(d) *Recordkeeping*. Licensees must retain the following records for at least 3 years or until the completion of all related legal proceedings, whichever is later:

(1) Records of work hours for individuals who are subject to the work hour controls in § 26.205;

(2) For licensees implementing the requirements of § 26.205(d)(3), records of shift schedules and shift cycles, or, for licensees implementing the requirements of § 26.205(d)(7), records of shift schedules and records showing the beginning and end times and dates of all averaging periods, of individuals who are subject to the work hour controls in § 26.205;

(3) The documentation of waivers that is required in § 26.207(a)(4), including the bases for granting the waivers;

(4) The documentation of work hour reviews that is required in § 26.205(e)(3) and (e)(4); and

(5) The documentation of fatigue assessments that is required in § 26.211(g).

(e) *Reporting*. Licensees must include the following information in a standard format in the annual FFD program performance report required under § 26.617(b)(2):

(1) A summary for each nuclear power plant site of all instances during the previous calendar year when the licensee waived one or more of the work hour controls specified in § 26.205(d)(1) through (d)(5)(i) and (d)(7) for individuals described in § 26.4(a). The summary must include only those waivers under which work was performed. If it was necessary to waive more than one work hour control during any single extended work period, the summary of instances must include each of the work hour controls that were waived during the period. For each category of individuals specified in § 26.4(a), the licensee must report—

(i) The number of instances when each applicable work hour control specified in § 26.205(d)(1)(i) through (iii), (d)(2)(i) and (ii), (d)(3)(i) through (v), and (d)(7) was waived for individuals not working on outage activities;

(ii) The number of instances when each applicable work hour control specified in § 26.205(d)(1)(i) through (iii), (d)(2)(i) and (ii), (d)(3)(i) through (v), (d)(4) and (d)(5)(i), and (d)(7) was waived for individuals working on outage activities; and

(iii) A summary that shows the distribution of waiver use among the individuals applicable within each category of individuals identified in § 26.4(a) (e.g., a table that shows the number of individuals who received only one waiver during the reporting period, the number of individuals who received a total of two waivers during the reporting period).

(2) A summary of corrective actions, if any, resulting from the analyses of these data, including fatigue assessments.

(f) *Audits*. Licensees must audit the management of worker fatigue under~~as required by~~ § 26.615.

90. In § 26.205, revise paragraphs (d)(7)(iii) and (d)(8) to read as follows:

§ 26.205 Work Hours.

* * * * *

(d) * * *

(7) * * *

(iii) Each licensee shall state, in its FFD policy and procedures required by either § 26.27 and § 26.203(a) and (b) or § 26.202(a) and (b) and § 26.606, the work hour counting system in § 26.205(d)(7)(ii) the licensee is using.

(8) Each licensee shall state, in its FFD policy and procedures required by either § 26.27 and § 26.203(a) and (b) or § 26.202(a) and (b) and § 26.606, the requirements with which the licensee is complying: the minimum days off requirements in § 26.205(d)(3) or maximum average work hours requirements in § 26.205(d)(7).

* * * * *

91. In § 26.207, revise paragraph (a)(1)(ii) to read as follows:

§ 26.207 Waivers and exceptions.

(a) * * *

(1) * * *

(ii) A supervisor assesses the individual face to face and determines that there is reasonable assurance that the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver will be granted. The supervisor performing the assessment shall be trained as required by either § 26.29 and § 26.203(c) or § 26.202(c) and § 26.608~~,~~ and must~~shall~~ be qualified to direct the work to be performed by the individual. If there is no supervisor on site who is qualified to direct the work, the assessment may be performed by a supervisor who is qualified to provide oversight of the work to be performed by the individual. At a minimum, the assessment must address the potential for acute and cumulative fatigue considering the individual's work history for at least the past 14 days, the potential for circadian degradations in alertness and performance considering the time of day for which the waiver will be granted, the potential for fatigue-related degradations in alertness and performance to affect risk-significant functions, and whether any controls and conditions must be established under which the individual will be permitted to perform work. For licensees and other entities in § 26.3(f), the assessment may be performed remotely using electronic communications. In such instances, the assessment must be supported by someone who is present in-person with the individual whose alertness may be impaired, and that supporting person must be trained ~~in accordance with~~under the requirements of either § 26.29 and § 26.203(c) or § 26.202(c) and § 26.608.

* * * * *

92. In § 26.211, revise paragraphs (a)(1) and (3), and (b) introductory text to read as follows:

§ 26.211 Fatigue assessments.

(a) * * *

(1) *For-cause*. In addition to any other test or determination of fitness that may be required under §§ 26.31(c), 26.77, 26.607(b), and 26.619, a fatigue assessment must be conducted in response to an observed condition of impaired individual alertness creating a reasonable suspicion that an individual is not fit to safely and competently perform his or her duties, except if the condition is observed during an individual's break period. If the observed condition is impaired alertness with no other behaviors or physical conditions creating a reasonable suspicion of possible substance abuse, then the licensee need only conduct a fatigue assessment. If the licensee has reason to believe that the observed condition is not due to fatigue, the licensee need not conduct a fatigue assessment;

* * * * *

(3) *Post-event*. A fatigue assessment must be conducted in response to events requiring post-event drug and alcohol testing as specified in § 26.31(c) or post-~~accident~~ event tests in § 26.607(b)(4). Licensees may not delay necessary medical treatment in order to conduct a fatigue assessment; and

* * * * *

(b) Only supervisors and FFD program personnel who are trained under either §§ 26.29 and 26.203(c) or §§ 26.202(c) and 26.608 may conduct a fatigue assessment. The fatigue assessment must be conducted face to face with the individual whose alertness may be impaired. For licensees and other entities in § 26.3(f), a fatigue assessment may be performed remotely using electronic communications. In such

instances, the fatigue assessment must be supported by someone who is present in-person with the individual whose alertness may be impaired, and that supporting person must be trained in accordance with the requirements of either §§ 26.29 and 26.203(c) or §§ 26.202(c) and 26.608.

* * * * *

93. Add subpart M – Fitness for Duty Programs for Facilities Licensed Under 10 CFR part 53 and new §§ 26.601 through 26.619 to read as follows:

Subpart M – Fitness for Duty Programs for Facilities Licensed Under 10 CFR Part 53

Sec.

§ 26.601 Applicability.

A licensee or other entity in § 26.3(f), at its discretion, may establish, implement, and maintain an FFD program that satisfies the requirements of this subpart for those categories of individuals in § 26.4, as applicable, and any NRC-licensed operator~~, as defined in § 26.5~~. If a licensee or other entity in § 26.3(f) does not elect to implement an FFD program that satisfies the requirements of this subpart, then those categories of individuals in § 26.4, as applicable, and any NRC-licensed operator~~, as defined in § 26.5~~ must be subject to an FFD program that satisfies all part 26 requirements, except for those requirements in subparts K and M.

§ 26.603 General provisions.

(a) *FFD program description*. An applicant's description of the FFD program in its Final Safety Analysis Report, required by subparts H or R of part 53 of this chapter, as applicable, must include—

(1) If the applicant performed the analysis under § 26.603(c), a summary of the analysis, including the assumptions, methodology, conclusion, and references;

(2) A statement whether the FFD program will be implemented pursuant to § 26.604 or § 26.605, or will satisfy all part 26 requirements, except for the requirements in subparts K and M;

(3) A discussion of the applicability of the FFD program to those individuals described in § 26.4 and how the program will be implemented offsite at an NRC-licensed facility authorized to assemble or test a manufactured reactor, if applicable;

(4) A description of the drug and alcohol testing and fitness determination process to be implemented through the licensee's or other entity's procedures, including the collection and testing facilities to be used, biological specimens to be collected, and sanctions to be imposed upon a confirmed FFD policy violation; and

(5) A summary of the FFD performance monitoring and review program, including the measures and thresholds required by § 26.603(d)(1).

(b) *FFD program implementation and availability*. For the licensees and other entities in § 26.3(f), other than the holder of a manufacturing license, the FFD program must be implemented no later than the start of construction activities, as defined in § 26.5, and maintained until the NRC's docketing of the license holder's certifications described in § 53.1070 or § 53.4670 of this chapter. For holders of a manufacturing license, the FFD program must be implemented no later than the start of activities that

assemble the manufactured reactor and maintained until expiration of the manufacturing license.

~~(c) *Criterion and analysis for an FFD program*. For a licensee or other entity to implement an FFD program under § 26.604, the licensee or other entity must perform a site-specific analysis to demonstrate that the facility and its operation satisfy the criterion in § 53.860(a)(2) or § 53.4330(a)(2) of this chapter. The licensee or other entity must maintain the analysis, including updates to reflect changes made to the staffing, FFD programs, or offsite support resources described in the analysis, to show that the facility and its operation continue to satisfy the criterion, until permanent cessation of operations under § 53.1070 or § 53.4670 of this chapter.~~

Commented [A58]: Moved to 26.604.

(c~~d~~) *FFD performance monitoring and review*. A licensee or other entity must establish performance measures and associated thresholds as described in § 26.603(c~~d~~)(1) and monitor the effectiveness of its FFD program by comparing performance data against these performance measures and thresholds, in a manner sufficient to satisfy the § 26.23 performance objectives.

(1) The performance monitoring and review program (PMRP) must be documented and maintained and include the following program elements:

(i) *Performance measures*. Performance measures must be identified and designed to monitor FFD program performance.

(A) If the licensee or other entity is subject to the requirements in § 26.604, then the monitoring program must include performance measures for the following: the behavioral observation program; occurrence of FFD policy violations categorized by licensee employee, contractor/vendor, and labor category; and occurrence of individuals with potentially disqualifying information or who possessed FFD prohibited items.

(B) If the licensee or other entity is subject to the requirements in § 26.604 and has implemented a drug testing program at its discretion or is subject to the requirements of § 26.605, then the monitoring program must include performance measures identified in § 26.603(d)(1)(i)(A). This monitoring program must also include performance measures for the pre-access and random positive testing rates, random testing rate for licensee employees and contractor/vendors, and the number of subversion attempts categorized by licensee employee, contractor/vendor, and labor category.

(ii) *Thresholds*. Licensee- or other entity-specific thresholds for its site-specific performance measures must be established and used to facilitate corrective actions to maintain FFD program performance. Initial thresholds must be based on FFD performance data from comparable facilities subject to part 26, the licensee's or other entity's fleet-level program performance if applicable, and industry FFD performance data.

(iii) *Monitoring program*. Licensees and other entities must monitor the performance of their FFD programs against licensee- or other entity-established performance measures and thresholds as FFD performance data is received to determine whether a threshold has been exceeded. Licensees and other entities must perform year-to-year comparisons of site-specific performance; site-specific performance to the licensee's or other entity's fleet-level program performance, if applicable; and site-specific to industry performance.

(iv) *Quantitative and qualitative reviews*. The PMRP must include a documented review of the elements in § 26.603(a~~d~~)(1)(i) through (iii) and the following qualitative elements.

(A) *Worker protections*. The review must include a documented assessment of the licensee's or other entity's implementation of the protections described in §§ 26.606(b)(1)(iii), 26.611, and 26.613.

(B) *Laboratory test results and Medical Review Officer performance*. The review must include a documented assessment of whether the actions taken by the Medical Review Officer (MRO) met the requirements in § 26.185 based on the laboratory test results reported under § 26.169. This review must include a comparative analysis between the point of collection testing and assessment (POCTA) screening result(s) and the corresponding specimen test results obtained from the U.S. Department of Health and Human Services (HHS)-certified laboratory if the POCTA indicated a positive, adulterated, substituted, or invalid screening result or discrepant biological marker, to assess the effectiveness of the POCTA and to inform MRO decisions under § 26.185 or § 26.607(m)(6).

(C) *Change control*. The review must include a documented assessment of the changes made under § 26.603(dе) to verify that the summation of program changes has not resulted in a reduction in FFD program effectiveness.

(2) *Corrective actions*. Corrective actions must be implemented to address when FFD performance meets a licensee-established performance threshold or to resolve a finding resulting from a qualitative review or audit in a manner that restores performance and corrects root causes, contributing causes, or both.

(3) *Program review periodicity*. The documented review in § 26.603(ad)(1)(iv) must be conducted biennially to assess and modify licensee or other entity implementation of its FFD program. This documented review must demonstrate that the performance measures and thresholds are appropriate and adjusted as necessary

based on site-level and licensee's or other entity's fleet-level, if applicable, program performance, and industry performance.

(i) Identified program weaknesses and corrective actions must be summarized in the annual reporting requirement described in § 26.617(b)(2) or § 26.717, as applicable.

(ii) The program review must be completed and approved by the licensee or other entity to support the reporting of PMRP weaknesses and corrective actions as required in § 26.603(cd)(3)(i) every odd-numbered year, and the implementation of corrective actions before May 15 of that odd-numbered year.

(de) *FFD program change control.*

(1) The licensee or other entity may make changes to its FFD program under this subpart if—

(i) The licensee or other entity performs and retains an analysis demonstrating that the changes do not reduce the effectiveness of the FFD program; or

(ii) The change was necessitated or justified by a change to part 26, laboratory processes or procedures, or guidance issued by the HHS or NRC, as implemented by the licensee or other entity though its procedures.

(2) A licensee or other entity desiring to make a change that decreases FFD program effectiveness must implement a mitigating strategy so the FFD program, as revised, will continue to satisfy the performance objectives in § 26.23 and not result in a reduction in program effectiveness.

(3) Except for phencyclidine, and notwithstanding § 26.603(be)(1)(ii), the change control process may not be used to reduce the minimum panel of drugs to be tested in § 26.607(c)(1).

(4) The licensee must retain a record of each change made under this section for a period of at least 5 years from the date the change was implemented and summarize

this change in its annual FFD performance report required by § 26.617(b)(2) or § 26.717, as applicable.

§ 26.604 FFD program requirements for low consequence facilities ~~that satisfy the § 26.603(c) criterion~~.

(a) *Low consequence facilities*. A low consequence facility is one for which the radiological consequences from a design-basis threat initiated event involving the loss of engineered systems for decay heat removal and possible breaches in physical structures surrounding the reactor, spent fuel, and other inventories of radioactive materials result in offsite doses below the values in § 53.210 of this chapter.

(b~~a~~) *FFD program*. A licensee or other entity ~~with an~~that performs a site-specific analysis that demonstrates that its facility and operation satisfies the criterion in paragraph (a) of this section ~~§ 26.603(c)~~ may elect to establish, implement, and maintain an FFD program under this section. That FFD program must contain the following elements:

(1) Applies to those individuals described in § 26.4, as applicable; and

(2) Implements the following requirements and subparts in this part:

(i) § 26.23, Performance objectives;

(ii) § 26.603, General provisions;

(iii) § 26.606, Written policies and procedures, (a) and, if applicable (b);

(iv) § 26.608, FFD program training;

(v) § 26.609, Behavioral observation;

(vi) § 26.610, Sanctions;

(vii) § 26.611, Protection of information;

(viii) § 26.613, Appeals process;

(ix) § 26.615, Audits;

(x) § 26.617, Recordkeeping and reporting;

(xi) § 26.619, Suitability and fitness determinations;

(xii) Subpart A—Administrative Provisions;

(xiii) Subpart I—Managing Fatigue; and

(xiv) Subpart O—Inspections, Violations, and Penalties.

(~~c~~b) ~~[Reserved]~~*Update of analysis*. A licensee that follows the provisions of this section must maintain the analysis, including updates to reflect changes made to the staffing, FFD programs, or offsite support resources described in the analysis to show that the facility and its operation continue to satisfy the criterion of paragraph (a) of this section until permanent cessation of operations under § 53.1070 of this chapter. If the criterion of paragraph (a) is no longer met, the licensee must establish, implement, and maintain an FFD program under § 26.605.

§ 26.605 FFD program requirements for facilities that do not implement § 26.604.

(a) *Program elements.* Licensees and other entities ~~who satisfy the criterion in § 26.603(c), at their discretion, and licensees and other entities who do not satisfy the criterion in § 26.603(c)~~subject to this subpart that do not meet the criteria in § 26.604(a) or do not elect to establish, implement and maintain a fitness-for-duty (FFD) program under § 26.604~~,~~ must establish, implement, and maintain an FFD program under this section ~~either during construction activities as defined in § 26.5, or during activities performed under a manufacturing license that allows the assembly, testing or both, of a manufactured reactor, as applicable. This FFD program must~~that contains the following elements:

Commented [A59]: Covered in 26.3.

(1) Applies to those individuals described in § 26.4, as applicable; and,

(2) Implements the following requirements and subparts in this part—

(i) § 26.23, Performance objectives;

(ii) § 26.603, General provisions;

(iii) § 26.606, Written policy and procedures;

(iv) § 26.607, Drug and alcohol testing;

(v) § 26.608, FFD program training;

(vi) § 26.609, Behavioral observation;

(vii) § 26.610, Sanctions;

(viii) § 26.611, Protection of information;

(ix) § 26.613, Appeals process;

(x) § 26.615, Audits;

(xi) § 26.617, Recordkeeping and reporting;

(xii) § 26.619, Suitability and fitness determinations;

(xiii) Subpart A—Administrative Provisions;

(xiv) Subpart I—~~—~~Managing Fatigue, in the case of holders of a manufacturing license that allows the assembly, testing, or both of a manufactured reactor; and

(xv) Subpart O—Inspections, Violations, and Penalties.

(b) Licensees and other entities ~~who satisfy the criterion in § 26.603(c), at their discretion, and licensees and other entities who do not satisfy the criterion in § 26.603(c)~~subject to this section, before the loading of fuel onsite into a reactor vessel; before receiving a manufactured reactor; or before individuals subject to part 26 operate, test, perform maintenance of, or direct the maintenance or surveillance of security-related equipment or equipment that a risk-informed evaluation process or alternative method for evaluating safety significance has shown to be significant to public health and safety, must establish, implement, and maintain an FFD program that—

(1) Applies to those individuals described in § 26.4, as applicable; and,

(2) Implements the following requirements and subparts—

(i) § 26.23, Performance objectives;

(ii) § 26.603, General provisions;

(iii) § 26.606, Written policy and procedures;

(iv) § 26.607, Drug and alcohol testing;

(v) § 26.608, FFD program training;

(vi) § 26.609, Behavioral observation;

(vii) § 26.611, Protection of information;

(viii) § 26.613, Appeals process;

(ix) § 26.615, Audits;

(x) Subpart A—Administrative Provisions;

(xi) Subpart C—Granting and Maintaining Authorization;

(xii) Subpart D—Management Actions and Sanctions to be Imposed;

(xiii) Subpart H—Determining Fitness-for-Duty Policy Violations and Determining Fitness, unless using the HHS Guidelines for MRO evaluation of drug test results, and determining fitness;

(xiv) Subpart I—Managing Fatigue;

(xv) Subpart N—Recordkeeping and Reporting Requirements; and

(xvi) Subpart O—Inspections, Violations, and Penalties.

§ 26.606 Written policy and procedures.

(a) Licensees and other entities that implement an FFD program under this subpart must ensure that—

(1) A written FFD policy statement is provided to each individual who is subject to the program before the individual is subject to behavioral observation, drug and alcohol testing, or both.

(2) The FFD policy statement describes the performance objectives in § 26.23.

(3) The FFD policy statement describes the minimum days off requirements in § 26.205(d)(3) or maximum average work hours requirements in § 26.205(d)(7), if applicable.

(4) The FFD policy statement must be written in sufficient detail to provide affected individuals with information on what is expected of them and what consequences may result from a lack of adherence to the policy, including those elements described in § 26.606(b), part 26-required sanctions, and required medical/clinical treatment and follow-up testing for FFD policy violations.

(5) The FFD policy statement describes the individual's responsibilities to report for work in a physiological and psychological condition that enables the safe and competent performance of assigned duties and responsibilities and inform a licensee- or other entity-designated representative when the individual determines that this cannot be accomplished.

(b) Licensees and other entities must establish, implement, and maintain written procedures that address the following topics:

(1) If implementing a drug and alcohol testing program under this subpart,

(i) The methods and techniques to collect and test for drugs and alcohol and for the shipping and temporary storage of biological specimens used for drug testing at HHS-certified laboratories,

(ii) The urine specimen volumes, techniques for split specimen collections, and the acceptability of a urine specimen as described in § 26.111 or as described in the HHS Guidelines,

(iii) Protecting the privacy of an individual who provides a specimen, protecting the integrity of the specimen, and ensuring that the test results are valid and attributable to the correct individual, and

(iv) If the licensee or other entity elects to use the HHS Guidelines, the name of the specific HHS Guideline and revision being implemented by the licensee or other entity and a description of the specific sections in the guideline that are being implemented in the procedure, including specimen collections, drug testing, and evaluation of test results.

(2) The immediate and follow-up actions that will be taken, and the procedures to be used, in those cases in which individuals who are subject to the FFD program:

(i) Have been involved in the use, sale, or possession of illegal substances, illegal drugs, or illicit substances;

(ii) Are impaired by any illegal substances, illegal drugs, or illicit substances or the consumption of alcohol as determined by behavioral observation or a test that measures blood alcohol concentration;

(iii) If drug and alcohol testing is conducted, attempted to subvert the testing process by adulterating or diluting specimens (*in vivo* or *in vitro*), substituting specimens, or by any other means;

(iv) If drug and alcohol testing is conducted, refused to provide a specimen for analysis or follow instructions provided by FFD program personnel;

(v) Had legal action taken relating to drug or alcohol use; or

(vi) Demonstrated character or actions indicating that the individual cannot be trusted or relied upon to perform those duties and responsibilities or maintain access to NRC-licensed facilities, SNM, or sensitive information.

(3) The process, including the duties and responsibilities of FFD program personnel, to be followed if an individual's behavior or condition raises a concern regarding the possible use, sale, or possession of illegal drugs on- or offsite; the possible use or possession of alcohol on the NRC-licensed facility; impairment from any

cause that in any way could adversely affect the individual's ability to safely and competently perform the individual's duties; or the receipt of credible information indicating that the individual cannot be trusted or relied on to perform those duties and responsibilities making the individual subject to this part.

(4) Operation and oversight of an onsite or offsite collection facility.

(5) The fatigue management requirements in §§ 26.202(b), 26.205(d)(3) and 26.205(d)(7), if applicable.

(6) Measures to prevent subversion of drug and alcohol tests conducted onsite and offsite.

§ 26.607 Drug and alcohol testing.

Licensees and other entities implementing § 26.604, at their discretion, and licensees and other entities implementing § 26.605 must perform drug and alcohol testing that complies with the following requirements—

(a) *Split specimens.* Split specimen collections of oral fluid or urine must be used for the test conditions described in § 26.607(b). A split specimen collection need not be used if the licensee or other entity elects to use a POCTA device for a screening test conducted during random testing under § 26.607(b)(2) and (h) or a protected area portal monitor indication that drugs or alcohol were detected under § 26.607(j). Testing of the split specimen (specimen B) requires the donor's permission unless ordered by the MRO to resolve an invalid test result obtained for specimen A.

(b) *Test conditions.* Individuals identified in § 26.4 must be subject to drug and alcohol testing under the following conditions:

(1) *Pre-access.* A pre-access test must be conducted for drugs and alcohol before performing or directing the conduct of roles and responsibilities making the individual subject to this subpart or being granted unescorted access to the protected

areas of the NRC-licensed facility. A pre-access test must have been conducted no more than 14 days before the individual is granted unescorted access.

(2) *Random testing*. Random testing for drugs and alcohol must—

(i) Be administered in a manner that provides reasonable assurance that individuals are unable to predict the time periods during which specimens will be collected;

(ii) Require individuals who are selected for random testing to report to the onsite collection site as soon as reasonably practicable after notification, within the time period specified in the FFD program procedure;

(iii) Ensure that all individuals in the population that is subject to random testing on a given day have an equal probability of being selected and tested;

(iv) Ensure that an individual completing a test is immediately eligible for another random test; and

(v) Ensure that the sampling process used to select individuals for random testing provides that the number of random tests performed annually is equal to at least 50 percent for licensee employees and 50 percent for contractor/vendors at the NRC-licensed site.

(3) *For-cause*. A for-cause drug test, alcohol test, or both, must be conducted onsite in response to an individual's observed behavior or physical condition indicating possible substance abuse or after receiving credible information that an individual is engaging in substance abuse, as defined in § 26.5;

(4) *Post-~~accident~~event*. A post-~~accident~~ event test for drugs and alcohol must be conducted—

(i) As soon as practical after an ~~accident~~ event involving a human error that was committed by an individual specified in § 26.4, where the human error may have caused

or contributed to the ~~accident~~event. This test must be conducted onsite unless the individual requires offsite medical care. The licensee or other entity must test the individual(s) who committed or directed the error and need not test individuals who were affected by the ~~accident~~ event and whose actions likely did not cause or contribute to the ~~accident~~ event for use in subpart M implementation. The licensee or other entity must describe in its procedures what constitutes a human error and ~~accident~~event.

(ii) Within 4 hours of an accident unless immediate medical intervention precludes the conduct of the test on the individual(s) who caused or contributed to the accident(s), if the accident results in—

(A) An illness or personal injury to any individual which results in death, days away from work, restricted work, transfer to another job, medical treatment beyond first aid, loss of consciousness, or other significant illness or injury, as diagnosed by a licensee- or other entity-designated physician or other licensed health care professional, even if the illness or injury does not result in death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness; or

(B) Damage to any safety- or security-related SSC; and

(5) *Follow-up*. An individual subject to part 26 who has violated the FFD policy for substance use or abuse, or the sale, use, or possession of illegal drugs must be subject to a follow-up series of tests for drugs, alcohol, or both to verify an individual's continued abstinence from substance abuse.

(c) *Urine and oral fluid specimens.*

(1) All urine or oral fluid specimens must be subject to validity testing, including an adulterant and biological marker, and tested for the substances listed in § 26.31(d)(1), except as allowed by § 26.603(e)(3).

(2) For the use of urine as the biological specimen to be tested, the following requirements must be implemented—

(i) § 26.115, Collecting a urine specimen under direct observation;

(ii) § 26.119, Determining “shy” bladder; and

(iii) § 26.163, Cutoff levels for validity testing, (a)(2) regarding special analysis testing.

(3) For alcohol testing onsite, the following requirements must be implemented—

(i) § 26.91, Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use;

(ii) § 26.93, Preparing for alcohol testing;

(iii) § 26.95, Conducting an initial test for alcohol using a breath specimen;

(iv) § 26.97, Conducting an initial test for alcohol using a specimen of oral fluids;

(v) § 26.99, Determining the need for a confirmatory test for alcohol;

(vi) § 26.101, Conducting a confirmatory test for alcohol; and,

(vii) § 26.103, Determining a confirmed positive test result for alcohol.

(4) For all test conditions in § 26.607(b), except for the use of a POCTA screening device in § 26.607(h), and for MRO-directed tests under § 26.185, drug testing must be performed at an HHS-certified laboratory for the specific biological specimen to be tested. Only HHS-certified laboratory test results using urine or oral fluid may be used for the issuance of a part 26-required sanction. The licensee or other entity must establish and maintain a contract with a primary and a back-up HHS-certified laboratory (with a different Certifying Scientist) for the specimen(s) to be tested. These contracts must stipulate that the laboratories are subject to inspection or audit by the licensee or other entity and that records and documents must be provided and/or able to be photocopied and removed from the premise to support the inspection or audit.

(d) *Privacy and integrity*. The specimen collection and drug and alcohol testing procedures of FFD programs must protect the donor's privacy and the integrity of the specimen and implement quality controls to ensure that test results are valid and attributable to the correct individual.

(e) *Offsite collection facilities.* At the licensee's or other entity's discretion, specimen collections and alcohol testing may be conducted at a local hospital or other facility licensed to conduct specimen collections and perform alcohol testing and audited by the State or a State-designated entity. The licensee or other entity must audit these facilities, if used, before their initial use and then on a biennial basis to confirm that the facility procedures are comparable to those described in subpart E of this part or the HHS Guidelines for urine and oral fluid.

(f) *Initial testing*. A licensee or other entity subject to this subpart performing an initial test must use an immunoassay, or an alternative technology established in its FFD program through § 26.603(e), that satisfies the requirements of the U.S. Food and Drug Administration (FDA) for commercial distribution. Specimens that yield positive, adulterated, substituted, or invalid initial validity or drug test results or discrepant biological markers must be subject to confirmatory testing by the HHS-certified laboratory, certified for that biological specimen, except for invalid specimens that cannot be tested.

(g) *Oral fluid testing.* If the licensee or other entity elects to use oral fluid for drug or alcohol testing, the collection, packaging, and temporary storage of the drug or alcohol test device, and shipment of an oral fluid specimen to an HHS-certified laboratory or the collection of an oral fluid specimen for alcohol testing must be performed in accordance with licensee- or other entity-established procedures based either on the requirements in part 26 or the procedures in HHS Guidelines identified by

the licensee or other entity in § 26.606(b)(1)(iv). The device must have received premarket approval from the FDA and must not expire before laboratory testing. The drugs, drug metabolites, initial and confirmatory testing cutoffs, and biological markers, if applicable, must be those established by HHS for oral fluid testing and the alcohol cutoffs in this part or, if not established by HHS or the NRC for the panel of drugs and drug metabolites to be tested, as determined and documented by a forensic toxicologist review conducted pursuant to § 26.31(d)(1)(i)(D).

(h) *Point of collection testing and assessment*. (1) If the licensee or other entity elects to use a POCTA device, then it may only be used for pre-access and random drug and alcohol initial testing in § 26.607(b), the alcohol testing process in § 26.607(c)(3), and the portal area screening process in § 26.607(j). Before the licensee or other entity uses a POCTA device, a forensic toxicologist must review and document their evaluation that the validity and accuracy of the device for alcohol and/or the drugs and drug metabolites listed in § 26.31(d) are comparable to the performance achieved by initial testing conducted using a similar technology at an HHS-certified laboratory. For initial testing of drugs and drug metabolites using a POCTA device, this review must include a documented evaluation of POCTA device performance against the requirements in § 26.161(b) for a urine specimen or the procedures in the HHS Guidelines for urine or oral fluid, as implemented by the licensee or other entity through its procedures.

(2) If the performance of the POCTA device is not comparable to that achieved from initial testing conducted by an HHS-certified laboratory as determined by the forensic toxicologist, then the licensee or other entity must implement a mitigating strategy to maintain program effectiveness under § 26.603(e)(2), as applicable.

(3) The licensee and other entity must implement procedures for the use of a POCTA that ensures the effectiveness of the collection process, assessment of the screening results, and prevention of subversion attempts.

(4) If the use of a POCTA device indicates a discrepant biological marker or that a test result exceeds the initial test cutoff, the specimen is invalid, or the individual subverted the drug or alcohol test, then the individual must be immediately removed from duties, responsibilities, and access making the individual subject to this subpart.

(i) The individual must be subject to an immediate drug and alcohol test using the alcohol testing process in § 26.607(c)(3) for a positive alcohol screen and either oral fluid or urine by a collection kit that is not a POCTA device, but of the same type of biological specimen collected by the POCTA, for validity, if required, and initial and confirmatory testing by an HHS-certified laboratory.

(ii) If this individual shows any signs of impairment, the individual's authorization must be temporarily removed until the MRO reviews the laboratory test result(s), interviews the individual, and performs a determination of fitness under § 26.189 or § 26.619, as applicable, that enables the restoration of authorization.

(i) *Hair testing*. The testing of hair specimens may only be used to inform a licensee's or other entity's determination of whether the individual is trustworthy and reliable under the test condition in § 26.607(b)(1) to supplement the information gained from a pre-access test using oral fluid or urine as the test specimen and must be conducted at an HHS-certified laboratory certified for hair specimens.

(1) If used, this process must be described in the licensee's or other entity's FFD policy and described in detail in its procedure. The panel of drugs and drug metabolites to be evaluated must only include those listed as Schedule I or II of section 202 of the Controlled Substances Act [21 U.S.C. 812]. The collection, packaging, and temporary

storage of a hair specimen and shipment of the specimen to an HHS-certified laboratory must be conducted in accordance with the HHS Guidelines. The test kit must be FDA cleared, and licensee- or other entity-designated FFD program personnel must conduct the collection, packaging, temporary storage, shipping, and custody and control of the specimen.

(2) Before the licensee or other entity begins to conduct hair testing, the initial and confirmatory testing cutoffs must be the cutoffs established by HHS for hair testing or, if not established by HHS or the NRC, as determined by a forensic toxicologist review conducted pursuant to § 26.31(d)(1)(i)(D).

(3) Confirmed positive test results must be considered potentially disqualifying FFD information until proven otherwise by a review under § 26.613. Sanctions under this subpart must not be issued for any FFD policy violation involving a drug test using a hair specimen unless the licensee or other entity determines that the individual subverted, as defined in § 26.5, the hair test.

(j) *Portal area screening*. A non-invasive point of collection testing instrument may be used to screen individuals for drugs, drug metabolites, and alcohol before the individuals' entry into or exit from a protected or vital area.

(1) If a licensee or other entity uses such an instrument, then before such use, a forensic toxicologist must review the instrument and document an evaluation that the instrument and setpoints used in the instrument are acceptable for use for the detection and screening of the drugs and drug metabolites selected for screening from the panel of drugs and drug metabolites to be tested under the FFD program and alcohol and its metabolites.

(2) The instrument must be operated in accordance with the manufacturer's specifications. If screening detects the presence of drugs, drug metabolites, or alcohol at

or above the instrument set point(s) , the individual screened by the instrument must be subject to a POCTA screening test using the process described in § 26.607(h) or an oral fluid or urine test that is sent to an HHS-certified laboratory.

(3) A part 26 sanction may not be issued to an individual based solely on a portal area screening instrument detection that drugs or alcohol exceed the instrument's established setpoint.

(k) *Blood testing*. The testing of blood specimens may only be conducted under the order of the licensee- or other entity-designated MRO for a valid medical reason as confirmed by the MRO pursuant to § 26.31(d)(5). This testing must be subject to testing by a laboratory that satisfies quality control requirements that are comparable to those required for certification by the HHS.

(l) *Custody-and-control form*. For the collection and packaging of urine, oral fluid, and hair specimens, the licensee or other entity must use a custody-and-control form approved by the U.S. Office of Management and Budget. For the use of a POCTA device, the licensee or other entity must implement a licensee- or other entity-approved and -maintained procedure that ensures the reliability of the tracking, handling, and storage of a specimen from the point of specimen collection to the final disposition of the specimen and the reliability of an identification system to uniquely assign the specimen to the donor.

(m) *Medical Review Officer.* Licensees or other entities must—

(1) Require their designated MRO to review positive, adulterated, substituted, and dilute confirmatory drug and validity test results and test results of questionable validity to determine whether the donor has violated the FFD policy for urine and oral fluid specimens. The review must be completed before reporting the results to the individual designated by the licensee or other entity to assess authorization or perform

the suitability and fitness determinations required under § 26.619, or, if required, that are described in subpart H of this part.

(2) Require their MRO to satisfy the requirements in § 26.183 and, prior to conducting any activities under this part, attend and pass a medical- or clinical-based training session to improve his/her knowledge of MRO duties and responsibilities, drug and alcohol testing processes and procedures, and evaluation of drug testing results. This training session must be conducted by a nationally recognized MRO training and certification organization that has been assessed by the licensee's or other entity's FFD program personnel to include the technical elements an MRO must implement under § 26.185. An MRO who performed the duties and responsibilities in §§ 26.185 and 26.187 for at least 3 continuous years in the last 10 years prior to being hired or contracted by the licensee or other entity satisfies the requirements in this paragraph.

(3) Require their MRO to attend a medical- or clinical-based training session on a triennial basis to improve his/her knowledge of changes in drug and alcohol testing processes and procedures and evaluation of drug testing results.

(4) Require their MRO to determine whether a biological specimen is positive, adulterated, substituted, dilute or of questionable validity by implementing the requirements in § 26.185 or the HHS Guidelines through the licensee's or other entity's procedures.

(i) If § 26.185 or the HHS Guidelines, as used by the licensee or other entity in its procedures, are insufficient to make this determination, then guidance issued by a State agency in the state in which the NRC-licensed facility is located, Federal agencies, or nationally recognized MRO training and certification organizations may be used to inform an MRO determination.

(ii) An MRO need not review a confirmed alcohol positive test result determined by an evidentiary breath testing device under § 26.607(c)(3)(vi) and (vii).

(5) Require their MRO to determine and approve the use of oral fluid or urine as an alternative biological specimen when the donor cannot provide a specimen for testing. This determination and the retest must be documented and completed as soon as reasonably practicable.

(6) Require the MRO to review all specimens screened and tested associated with a drug-related FFD policy violation. This review includes POCTA, split specimens, and all specimens taken to resolve a discrepant condition, such as a possible subversion attempt, impairment without a known cause, or a donor-requested or MRO-directed re-test. To resolve a discrepant condition, the MRO is authorized to test a specimen for a biological marker, adulterants, or additional drugs.

(n) *Limitations of screening and testing*. Specimens collected under NRC regulations may only be designated or approved for screening and testing as described in this part and may not be used to conduct any other analysis or test without the written permission of the donor. Analyses, screens, and tests that may not be conducted include, but are not limited to, DNA testing, serological typing, or any other medical or genetic test used for diagnostic or specimen identification purposes. No biological specimens may be passively sampled and analyzed in a manner different than described in this subpart.

(o) All onsite specimen collections, except a collection by a portal area screening instrument in § 26.607(j), must be conducted by licensee- or other entity-designated and -trained personnel.

§ 26.608 FFD program training.

(a) *FFD program training.* (1) Individuals must be trained in the FFD policy and procedure, including fatigue management, and their FFD program responsibilities. Individuals who collect specimens for testing or screening must also be trained in specimen collector duties and responsibilities, including, at a minimum, specimen collection, custody and control, identification and response to subversion attempts, and privacy. For licensees and other entities of commercial nuclear plants, the FFD program training program must use a systems approach to training as defined in § 53.020~~725~~ of this chapter and described in § 53.830 of this chapter for those individuals in § 26.4.

(2) FFD program training must include training on the behavioral observation program (BOP). The BOP training must include the detection of physiological or physiological behaviors or conditions that may indicate—

(i) Possible use, sale, or possession of illegal drugs or illicit drugs, or substance abuse on- or offsite;

(ii) Use or possession of alcohol onsite or use while on duty offsite;

(iii) Impairment from fatigue or any cause that, if left unattended, could result in inattentiveness or human errors; and

(iv) Any individual's inability to safely and competently perform assigned duties and responsibilities or act in a trustworthy and reliable manner while having access to protected areas, SNM, or sensitive information.

(3) Training must explain that an individual's FFD policy violation will—

(i) Subject the individual to an FFD program-required sanction designed to preclude recurrence of an FFD policy violation;

(ii) Contribute to the licensee's or other entity's assessment of whether the individual can be trusted and relied upon to safely and competently perform the assigned duties and responsibilities making the individual subject to this subpart;

(iii) Be used to inform the licensee's or other entity's insider mitigation and access authorization programs under § 73.55, § 73.56, § 73.100 or § 73.120 of this chapter; and,

(iv) Be used to inform other NRC licensees and other entities subject to part 26 when FFD program information is requested to support authorization determinations under subpart C of part 26; § 73.56; or § 73.120 of this chapter.

(b) *Training and assessments*. Training and a trainee assessment must be conducted before pre-access testing, and refresher training and trainee assessments must be conducted periodically thereafter.

(c) *Training program review*. The licensee or other entity must periodically evaluate its FFD training program and revise it as appropriate to reflect industry experience as well as applicable changes to the regulations in this part, the HHS Guidelines, if used, and specimen collection and testing processes implemented by the licensee or other entity.

§ 26.609 Behavioral observation.

(a) Licensees and other entities must ensure that the individuals who are subject to this subpart are subject to behavioral observation and that behavioral observation is performed by all individuals subject to this subpart.

(b) Licensees and other entities must require all individuals subject to the FFD program to report to the licensee- or other entity-designated representative any onsite or offsite behaviors or activities by individuals subject to this part that may constitute an unreasonable risk to the safety or security of the NRC-licensed facility or SNM, or may cause harm to others. This reporting must include any information relating to character or reputation of the individual indicating that the individual cannot be trusted or relied

upon to perform those duties and responsibilities or maintain access to NRC-licensed facilities, SNM, or sensitive information that makes them subject to part 26.

(c) Behavioral observation must be performed visually, in-person, and, when necessary, remotely by live video and audible streaming and capture, to observe the behavior of individuals in the workforce subject to the requirements in this subpart.

(d) Not withstanding § 26.609(c), for a reactor facility where individual task loading does not allow for the effective conduct of behavior observation in addition to assigned operational tasks, the licensee or other entity must implement a live video and audible streaming and capture system to conduct behavioral observation of NRC-licensed operators who manipulate the controls of any commercial nuclear plant licensed under part 53 of this chapter.

§ 26.610 Sanctions.

Licensees and other entities that implement an FFD program under this subpart must establish sanctions for FFD policy violations that, at a minimum, prohibit the individuals specified in § 26.4 from being assigned to perform or direct those duties and responsibilities or maintaining authorization making them subject to this subpart. The severity of the sanction must escalate with the number of occurrences and severity of the FFD policy violation. The sanction must be long enough to act as a deterrent and, if the individual is retained as a licensee employee or contractor/vendor, facilitate the individual to complete counseling or treatment. The sanctions must include a minimum 5-year denial of access to the NRC-licensed facility for any individual who is determined to have been involved in the sale, use, or possession of illegal drugs or the consumption of alcohol within a protected area of any facility licensed under part 53 of this chapter or within a transporter's facility or vehicle used in the conveyance of formula quantities of strategic SNM while the individual is subject to this subpart, and a permanent denial of

access to the NRC-licensed facility for three FFD policy violations or any subversion attempt of any drug or alcohol test or screening process, including subversion attempts at any licensee or other entity subject to part 26.

§ 26.611 Protection of information.

(a) Licensees and other entities that collect personal information about an individual for the purpose of complying with this subpart must establish and maintain a system of files and procedures to prevent unauthorized disclosure.

(b) Licensees and other entities must obtain a signed consent that documents the individual's acceptance of being subject to the FFD program and authorizes the disclosure of the personal information collected and maintained under this subpart, except for disclosures to the individuals and entities specified in § 26.37(b)(1) through (b)(6), (b)(8), and persons deciding matters under review in § 26.613. This signed and dated consent must be obtained before making the individual subject to the FFD program.

§ 26.613 Appeals process.

Licensees and other entities that implement an FFD program under this subpart must establish and implement procedures for the review of a determination that an individual in § 26.4 has violated the FFD policy. The procedure must provide for an objective and impartial review of the facts related to the determination that the individual has violated the FFD policy and a schedule for the completion of the review.

§ 26.615 Audits.

(a) Licensees and other entities that implement an FFD program under this subpart must audit their programs at a frequency that ensures the continuing effectiveness of their FFD program, FFD program elements that are provided by C/Vs, and the FFD programs of C/Vs that are accepted by the licensee or other entity.

Corrective actions must be as soon as reasonably practicable to resolve any problems identified in an audit and preclude recurrence.

(b) The subject matter, scope, and frequency of audits must be revised as necessary to improve or maintain program performance based on findings resulting from licensee or other entity implementation of its FFD PMRP in § 26.603(d).

(c) Licensees and other entities may conduct joint audits or accept audits of C/Vs so long as the audit addresses the relevant services of the C/Vs.

(d) Licensees and other entities must audit HHS-certified laboratories unless the licensee's or other entity's panel of drugs and drug metabolites to be tested is equivalent to the panel by which the laboratory is certified by HHS or is subject to the standards and procedures for drug testing and evaluation used by the laboratory under the HHS Guidelines. Licensees and other entities must audit any hospital or other facility licensed by the State (or State-designated entity) if used to conduct specimen collections and perform alcohol testing under this part on a biennial basis to confirm that the facility procedures are comparable to those described in subpart E of this part, for urine and oral fluid.

§ 26.617 Recordkeeping and reporting.

(a) Licensees and other entities that implement FFD programs under this subpart must ensure that records pertaining to the administration of their program, which may be stored and archived electronically, are maintained so that they are available for NRC inspection purposes and for any legal proceedings resulting from the administration of the program. Records pertaining to the administration of the FFD program and FFD performance data required by § 26.717 must be retained until license termination.

(b) Licensees and other entities must make the following reports:

(1) Reports to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers any intentional act that casts doubt on the integrity of the FFD program and any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by individuals who are subject to this subpart. These events must be reported under this subpart, rather than under the provisions of § 73.71 of this chapter; and

(2) Annual program performance reports for the FFD program, including the FFD program performance data listed in § 26.717(b), as applicable. Licensees and other entities must submit FFD program performance data (for January through December) to the NRC annually, before March 1 of the following year and must use unexpired NRC-provided forms for the electronic submission of FFD information to the NRC.

(c) Licensees and other entities subject to this subpart must describe in sufficient detail to support an authorization determination, an individual's FFD policy violation (while protecting privacy information under § 26.611) and FFD program weakness to NRC, licensees, and other entities subject to part 26 when requested to support authorization determinations under subpart C of part 26 or § 73.120 of this chapter, as applicable, or to support licensee or other entity performance monitoring.

§ 26.619 Suitability and fitness determinations.

Licensees and other entities that implement FFD programs under this subpart must develop, implement, and maintain procedures for evaluating whether to assign individuals to perform or direct those duties and responsibilities making them subject to this subpart. A suitability or fitness determination conducted for cause must be performed face to face. A suitability or fitness determination conducted for cause may be performed remotely using electronic communications only when supported by someone

who is present in-person with the individual being assessed, and that supporting person must be trained in accordance with the requirements of either § 26.29 or § 26.608.

94. In § 26.709, redesignate the introductory text as new paragraph (a), revise and add new paragraph (b) to read as follows:

§ 26.709 Applicability.

(a) The requirements of this subpart apply to the FFD programs of licensees and other entities specified in § 26.3(a) through (d), except for FFD programs that are implemented under subpart K of this part.

(b) The requirements in this subpart apply to the FFD programs of licensees and other entities specified in § 26.3(f) that elect not to implement the requirements in subpart M or elect to implement the requirements in § 26.605(b).

§ 26.711 [Amended]

95. In § 26.711, add ", (d) and (f)" after "as applicable, (c)", wherever it may appear.

§ 26.825 [Amended]

96. In § 26.825, revise paragraph (b) to read as follows:

(b) The regulations in Part 26 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 26.1, 26.3, 26.5, 26.7, 26.8, 26.9, 26.11, 26.51, 26.81, 26.121, 26.151, 26.181, 26.201, 26.601, 26.823, and 26.825.

PART 30 – RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

97~~6~~. The authority citation for part 30 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 81, 161, 181, 182, 183, 184, 186, 187, 223, 234, 274 (42 U.S.C. 2014, 2111, 2201, 2231, 2232, 2233, 2234, 2236, 2237, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 44 U.S.C. 3504 note.

§ 30.4 [Amended]

9~~7~~8. In § 30.4, in the definition for "*Utilization facility",* add "or part 53" after "in part 50".

9~~9~~8. In § 30.50, revise paragraph (c)(3) to read as follows:

§ 30.50 Reporting requirements.

* * * * *

(c) * * *

(3) The provisions of § 30.50 do not apply to licensees subject to the notification requirements in § 50.72~~,~~ or § 53.1630~~, or § 53.6330~~. They do apply to those part 50, 52 and 53 licensees possessing material licensed under part 30, who are not subject to the notification requirements in § 50.72 or § 53.1630.

PART 40 – DOMESTIC LICENSING OF SOURCE MATERIAL

100~~99~~. The authority citation for part 40 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 62, 63, 64, 65, 69, 81, 83, 84, 122, 161, 181, 182, 183, 184, 186, 187, 193, 223, 234, 274, 275 (42 U.S.C. 2092, 2093, 2094, 2095, 2099, 2111, 2113, 2114, 2152, 2201, 2231, 2232, 2233, 2234, 2236, 2237, 2243, 2273, 2282, 2021, 2022); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Uranium Mill Tailings Radiation Control Act of 1978, sec. 104 (42 U.S.C. 7914); 44 U.S.C. 3504 note.

101~~0~~. In § 40.60, revise paragraph (c)(3) to read as follows:

§ 40.60 Reporting requirements.

* * * * *

(c) * * *

(3) The provisions of § 40.60 do not apply to licensees subject to the notification requirements in § 50.72~~,~~ or § 53.1630~~, or § 53.6330~~. They do apply to those part 50, 52, and 53 licensees possessing material licensed under part 40 who are not subject to the notification requirements in § 50.72 or § 53.1630.

PART 50 – DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

10~~2~~4. The authority citation for part 50 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 62, 63, 64, 65, 69, 81, 83, 84, 122, 161, 181, 182, 183, 184, 186, 187, 193, 223, 234, 274, 275 (42 U.S.C. 2092, 2093, 2094, 2095, 2099, 2111, 2113, 2114, 2152, 2201, 2231, 2232, 2233, 2234, 2236, 2237, 2243, 2273, 2282, 2021, 2022); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Uranium Mill Tailings Radiation Control Act of 1978, sec. 104 (42 U.S.C. 7914); 44 U.S.C. 3504 note.

103. In § 50.11, revise the introductory text to read as follows:

§ 50.11 Exceptions and exemptions from licensing requirements.

Nothing in this part or parts 52, 53, or 54 of this chapter will be deemed to require a license for:

* * * * *

~~102. In § 50.44, revise paragraphs (c) introductory text and (d) introductory text to read as follows:~~

~~**§ 50.44 Combustible gas control for nuclear power reactors.**~~

* * * * *

~~(c) *Requirements for future water-cooled reactor applicants and licensees.*[2] The requirements in this paragraph apply to all water-cooled reactor construction permits or operating licenses under this part or Framework B of part 53 of this chapter, and to all water-cooled reactor design approvals, design certifications, combined licenses or manufacturing licenses under part 52 or Framework B of part 53 of this chapter, any of which are issued after October 16, 2003.~~

* * * * *

~~(d) *Requirements for future non water-cooled reactor applicants and licensees and certain water-cooled reactor applicants and licensees.* The requirements in this paragraph apply to all construction permits and operating licenses under this part and Framework B of part 53 of this chapter, and to all design approvals, design certifications, combined licenses, or manufacturing licenses under part 52 and Framework B of part 53~~

of this chapter, for non-water-cooled reactors and water-cooled reactors that do not fall within the description in paragraph (c), footnote 1 of this section, any of which are issued after October 16, 2003. Applications subject to this paragraph must include:

* * * * *

103. In § 50.46, revise paragraphs (a)(1)(i) and (a)(3)(i) through (iii) to read as follows:

§ 50.46 Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors

(a)(1)(i) Each boiling or pressurized light-water nuclear power reactor fueled with uranium oxide pellets within cylindrical zircaloy or ZIRLO cladding must be provided with an emergency core cooling system (ECCS) that must be designed so that its calculated cooling performance following postulated loss-of-coolant accidents conforms to the criteria set forth in paragraph (b) of this section. ECCS cooling performance must be calculated in accordance with an acceptable evaluation model and must be calculated for a number of postulated loss-of-coolant accidents of different sizes, locations, and other properties sufficient to provide assurance that the most severe postulated loss-of-coolant accidents are calculated. Except as provided in paragraph (a)(1)(ii) of this section, the evaluation model must include sufficient supporting justification to show that the analytical technique realistically describes the behavior of the reactor system during a loss-of-coolant accident. Comparisons to applicable experimental data must be made and uncertainties in the analysis method and inputs must be identified and assessed so that the uncertainty in the calculated results can be estimated. This uncertainty must be accounted for, so that, when the calculated ECCS cooling performance is compared to the criteria set forth in paragraph (b) of this section, there is a high level of probability that the criteria would not be exceeded. Appendix K, Part II Required Documentation,

sets forth the documentation requirements for each evaluation model. This section does not apply to a nuclear power reactor facility for which the certifications required under § 50.82(a)(1) or § 53.4670(a) have been submitted, or to those licensed under Framework A of part 53 of this chapter.

* * * * *

(3)(i) Each applicant for or holder of an operating license or construction permit issued under this part or Framework B of part 53 of this chapter subject to this section, applicant for a standard design certification under part 52 or Framework B of part 53 of this chapter (including an applicant after the Commission has adopted a final design certification regulation) subject to this section, or an applicant for or holder of a standard design approval, a combined license, or a manufacturing license issued under part 52 or Framework B of part 53 of this chapter subject to this section, shall estimate the effect of any change to or error in an acceptable evaluation model or in the application of such a model to determine if the change or error is significant. For this purpose, a significant change or error is one which results in a calculated peak fuel cladding temperature different by more than 50 °F from the temperature calculated for the limiting transient using the last acceptable model, or is a cumulation of changes and errors such that the sum of the absolute magnitudes of the respective temperature changes is greater than 50 °F.

(ii) For each change to or error discovered in an acceptable evaluation model or in the application of such a model that affects the temperature calculation, the applicant or holder of a construction permit, operating license, combined license, or manufacturing license shall report the nature of the change or error and its estimated effect on the limiting ECCS analysis to the Commission at least annually as specified in § 50.4, § 52.3, or § 53.040 of this chapter, as applicable. If the change or error is significant, the

applicant or licensee shall provide this report within 30 days and include with the report a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with § 50.46 requirements. This schedule may be developed using an integrated scheduling system previously approved for the facility by the NRC. For those facilities not using an NRC approved integrated scheduling system, a schedule will be established by the NRC staff within 60 days of receipt of the proposed schedule. Any change or error correction that results in a calculated ECCS performance that does not conform to the criteria set forth in paragraph (b) of this section is a reportable event as described in §§ 50.55(e), 50.72, and 50.73. For applicants or holders of a construction permit, operating license, combined license, or manufacturing license under Framework B of part 53 of this chapter, the reporting requirements of §§ 53.4105, 53.6330, and 53.6340 of this chapter apply in lieu of the reporting requirements of §§ 50.55(e), 50.72, and 50.73. The affected applicant or licensee shall propose immediate steps to demonstrate compliance or bring plant design or operation into compliance with § 50.46 requirements.

(iii) For each change to or error discovered in an acceptable evaluation model or in the application of such a model that affects the temperature calculation, the applicant or holder of a standard design approval or the applicant for a standard design certification (including an applicant after the Commission has adopted a final design certification rule) shall report the nature of the change or error and its estimated effect on the limiting ECCS analysis to the Commission and to any applicant or licensee referencing the design approval or design certification at least annually as specified in § 52.3 or § 53.040 of this chapter. If the change or error is significant, the applicant or holder of the design approval or the applicant for the design certification shall provide this report within 30 days and include with the report a proposed schedule for providing a

~~reanalysis or taking other action as may be needed to show compliance with § 50.46 requirements. The affected applicant or holder shall propose immediate steps to demonstrate compliance or bring plant design into compliance with § 50.46 requirements.~~

* * * * *

104. In § 50.47, revise paragraphs (a)(1) to read as follows:

§ 50.47 Emergency plans.

(a)(1)(i) Except as provided in paragraph (d) of this section, no initial operating license for a nuclear power reactor will be issued under this part or under part 53 of this chapter unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. No finding under this section is necessary for issuance of a renewed nuclear power reactor operating license.

(ii) No initial combined license under part 52 or part 53 of this chapter will be issued unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. No finding under this section is necessary for issuance of a renewed combined license.

(iii) If an application for an early site permit under subpart A of part 52 or subpart H of part 53 of this chapter includes complete and integrated emergency plans under 10 CFR 52.17(b)(2)(ii) or § 53.1146(b)(2)(ii), respectively, ~~or an application for an early site permit under subparts H or R of part 53 of this chapter includes complete and integrated emergency plans under § 53.1146(b)(2)(ii) or § 53.4756(b)(2)(ii) of this chapter,~~ no early site permit will be issued unless a finding is made by the NRC that the emergency plans

provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

(iv) If an application for an early site permit proposes major features of the emergency plans under § 52.17(b)(2)(i)~~,~~ or § 53.1146(b)(2)(i)~~, or § 53.4756(b)(2)(i)~~ of this chapter, no early site permit will be issued unless a finding is made by the NRC that the major features are acceptable in accordance with the applicable standards of 10 CFR 50.47 and 10 CFR part 50, appendix E, within the scope of emergency preparedness matters addressed in the major features.

* * * * *

~~105. In § 50.55a:~~

~~a. Revise paragraphs (b)(1), (b)(2)(xxi)(B)(*3*), (b)(3)(iii), and (b)(4);~~

~~b. Revise paragraph (c) introductory text;~~

~~c. Revise paragraphs (d) introductory text and (d)(1);~~

~~d. Revise paragraph (e) introductory text and (e)(1);~~

~~e. Revise paragraph (f) introductory text and paragraphs (f)(3), (f)(3)(iii)(B), (f)(3)(iv)(B), and (f)(4)(i);~~

~~f. Revise paragraph (g) introductory text and paragraphs (g)(2)(ii), (g)(3)(ii), (g)(4)(i) and (v).~~

~~The revisions to read as follows:~~

~~§ 50.55a Codes and standards.~~

* * * * *

~~(b) * * *~~

~~(1) *Conditions on ASME BPV Code Section III.* Each manufacturing license, standard design approval, and design certification under 10 CFR part 52 and each manufacturing license, standard design approval, and design certification for a boiling or pressurized water-cooled commercial nuclear plant under Framework B of~~

10 CFR part 53 is subject to the following conditions. As used in this section, references to Section III refer to Section III of the ASME BPV Code and include the 1963 Edition through 1973 Winter Addenda and the 1974 Edition (Division 1) through the 2017 Edition (Division 1), subject to the following conditions:

* * * * *

(2) * * *

(xxi) * * *

(B) * * *

(*3*) The provisions of IWB-2500(g) and Table IWB-2500-1 Notes 6 and 7 for examination of Examination Category B-D Item Numbers B3.90 and B3.100 shall not be used to eliminate the preservice or inservice volumetric examination of plants with a Combined License pursuant to 10 CFR part 52 or of boiling or pressurized water-cooled commercial nuclear plants under Framework B of 10 CFR part 53, or a plant that receives its operating license after October 22, 2015.

* * * * *

(3) * * *

(iii) *OM condition: New reactors.* In addition to complying with the provisions in the ASME OM Code with the conditions specified in paragraph (b)(3) of this section, holders of operating licenses for nuclear power reactors that received construction permits under this part on or after the date 12 months after August 17, 2017, and holders of combined licenses issued under 10 CFR part 52, whose initial fuel loading occurs on or after the date 12 months after August 17, 2017, and holders of operating licenses or combined licenses for boiling or pressurized water-cooled commercial nuclear plants under Framework B of 10 CFR part 53, shall also comply with the following conditions, as applicable:

* * * * *

(4) *Conditions on Design, Fabrication, and Materials Code Cases.* Each manufacturing license, standard design approval, and design certification application under part 52 and each manufacturing license, standard design approval, and design certification for a boiling or pressurized water-cooled commercial nuclear plants under Framework B of part 53 of this chapter is subject to the following conditions. Licensees may apply the ASME BPV Code Cases listed in NRC Regulatory Guide 1.84, as incorporated by reference in paragraph (a)(3)(i) of this section, without prior NRC approval, subject to the following conditions:

* * * * *

(c) *Reactor coolant pressure boundary.* Systems and components of boiling and pressurized water-cooled nuclear power reactors must satisfy the requirements of the ASME BPV Code as specified in this paragraph. Each manufacturing license, standard design approval, and design certification application under part 52 or Framework B of part 53 of this chapter and each combined license under part 52 or boiling or pressurized water-cooled commercial nuclear plants Framework B of part 53 for a utilization facility is subject to the following conditions:

* * * * *

(d) *Quality Group B components.* Systems and components of boiling and pressurized water-cooled nuclear power reactors must satisfy the requirements of the ASME BPV Code as specified in this paragraph. Each manufacturing license, standard design approval, and design certification application under part 52 of this chapter, each combined license under part 52 of this chapter for a utilization facility, and each manufacturing license, standard design approval, design certification and combined

license for a boiling or pressurized water-cooled commercial nuclear plant under Framework B of part 53 of this chapter is subject to the following conditions:

(1) *Standards requirement for Quality Group B components.* For a nuclear power plant whose application for a construction permit under this part, or a combined license or manufacturing license under part 52 of this chapter, docketed after May 14, 1984, or for an application for a standard design approval or a standard design certification docketed after May 14, 1984, components classified Quality Group B[6] must satisfy the requirements for Class 2 Components in Section III of the ASME BPV Code. For a commercial nuclear plant whose application for a construction permit, combined license, manufacturing license, standard design approval, or standard design certification, uses a design for a boiling or pressurized water cooled commercial nuclear plant under Framework B of part 53, components classified Quality Group B[7] must satisfy the requirements for Class 2 Components in Section III of the ASME BPV Code.

* * * * *

(e) *Quality Group C components.* Systems and components of boiling and pressurized water-cooled nuclear power reactors must satisfy the requirements of the ASME BPV Code as specified in this paragraph. Each manufacturing license, standard design approval, and design certification application under part 52 of this chapter and each combined license under part 52 of this chapter for a utilization facility, and each manufacturing license, standard design approval, design certification and combined license for a boiling or pressurized water-cooled commercial nuclear plant under Framework B of part 53 of this chapter is subject to the following conditions.

(1) *Standards requirement for Quality Group C components.* For a nuclear power plant whose application for a construction permit under this part, or a combined license or manufacturing license under part 52 of this chapter, docketed after May 14, 1984, or

for an application for a standard design approval or a standard design certification docketed after May 14, 1984, or for a boiling or pressurized water-cooled commercial nuclear plants application for a construction permit , combined license, or manufacturing license under Framework B of part 53 of this chapter, components classified Quality Group C[7] must satisfy the requirements for Class 3 components in Section III of the ASME BPV Code.

* * * * *

(f) *Preservice and inservice testing requirements.* Systems and components of boiling and pressurized water-cooled nuclear power reactors licensed under this part, part 52 of this chapter, or Framework B of part 53 of this chapter must satisfy the requirements for preservice and inservice testing (referred to in this paragraph (f) collectively as inservice testing) of the ASME BPV Code and ASME OM Code as specified in this paragraph (f). Each operating license for a boiling or pressurized water-cooled nuclear facility is subject to the following conditions. Each combined license for a boiling or pressurized water-cooled nuclear facility is subject to the following conditions, but the conditions in paragraphs (f)(4) through (6) of this section must be met only after the Commission makes the finding under § 52.103(g) or § 53.5052(g) of this chapter. Requirements for inservice inspection of Class 1, Class 2, Class 3, Class MC, and Class CC components (including their supports) are located in paragraph (g) of this section.

* * * * *

(3) *Design and accessibility requirements for performing inservice testing in plants with CPs issued after 1974.* For a boiling or pressurized water-cooled nuclear power facility whose construction permit under this part or boiling or pressurized water-cooled commercial nuclear plants under Framework B of part 53 of this chapter, or design approval, design certification, combined license, or manufacturing license under

part 52 or boiling or pressurized water-cooled commercial nuclear plants under Framework B of part 53 of this chapter was issued on or after July 1, 1974:

* * * * *

(iii) * * *

(B) *Class 1 pumps and valves: Second provision.* In facilities whose construction permit under this part or boiling or pressurized water-cooled commercial nuclear plants under Framework B of part 53 of this chapter, or design certification, design approval, combined license, or manufacturing license under part 52 or boiling or pressurized water-cooled commercial nuclear plants under Framework B of part 53 of this chapter, issued on or after November 22, 1999, pumps and valves that are classified as ASME BPV Code Class 1 must be designed and provided with access to enable the performance of inservice testing of the pumps and valves for assessing operational readiness set forth in editions and addenda of the ASME OM Code (or the optional ASME OM Code Cases listed in NRC Regulatory Guide 1.192, as incorporated by reference in paragraph (a)(3)(iii) of this section), incorporated by reference in paragraph (a)(1)(iv) of this section at the time the construction permit, combined license, manufacturing license, design certification, or design approval is issued.

(iv) * * *

(B) *Class 2 and 3 pumps and valves: Second provision.* In facilities whose construction permit under this part, design certification, design approval, combined license, or manufacturing license under part 52, issued on or after November 22, 1999, or construction permit, design certification, design approval, combined license, or manufacturing license for a boiling or pressurized water-cooled commercial nuclear plant under Framework B of part 53 of this chapter, pumps and valves that are classified as ASME BPV Code Class 2 and 3 must be designed and provided with access to enable

the performance of inservice testing of the pumps and valves for assessing operational readiness set forth in editions and addenda of the ASME OM Code (or the optional ASME OM Code Cases listed in NRC Regulatory Guide 1.192, as incorporated by reference in paragraph (a)(3)(iii) of this section), incorporated by reference in paragraph (a)(1)(iv) of this section at the time the construction permit, combined license, or design certification is issued.

* * * * *

(4) * * *

(i) *Applicable IST Code: Initial 120-month interval.* Inservice tests to verify operational readiness of pumps and valves, whose function is required for safety, conducted during the initial 120-month interval must comply with the requirements in the latest edition and addenda of the ASME OM Code incorporated by reference in paragraph (a)(1)(iv) of this section on the date 18 months before the date of issuance of the operating license under this part or operating license for a boiling or pressurized water-cooled commercial nuclear plant under Framework B of part 53 of this chapter, or 18 months before the date scheduled for initial loading of fuel under a combined license under part 52 or under a combined license for a boiling or pressurized water-cooled commercial nuclear plant under Framework B of part 53 of this chapter (or the optional ASME OM Code Cases listed in NRC Regulatory Guide 1.192, as incorporated by reference in paragraph (a)(3)(iii) of this section, subject to the conditions listed in paragraph (b) of this section).

* * * * *

(g) *Preservice and inservice inspection requirements.* Systems and components of boiling and pressurized water-cooled nuclear power reactors licensed under part 52 or Framework B of part 53 of this chapter must satisfy the requirements of the ASME BPV

Code as specified in this paragraph. Each operating license for a boiling or pressurized water-cooled nuclear facility is subject to the following conditions. Each combined license for a boiling or pressurized water-cooled nuclear facility is subject to the following conditions, but the conditions in paragraphs (g)(4) through (6) of this section must be met only after the Commission makes the finding under § 52.103(g) or § 53.5052(g) of this chapter. Requirements for inservice testing of Class 1, Class 2, and Class 3 pumps and valves are located in paragraph (f) of this section.

* * * * *

(2) * * *

(ii) *Accessibility requirements for plants with CPs issued after 1974.* For a boiling or pressurized water-cooled nuclear power facility, whose construction permit under this part or design certification, design approval, combined license, or manufacturing license under part 52 or construction permit, design certification, design approval, combined license, or manufacturing license for a boiling or pressurized water-cooled commercial nuclear plants under Framework B of part 53 of this chapter, was issued on or after July 1, 1974, components that are classified as ASME BPV Code Class 1, Class 2, and Class 3 and supports for components that are classified as ASME BPV Code Class 1, Class 2, and Class 3 must be designed and provided with the access necessary to perform the required preservice and inservice examinations set forth in editions and addenda of Section III or Section XI of the ASME BPV Code incorporated by reference in paragraph (a)(1) of this section (or the optional ASME BPV Code Cases listed in NRC Regulatory Guide 1.147, as incorporated by reference in paragraph (a)(3)(ii) of this section) applied to the construction of the particular component.

* * * * *

(3) * * *

(ii) *Preservice examination requirements for plants with CPs issued after 1974.* For a boiling or pressurized water-cooled nuclear power facility, whose construction permit under this part or design certification, design approval, combined license, or manufacturing license under part 52 of this chapter, was issued on or after July 1, 1974, or for construction permit, design certification, design approval, combined license, or manufacturing license for a boiling or pressurized water-cooled commercial nuclear plants under Framework B of part 53 of this chapter, components that are classified as ASME BPV Code Class 1, Class 2, and Class 3 and supports for components that are classified as ASME BPV Code Class 1, Class 2, and Class 3 must satisfy the preservice examination requirements set forth in the editions and addenda of Section III or Section XI of the ASME BPV Code incorporated by reference in paragraph (a)(1) of this section (or the optional ASME BPV Code Cases listed in NRC Regulatory Guide 1.147, as incorporated by reference in paragraph (a)(3)(ii) of this section) applied to the construction of the particular component.

* * * * *

(4) * * *

(i) *Applicable ISI Code: Initial 120-month interval.* Inservice examination of components and system pressure tests conducted during the initial 120-month inspection interval must comply with the requirements in the latest edition and addenda of the ASME Code incorporated by reference in paragraph (a) of this section on the date 18 months before the date of issuance of the operating license under this part or for the operating license for a boiling or pressurized water-cooled commercial nuclear plant under Framework B of part 53 of this chapter, or 18 months before the date scheduled for initial loading of fuel under a combined license under part 52 or under a combined license for a boiling or pressurized water-cooled commercial nuclear plant under

Framework B of part 53 of this chapter (or the optional ASME Code Cases listed in NRC Regulatory Guide 1.147, when using ASME BPV Code, Section XI, or NRC Regulatory Guide 1.192, when using the ASME OM Code, as incorporated by reference in paragraphs (a)(3)(ii) and (iii) of this section, respectively), subject to the conditions listed in paragraph (b) of this section. Licensees may, at any time in their 120-month ISI interval, elect to use the Appendix VIII in the latest edition and addenda of the ASME BPV Code incorporated by reference in paragraph (a) of this section, subject to any applicable conditions listed in paragraph (b) of this section. Licensees using this option must also use the same edition and addenda of Appendix I, Subarticle I-3200, as Appendix VIII, including any applicable conditions listed in paragraph (b) of this section.

* * * * *

(v) *Applicable ISI Code: Metal and concrete containments.* For a boiling or pressurized water-cooled nuclear power facility whose construction permit under this part or under Framework B of part 53 of this chapter, or combined license under part 52 or under Framework B of part 53 of this chapter was issued after January 1, 1956, the following are required:

* * * * *

106. Revise § 50.60 to read as follows:

§ 50.60 Acceptance criteria for fracture prevention measures for light-water nuclear power reactors for normal operation.

(a) Except as provided in paragraph (b) of this section, all light-water nuclear power reactors for which a license, certification, or approval has been issued under this part, part 52, or Framework B of part 53 of this chapter, other than reactor facilities for which the certifications required under § 50.82(a)(1) or § 53.4670(a) of this chapter have been submitted, must satisfy the fracture toughness and material surveillance program

requirements for the reactor coolant pressure boundary set forth in appendices G and H to this part.

(b) Proposed alternatives to the described requirements in Appendices G and H of this part or portions thereof may be used when an exemption is granted by the Commission under § 50.12 or § 53.080 of this chapter.

107. In § 50.61, revise paragraph (b)(1) to read as follows:

§ 50.61 Fracture toughness requirements for protection against pressurized thermal shock events.

* * * * *

(b) *Requirements*. (1) For each pressurized-water nuclear power reactor for which an operating license has been issued under this part or Framework B of part 53 of this chapter, or a combined license issued under Part 52 or Framework B of part 53 of this chapter, other than a nuclear power reactor facility for which the certification required under § 50.82(a)(1) or § 53.4670(a) has been submitted, the licensee shall have projected values of RT_{PTS} or RT_{MAX-X}, accepted by the NRC, for each reactor vessel beltline material. For pressurized-water nuclear power reactors for which a construction permit was issued under this part before February 3, 2010, and whose reactor vessel was designed and fabricated to the 1998 Edition or earlier of the ASME Code, the projected values must be in accordance with this section or § 50.61a. For pressurized-water nuclear power reactors for which a construction permit is issued under this part or Framework B of part 53 of this chapter after February 3, 2010, and whose reactor vessel is designed and fabricated to an ASME Code after the 1998 Edition, or for which a combined license is issued under Part 52 or Framework B of part 53 of this chapter, the projected values must be in accordance with this section. When determining compliance with this section, the assessment of RT_{PTS} must use the calculation procedures described in paragraph (c)(1) of this section and perform the evaluations

described in paragraphs (c)(2) and (c)(3) of this section. The assessment must specify the bases for the projected value of RT_{PTS} for each vessel beltline material, including the assumptions regarding core loading patterns, and must specify the copper and nickel contents and the fluence value used in the calculation for each beltline material. This assessment must be updated whenever there is a significant[2] change in projected values of RT_{PTS}, or upon request for a change in the expiration date for operation of the facility.

* * * * *

108. In § 50.62, revise paragraphs (a), (b), (c)(4) and (6), and (d) to read as follows:

§ 50.62 Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants.

(a) *Applicability*. The requirements of this section apply to all commercial light-water-cooled nuclear power plants licensed under this part, part 52, or Framework B of part 53 of this chapter, other than nuclear power reactor facilities for which the certifications required under § 50.82(a)(1), § 52.110(a), or § 53.4670(a) of this chapter have been submitted.

(b) *Definition*. For purposes of this section, *Anticipated Transient Without Scram* (ATWS) means an anticipated operational occurrence as defined in appendix A of this part or as defined in § 53.028 of this chapter for commercial nuclear plants licensed under Framework B of part 53, followed by the failure of the reactor trip portion of the protection system specified in General Design Criterion 20 of appendix A of this part.

(c) * * *

(4) Each boiling-water reactor must have a standby liquid control system (SLCS) with the capability of injecting into the reactor pressure vessel a borated water solution at

such a flow rate, level of boron concentration and boron-10 isotope enrichment, and accounting for reactor pressure vessel volume, that the resulting reactivity control is at least equivalent to that resulting from injection of 86 gallons per minute of 13 weight percent sodium pentaborate decahydrate solution at the natural boron-10 isotope abundance into a 251-inch inside diameter reactor pressure vessel for a given core design. The SLCS and its injection location must be designed to perform its function in a reliable manner. The SLCS initiation must be automatic and must be designed to perform its function in a reliable manner for plants granted a construction permit after July 26, 1984, under this part or Framework B of part 53 of this chapter and for plants granted a construction permit prior to July 26, 1984, that have already been designed and built to include this feature.

* * * * *

(6) Information sufficient to demonstrate to the Commission the adequacy of items in paragraphs (c)(1) through (c)(5) of this section shall be submitted to the Commission as specified in § 50.4 or § 53.040 of this chapter.

(d) *Implementation.* For each light-water-cooled nuclear power plant operating license issued before September 27, 2007, by 180 days after the issuance of the QA guidance for non-safety-related components, each licensee shall develop and submit to the Commission, as specified in § 50.4 or § 53.040 of this chapter, a proposed schedule for meeting the requirements of paragraphs (c)(1) through (c)(5) of this section. Each shall include an explanation of the schedule along with a justification if the schedule calls for final implementation later than the second refueling outage after July 26, 1984, or the date of issuance of a license authorizing operation above 5 percent of full power. A final schedule shall then be mutually agreed upon by the Commission and licensee. For each light-water-cooled nuclear power plant operating license application under this part, or

operating license or combined license application for a light-water-cooled commercial nuclear plant under Framework B of part 53 of this chapter, submitted after September 27, 2007, the applicant shall submit information in its Final Safety Analysis Report demonstrating how it will comply with paragraphs (c)(1) through (c)(5) of this section.

109. In § 50.63, revise paragraphs (a)(1) introductory text and (c)(2) to read as follows:

§ 50.63 Loss of all alternating current power.

(a) *Requirements.* (1) Each light-water-cooled nuclear power plant licensed to operate under this part or under § 53.4960 of this chapter, each light-water-cooled nuclear power plant licensed under subpart C of 10 CFR part 52 after the Commission makes the finding under § 52.103(g) of this chapter, each light-water-cooled nuclear power plant licensed under § 53.5010 of this chapter after the Commission makes the finding under § 53.5052(g) of this chapter, and each design for a light-water-cooled nuclear power plant approved under a standard design approval, standard design certification, and manufacturing license under part 52 or under Framework B of part 53 of this chapter must be able to withstand for a specified duration and recover from a station blackout as defined in § 50.2. The specified station blackout duration shall be based on the following factors:

* * * * *

(c) * * *

(2) *Alternate ac source*: The alternate ac power source(s), as defined in § 50.2, will constitute acceptable capability to withstand station blackout provided an analysis is performed which demonstrates that the plant has this capability from onset of the station blackout until the alternate ac source(s) and required shutdown equipment are started and lined up to operate. The time required for startup and alignment of the alternate ac

power source(s) and this equipment shall be demonstrated by test. Alternate ac source(s) serving a multiple unit site where onsite emergency ac sources are not shared between units must have, as a minimum, the capacity and capability for coping with a station blackout in any of the units. At sites, subject to this section, where onsite emergency ac sources are shared between units, the alternate ac source(s) must have the capacity and capability as required to ensure that all units can be brought to and maintained in safe shutdown (non-DBA) as defined in § 50.2. If the alternate ac source(s) meets the above requirements and can be demonstrated by test to be available to power the shutdown buses within 10 minutes of the onset of station blackout, then no coping analysis is required.

* * * * *

110. In Appendix A to part 50, revise the first paragraph in the Introduction section and the last paragraph of Criterion 19 to read as follows:

Appendix A to Part 50—General Design Criteria for Nuclear Power Plants

Introduction

Under the provisions of § 50.34 and § 53.4909 of this chapter, an application for a construction permit must include the principal design criteria for a proposed facility. Under the provisions of § 52.47 and § 53.4839 of this chapter, § 52.79 and § 53.5016 of this chapter, § 52.137 and § 53.4809 of this chapter, and § 52.157 and § 53.4879 of this chapter, an application for a design certification, combined license, design approval, or manufacturing license, respectively, must include the principal design criteria for a proposed facility. The principal design criteria establish the necessary design, fabrication, construction, testing, and performance requirements for structures, systems, and components important to safety; that is, structures, systems, and components that

~~provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public.~~

* * * * *

~~**Criteria**~~

* * * * *

~~*Criterion 19—Control room.* * * *~~

~~Applicants for and holders of construction permits and operating licenses under this part or construction permits and operating licenses for water-cooled commercial nuclear reactors under Framework B of part 53 of this chapter who apply on or after January 10, 1997, applicants for design approvals or certifications under part 52 or design approvals or certifications for water-cooled commercial nuclear reactors under Framework B of part 53 of this chapter who apply on or after January 10, 1997, applicants for and holders of combined licenses or manufacturing licenses under part 52 of this chapter or applicants for and holders of combined licenses or manufacturing licenses for water-cooled commercial nuclear reactors under Framework B of part 53 of this chapter who do not reference a standard design approval or certification, or holders of operating licenses using an alternative source term under § 50.67, shall satisfy the requirements of this criterion, except that with regard to control room access and occupancy, adequate radiation protection shall be provided to ensure that radiation exposures shall not exceed 0.05 Sv (5 rem) total effective dose equivalent (TEDE) as defined in § 50.2 for the duration of the accident.~~

* * * * *

105. In Appendix B to part 50, revise the first paragraph in the Introduction section, the first paragraph of section III. Design Control, and the first paragraph of section IV. Procurement Document Control, to read as follows:

Appendix B to Part 50—Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

Introduction. Every applicant for a construction permit is required by the provisions of § 50.34 or § 53.1309 of this chapter to include in its preliminary safety analysis report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Every applicant for an operating license is required to include, in its final safety analysis report, information pertaining to the managerial and administrative controls to be used to assure safe operation. Every applicant for a combined license is required by the provisions of §§ 52.79 or 53.1416 of this chapter to include in its final safety analysis report a description of the quality assurance applied to the design, and to be applied to the fabrication, construction, and testing of the structures, systems, and components of the facility and to the managerial and administrative controls to be used to assure safe operation. For applications submitted after September 27, 2007, every applicant for an early site permit is required by the provisions of §§ 52.17 or 53.1146 of this chapter to include in its site safety analysis report a description of the quality assurance program applied to site activities related to the design, fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site. Every applicant for a design approval is required by the provisions of §§ 52.137 or 53.1209 of this chapter to include in its final safety analysis report a description of the quality assurance program applied to the design of the structures, systems, and components of the facility. Every applicant for a design certification is required by the provisions of §§ 52.47 or 53.1239 of this chapter to include in its final safety analysis report a description of the quality assurance program applied to the design of the structures, systems, and components of the facility. Every applicant for a manufacturing

license is required by the provisions of §§ 52.157 or 53.1279 of this chapter to include in its final safety analysis report a description of the quality assurance program applied to the design, and to be applied to the manufacture of, the structures, systems, and components of the reactor. Nuclear power plants and fuel reprocessing plants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of those structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

* * * * *

III. Design Control

Measures shall be established to assure that applicable regulatory requirements and the design bases, as defined in § 50.2 and as specified in the license application, or the functional design criteria, as defined in § 53.020 of this chapter and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components.

* * * * *

IV. Procurement Document Control

Measures shall be established to assure that applicable regulatory requirements, design bases, functional design criteria and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix.

* * * * *

~~111. In Appendix G to part 50, revise sections I. and IV.A.1.c to read as follows:~~

~~Appendix G to Part 50—Fracture Toughness Requirements~~

* * * * *

~~I. Introduction and Scope~~

~~This appendix specifies fracture toughness requirements for ferritic materials of pressure-retaining components of the reactor coolant pressure boundary of light water nuclear power reactors under this part, part 52 of this chapter, or Framework B of part 53 of this chapter to provide adequate margins of safety during any condition of normal operation, including anticipated operational occurrences and system hydrostatic tests, to which the pressure boundary may be subjected over its service lifetime.~~

* * * * *

~~IV. Fracture Toughness Requirements~~

~~A. * * *~~

~~*1.* * * *~~

~~c. The analysis for satisfying the requirements of section IV.A.1 of this appendix must be submitted, as specified in § 50.4 or § 53.040 of this chapter, for review and approval on~~

an individual case basis at least three years prior to the date when the predicted Charpy upper-shelf energy will no longer satisfy the requirements of section IV.A.1 of this appendix, or on a schedule approved by the Director, Office of Nuclear Reactor Regulation.

* * * * *

112. In appendix H to part 50, revise sections III.B.3 and IV.A to read as follows:

Appendix H to Part 50—Reactor Vessel Material Surveillance Program Requirements

* * * * *

III. Surveillance Program Criteria

* * * * *

B. * * *

3. A proposed withdrawal schedule must be submitted with a technical justification as specified in § 50.4 or § 53.040 of this chapter. The proposed schedule must be approved prior to implementation.

* * * * *

IV. Report of Test Results

A. Each capsule withdrawal and the test results must be the subject of a summary technical report to be submitted, as specified in § 50.4 or § 53.040 of this chapter, within eighteen months of the date of capsule withdrawal, unless an extension is granted by the Director, Office of Nuclear Reactor Regulation.

* * * * *

113. In appendix J to part 50, under Option A revise the Introduction paragraph and section II.A; under Option B revise the Introduction paragraph, section IV. Second paragraph and section V.A. and V.B.1 through 3 to read as follows:

~~**Appendix J to Part 50—Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors**~~

~~* * * * *~~

~~Option A—Prescriptive Requirements~~

~~* * * * *~~

~~I. Introduction~~

~~One of the conditions of all operating licenses under this part and combined licenses under part 52 of this chapter for water-cooled power reactors, and for operating licenses and combined licenses for water-cooled commercial nuclear reactors under Framework B of part 53 of this chapter, as specified in § 50.54(o) or § 53.4410, as applicable, is that primary reactor containments shall satisfy the containment leakage test requirements set forth in this appendix. These test requirements provide for preoperational and periodic verification by tests of the leak-tight integrity of the primary reactor containment, and systems and components which penetrate containment of water-cooled power reactors and establish the acceptance criteria for these tests. The purposes of the tests are to assure that (a) leakage through the primary reactor containment and systems and components penetrating primary containment shall not exceed allowable leakage rate values as specified in the technical specifications or associated bases; and (b) periodic surveillance of reactor containment penetrations and isolation valves is performed so that proper maintenance and repairs are made during the service life of the containment, and systems and components penetrating primary containment. These test requirements may also be used for guidance in establishing appropriate containment leakage test requirements in technical specifications or associated bases for other types of nuclear power reactors.~~

~~II. Explanation of Terms~~

A. "Primary reactor containment" means the structure or vessel that encloses the components of the reactor coolant pressure boundary, as defined in § 50.2 or § 53.028, and serves as an essentially leak-tight barrier against the uncontrolled release of radioactivity to the environment.

* * * * *

Option B—Performance-Based Requirements

* * * * *

I. Introduction

One of the conditions required of all operating licenses and combined licenses for light water-cooled power reactors as specified in § 50.54(o) or § 53.4410 of this chapter is that primary reactor containments satisfy the leakage-rate test requirements in either Option A or B of this appendix. These test requirements ensure that (a) leakage through these containments or systems and components penetrating these containments does not exceed allowable leakage rates specified in the technical specifications; and (b) integrity of the containment structure is maintained during its service life. Option B of this appendix identifies the performance-based requirements and criteria for preoperational and subsequent periodic leakage-rate testing.[3]

* * * * *

IV. Recordkeeping

* * * * *

If the test results exceed the performance criteria (La) as defined in the plant Technical Specifications, those exceedances must be assessed for Emergency Notification System reporting under § 50.72 (b)(2)(i) or § 53.6330(b)(2)(i) of this chapter, and for a Licensee Event Report under § 50.73 (a)(2)(ii) or § 53.6340(a)(2)(ii) of this chapter.

* * * * *

V. Application

A. Applicability

The requirements in either or both Option B, III.A for Type A tests, and Option B, III.B for Type B and C tests, may be adopted on a voluntary basis by an operating nuclear power reactor licensee as specified in § 50.54 or § 53.4410 of this chapter in substitution of the requirements for those tests contained in Option A of this appendix. If the requirements for tests in Option B, III.A or Option B, III.B are implemented, the recordkeeping requirements in Option B, IV for these tests must be substituted for the reporting requirements of these tests contained in Option A of this appendix.

B. Implementation

1. Specific exemptions to Option A of this appendix that have been formally approved by the AEC or NRC, according to § 50.12 or § 53.080 of this chapter, are still applicable to Option B of this appendix if necessary, unless specifically revoked by the NRC.

2. A licensee or applicant for an operating license under this part or under Framework B of part 53 of this chapter or a combined license under part 52 or under Framework B of part 53 of this chapter may adopt Option B, or parts thereof, as specified in Section V.A of this appendix, by submitting its implementation plan and request for revision to technical specifications (see paragraph B.3 of this section) to the Director, Office of Nuclear Reactor Regulation.

3. The regulatory guide or other implementation document used by a licensee or applicant for an operating license under this part or under Framework B of part 53 of this chapter, or a combined license under part 52 or under Framework B of part 53 of this chapter to develop a performance-based leakage-testing program must be included, by general reference, in the plant technical specifications. The submittal for technical specification revisions must contain justification, including supporting analyses, if the

licensee chooses to deviate from methods approved by the Commission and endorsed in a regulatory guide.

* * * * *

114. In appendix S to part 50, revise the paragraph under "General Information," and section I.(a) and in section III revise the definitions for "*Combined license*", "*Design approval*", "*Design certification*", "*Manufacturing license*", "*Structures, systems, and components required to withstand the effects of the safe-shutdown earthquake ground motion or surface deformation*".

The revisions to read as follows:

Appendix S to Part 50—Earthquake Engineering Criteria for Nuclear Power Plants

General Information

This appendix applies to applicants for a construction permit or operating license under part 50, a design certification, combined license, design approval, or manufacturing license under part 52 of this chapter, on or after January 10, 1997, or a construction permit, operating license, design certification, combined license, design approval, or manufacturing license under Framework B of part 53 of this chapter except for those using the alternative seismic design criteria of § 53.4733. However, for either an operating license applicant or holder whose construction permit was issued before January 10, 1997, the earthquake engineering criteria in Section VI of appendix A to 10 CFR part 100 continue to apply. Paragraphs IV.a.1.i, IV.a.1.ii, IV.4.b, and IV.4.c of this appendix apply to applicants for an early site permit under part 52.

I. *Introduction*

(a) Each applicant for a construction permit, operating license, design certification, combined license, design approval, or manufacturing license under part 50 or 52 of this chapter, as applicable, and each applicant for a construction permit,

operating license, design certification, combined license, design approval, or manufacturing license under Framework B of part 53 of this chapter is required by § 50.34(a)(12), § 50.34(b)(10), § 52.47, § 52.79, § 52.137, § 52.157, § 53.4809, § 53.4839, § 53.4879, § 53.4909, § 53.4969, or § 53.5016 and General Design Criterion 2 of appendix A to this part, to design nuclear power plant structures, systems, and components important to safety to withstand the effects of natural phenomena, such as earthquakes, without loss of capability to perform their safety functions. Also, as specified in § 50.54(ff) or § 53.4215, nuclear power plants that have implemented the earthquake engineering criteria described herein must shut down if the criteria in paragraph IV(a)(3) of this appendix are exceeded.

* * * * *

III. *Definitions*

As used in these criteria:

Combined license means a combined construction permit and operating license with conditions for a nuclear power facility issued under subpart C of part 52 or Framework B of part 53 of this chapter.

Design Approval means an NRC staff approval, issued under subpart E of part 52 or Framework B of part 53 of this chapter, of a final standard design for a nuclear power reactor of the type described in 10 CFR 50.22.

Design Certification means a Commission approval, issued under subpart B of part 52 or Framework B of part 53 of this chapter, of a standard design for a nuclear power facility.

Manufacturing license means a license, issued under subpart F of part 52 or Framework B of part 53 of this chapter, authorizing the manufacture of nuclear power

reactors but not their installation into facilities located at the sites on which the facilities are to be operated.

* * * * *

Structures, systems, and components required to withstand the effects of the safe-shutdown earthquake ground motion or surface deformation are those necessary to assure:

(1) The integrity of the reactor coolant pressure boundary;

(2) The capability to shut down the reactor and maintain it in a safe shutdown condition; or

(3) The capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the guideline exposures of § 50.34(a)(1); or

(4) For applicants or holders of a construction permit, operating license, design certification, combined license, design approval, or manufacturing license under Framework B of part 53 of this chapter, except those using the alternative seismic design criteria of § 53.4733 of this chapter, structures, systems, and components required to withstand the effects of the safe-shutdown earthquake ground motion or surface deformation are safety-related structures, systems, and components as defined in § 53.028, including those that perform safety functions as defined in § 53.020 of this chapter.

* * * * *

PART 51 – ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

1071~~5~~. The authority citation for part 51 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 161, 193 (42 U.S.C. 2201, 2243); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); National

Environmental Policy Act of 1969 (42 U.S.C. 4332, 4334, 4335); Nuclear Waste Policy Act of 1982, secs. 144(f), 121, 135, 141, 148 (42 U.S.C. 10134(f), 10141, 10155, 10161, 10168); 44 U.S.C. 3504 note.

10816. In § 51.20, revise paragraphs (b)(1) and (2) to read as follows:

§ 51.20 Criteria for and identification of licensing and regulatory actions requiring environmental impact statements.

* * * * *

(b) * * *

(1) Issuance of a limited work authorization or a permit to construct a nuclear power reactor, testing facility, or fuel reprocessing plant under part 50 of this chapter, issuance of an early site permit under part 52 of this chapter, or issuance of a limited work authorization, construction permit, or early site permit under part 53 of this chapter.

(2) Issuance or renewal of a full power or design capacity license to operate a nuclear power reactor, testing facility, or fuel reprocessing plant under parts 50 or 53 of this chapter, or a combined license under parts 52 or 53 of this chapter.

* * * * *

10917. In § 51.22, revise paragraphs (c)(3) introductory text, (c)(9) introductory text, (c)(12) introductory text, (c)(17), and (c)(22) and (23) to read as follows:

§ 51.22 Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.

* * * * *

(c) * * *

(3) Amendments to parts 20, 30, 31, 32, 33, 34, 35, 37, 39, 40, 50, 51, 52, 53, 54, 60, 61, 63, 70, 71, 72, 73, 74, 81, and 100 of this chapter which relate to—

* * *

(9) Issuance of an amendment to a permit or license for a reactor under parts 50, 52, or 53 of this chapter that changes a requirement or issuance of an exemption from a requirement, with respect to installation or use of a facility component located within the restricted area, as defined in part 20 of this chapter; or the issuance of an amendment to a permit or license for a reactor under parts 50, 52, or 53 of this chapter that changes an inspection or a surveillance requirement; provided that:

* * * * *

(12) Issuance of an amendment to a license under parts 50, 52, 53, 60, 61, 63, 70, 72, or 75 of this chapter relating solely to safeguards matters (i.e., protection against sabotage or loss or diversion of special nuclear material) or issuance of an approval of a safeguards plan submitted under parts 50, 52, 53, 70, 72, and 73 of this chapter, provided that the amendment or approval does not involve any significant construction impacts. These amendments and approvals are confined to—

* * * * *

(17) Issuance of an amendment to a permit or license under parts 30, 40, 50, 52, 53, or part 70 of this chapter which deletes any limiting condition of operation or monitoring requirement based on or applicable to any matter subject to the provisions of the Federal Water Pollution Control Act.

* * * * *

(22) Issuance of a standard design approval under parts 52 or 53 of this chapter.

(23) The Commission finding for a combined license under § 52.103(g)~~,~~ or § 53.1452(g)~~, or § 53.5052(g)~~ of this chapter.

* * * * *

§ 51.26 [Amended]

11~~08~~. In § 51.26(d), remove “under part 52” and add in its place “under 10 CFR parts 52 or 53,”.

11~~19~~. In § 51.30, revise paragraph (a) introductory text and paragraphs (d) and (e) to read as follows:

§ 51.30 Environmental assessment.

(a) An environmental assessment for proposed actions, other than those for a standard design certification under 10 CFR parts 52 or 53, or a manufacturing license under parts 52 or 53, shall identify the proposed action and include:

* * * * *

(d) An environmental assessment for a standard design certification under subpart B of part 52~~,~~ or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter must identify the proposed action and will be limited to the consideration of the costs and benefits of severe accident mitigation design alternatives and the bases for not incorporating severe accident mitigation design alternatives in the design certification. An environmental assessment for an amendment to a design certification will be limited to the consideration of whether the design change which is the subject of the proposed amendment renders a severe accident mitigation design alternative previously rejected in the earlier environmental assessment to become cost beneficial, or results in the identification of new severe accident mitigation design alternatives, in which case the costs and benefits of new severe accident mitigation design alternatives and the bases for not incorporating new severe accident mitigation design alternatives in the design certification must be addressed.

(e) An environmental assessment for a manufacturing license under subpart F of part 52 of this chapter or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter must identify the proposed action and will be limited to the consideration of the costs and benefits of

severe accident mitigation design alternatives and the bases for not incorporating severe accident mitigation design alternatives in the manufacturing license. An environmental assessment for an amendment to a manufacturing license will be limited to consideration of whether the design change which is the subject of the proposed amendment either renders a severe accident mitigation design alternative previously rejected in an environmental assessment to become cost beneficial, or results in the identification of new severe accident mitigation design alternatives, in which case the costs and benefits of new severe accident mitigation design alternatives and the bases for not incorporating new severe accident mitigation design alternatives in the manufacturing license must be addressed. In either case, the environmental assessment will not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

§ 51.31 [Amended]

112~~0~~. In § 51.31(a), remove “part 52” and add in its place “parts 52 or 53”.

§ 51.32 [Amended]

12~~1~~3. In § 51.32, in paragraphs (b)(1) and (3) after “of this chapter” add “or under subpart~~s~~ H ~~or R of~~ part 53 of this chapter”.

§ 51.49 [Amended]

1142~~2~~. In § 51.49(c) introductory text, add “or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter” after “part 52 of this chapter”.

§ 51.50 [Amended]

1152~~3~~. In § 51.50, in (a), (b)(4), and (c) introductory text add “~~,~~or § 53.1112~~, or § 53.4712~~” after “§ 50.36b”.

§ 51.53 [Amended]

1162~~4~~. In § 51.53(d), add “, § 52.110 or § 53.1080~~, or § 53.4680~~” after “§ 50.82”.

§ 51.54 [Amended]

1172~~5~~. In § 51.54(a), add “or under subpart~~s~~ H ~~or R~~ of part 53” after “of part 52”.

§ 51.55 [Amended]

1182~~6~~. In § 51.55(a), add “or under subpart~~s~~ H ~~or R~~ of part 53” after “of part 52”.

1192~~7~~. In § 51.58, revise paragraph (b) to read as follows:

§ 51.58 Environmental report – number of copies; distribution.

* * * * *

(b) Each applicant for a license to manufacture a nuclear power reactor, or for an amendment to a license to manufacture, seeking approval of the final design of the nuclear power reactor under subpart F of part 52 or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter, shall submit to the Commission an environmental report or any supplement to an environmental report in the manner specified in § 52.3 or § 53.040 of this chapter. The applicant shall maintain the capability to generate additional copies of the environmental report or any supplement to the environmental report for subsequent distribution to parties and Boards in the NRC proceeding; Federal, State, and local officials; and any affected Indian Tribes, in accordance with written instructions issued by the Director, Office of Nuclear Reactor Regulation.

§ 51.77 [Amended]

120~~8~~. In § 51.77(a) introductory text, insert the word “impact” after the word “environmental” and remove “, except an action authorizing issuance, amendment or renewal of a license to manufacture a nuclear power reactor pursuant to 10 CFR part 52, appendix M” ~~and add in its place “subpart F of part 52 or subparts H or R of part 53 of this chapter”~~.

Commented [A60]: Edited to reflect the use of environmental assessments rather than environmental impact statements for the issuance, amendment, or renewal of MLs. See, e.g., 51.30(e).

§ 51.92 [Amended]

12~~19~~. In § 51.92(b), remove “part 52”, wherever it may appear and add in its place “parts 52 or 53”.

§ 51.95 [Amended]

12~~2330~~. In § 51.95(c) introductory text, remove “under 10 CFR parts 52 or 54” and add in its place “under parts 50, 52, 53, or 54” ~~after “parts 52”~~.

12~~31~~. In § 51.101, revise paragraph (a)(2) to read as follows:

§ 51.101 Limitations on actions.

(a) * * *

(2) Any action concerning the proposal taken by an applicant which would—

(i) Have an adverse environmental impact, or

(ii) Limit the choice of reasonable alternatives that may be grounds for denial of the license. In the case of an application covered by § 30.32(f), § 40.31(f), § 50.10(~~c~~d), § 53.1130, ~~§ 53.4740,~~ § 70.21(f), or §§ 72.16 and 72.34 of this chapter, the provisions of this paragraph will be applied in accordance with § 30.33(a)(5), § 40.32(e), § 50.10(d~~c~~) and (e), § 53.1130, ~~§ 53.4740,~~ § 70.23(a)(7), or §~~§~~ 72.40(b) of this chapter, as appropriate.

* * * * *

§ 51.103 [Amended]

1~~3~~24. In § 51.103(a)(6), remove “10 CFR 50.10” and add in its place “§ 50.10~~,~~ or § 53.1130~~, or § 53.4740~~ of this chapter".

12533. In § 51.105, revise paragraph (c)(1) to read as follows:

§ 51.105 Public hearings in proceedings for issuance of construction permits or early site permits; limited work authorizations.

* * * * *

(c)(1) In addition to complying with the applicable provisions of § 51.104, in any proceeding for the issuance of a construction permit for a nuclear power plant or an early

site permit under parts 52 or 53 of this chapter, where the applicant requests a limited work authorization under § 50.10(d)~~,~~ or § 53.1130~~, or § 53.4740~~ of this chapter, the presiding officer will~~shall~~—

* * * * *

12634. In § 51.107, revise paragraphs (a) introductory text, (b) introductory text, and paragraph (d)(1) to read as follows:

§ 51.107 Public hearings in proceedings for issuance of combined licenses; limited work authorizations.

(a) In addition to complying with the applicable requirements of § 51.104, in a proceeding for the issuance of a combined license for a nuclear power reactor under parts 52 or 53 of this chapter, the presiding officer will:

* * * * *

(b) If a combined license application references an early site permit, then the presiding officer in the combined license hearing must~~shall~~ not admit any contention proffered by any party on environmental issues that~~which~~ have been accorded finality under § 52.39~~,~~ or § 53.1188~~, or § 53.4798~~ of this chapter, unless the contention:

* * * * *

(d)(1) In any proceeding for the issuance of a combined license where the applicant requests a limited work authorization under § 50.10(d)~~,~~ or § 53.1130(a)~~, or § 53.4740(a)~~ of this chapter, the presiding officer, in addition to complying with any applicable provision of § 51.104, will~~shall~~:

* * * * *

12735. Revise § 51.108 to read as follows:

§ 51.108 Public hearings on Commission findings that inspections, tests, analyses, and acceptance criteria of combined licenses are met.

In any public hearing requested under § 52.103(b)~~,~~ or § 53.1452(b)~~, or § 53.5052(b)~~, the Commission will not admit any contentions on environmental issues, the adequacy of the environmental impact statement for the combined license issued under subpart C of part 52 or under subpart~~s~~ H ~~or R~~ of part 53 of this chapter, or the adequacy of any other environmental impact statement or environmental assessment referenced in the combined license application. The Commission will not make any environmental findings in connection with the finding under § 52.103(g)~~,~~ or § 53.1452(g)~~, or § 53.5052(g)~~.

1283~~3~~6. Part 53 is added to read as follows:

PART 53—RISK-INFORMED, TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK FOR COMMERCIAL NUCLEAR PLANTS

Sec.

Subpart I — Maintaining and Revising Licensing Basis Information

§ 53.1890 Audits.

Subparts KL through and WM [Reserved]

Subpart N — Siting Requirements

§ 53.3505 Scope.

§ 53.3510 Definitions.

§ 53.3515 Factors to be considered when evaluating sites.

§ 53.3520 Non-seismic siting criteria.

§ 53.3525 Geologic and seismic siting criteria.

Subpart O — Construction and Manufacturing Requirements

§ 53.4100 Construction and manufacturing - scope and purpose.

§ 53.4105 Reporting of defects and noncompliance.

§ 53.4110 Construction.

§ 53.4120 Manufacturing.

Subpart P — Requirements for Operation

§ 53.4200 Operational objectives.

§ 53.4210 Maintenance, repair, and inspection programs.

§ 53.4213 Technical specifications.

§ 53.4215 Response to seismic events.

§ 53.4220 General staffing, training, personnel qualifications, and human factors engineering requirements.

§ 53.4300 Programs.

§ 53.4310 Radiation protection.

§ 53.4320 Emergency preparedness.

§ 53.4330 Security programs.

§ 53.4340 Quality assurance.

§ 53.4350 Fire protection.

§ 53.4360 Inservice inspection and inservice testing.

§ 53.4380 Environmental qualification of electric equipment important to safety for nuclear plants.

§ 53.4390 Procedures and guidelines.

§ 53.4400 Integrity assessment program.

§ 53.4410 Primary containment leakage rate testing program.

§ 53.4420 Mitigation of beyond-design-basis events.

Subpart Q — Decommissioning

§ 53.4600 Scope and purpose.

§ 53.4610 Financial assurance for decommissioning.

§ 53.4620 Cost estimates for decommissioning.

§ 53.4630 Annual adjustments to cost estimates for decommissioning.

§ 53.4640 Methods for providing financial assurance for decommissioning.

§ 53.4645 Limitations on the use of decommissioning trust funds.

§ 53.4650 NRC oversight.

§ 53.4660 Reporting and recordkeeping requirements.

§ 53.4670 Termination of license.

§ 53.4675 Program requirements during decommissioning.

§ 53.4680 Release of part of a commercial nuclear plant or site for unrestricted use.

Subpart R — Licenses, Certifications, and Approvals

§ 53.4700 Filing of application for licenses, certifications, or approvals; oath or affirmation.

§ 53.4701 Requirement for license.

§ 53.4703 Combining applications and licenses.

~~Subpart U — Quality Assurance Criteria for Commercial Nuclear Plants~~
~~§ 53.6600 General provisions.~~
~~§ 53.6605 Organization.~~
~~§ 53.6610 Quality assurance program.~~
~~§ 53.6615 Design control.~~
~~§ 53.6620 Procurement document control.~~
~~§ 53.6625 Instructions, procedures, and drawings.~~
~~§ 53.6630 Document control.~~
~~§ 53.6635 Control of purchased material, equipment, and services.~~
~~§ 53.6640 Identification and control of materials, parts, and components.~~
~~§ 53.6645 Control of special processes.~~
~~§ 53.6650 Inspection.~~
~~§ 53.6655 Test control.~~
~~§ 53.6660 Control of measuring and test equipment.~~
~~§ 53.6665 Handling, storage, and shipping.~~
~~§ 53.6670 Inspection, test, and operating status.~~
~~§ 53.6675 Nonconforming materials, parts, or components.~~
~~§ 53.6680 Corrective action.~~
~~§ 53.6685 Quality assurance records.~~
~~§ 53.6690 Audits.~~
~~Subparts V and W [Reserved]~~
Subpart X — Enforcement
§ 53.9000 Violations.
§ 53.9010 Criminal penalties.

Authority: Atomic Energy Act of 1954, secs. 11, 101, 103, 108, 122, 147, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note; Sec. 109, Pub. L. 96-295, 94 Stat. 783; Pub. L. 115-439, 132 Stat. 5571.

§ 53.000 Purpose.

This part provides optional a technology-inclusive, performance-based frameworks for the issuance, amendment, renewal, and termination of licenses, permits, certifications, and approvals for commercial nuclear plants licensed under Section 103 of the Atomic Energy Act of 1954, as amended (AEA) (68 Stat. 919), and Title II of the Energy Reorganization Act of 1974, as amended (ERA) (88 Stat. 1242). Also, this part gives notice to all persons who knowingly provide to any holder of or applicant for an approval, certification, permit, or license, or to a contractor, subcontractor, or consultant of any of them, components, equipment, materials, or other goods or services that relate

Commented [A61]: *Passim*, for useability, staff should adopt the practice of spelling out acronyms and initialisms for their first usage within a section of the rule text or at the first usage within a portion of a section that a reader is likely to consult without regard to earlier portions, such as an individual definition in a section dedicated to providing definitions (e.g., 53.020).

Staff should omit parenthetical definitions of acronyms and initialisms when they are not later used in the section or portion of a section that would necessitate their definition.

For acronyms and initialisms that are to be used universally throughout the part, as is the case with the term "Act" in 50.2 defined as "the Atomic Energy Act of 1954, as amended (68 Stat. 919) including any amendment thereto," the staff should include them in the definitions section and consistently use them throughout the part. These edits adopt the part 50 usage for the term "Act" and will endeavor to correct the treatment of acronyms and initialisms that remain.

to the activities of a holder of or applicant for an approval, certification, permit, or license, subject to this part, that they may be individually subject to U.S. Nuclear Regulatory Commission (NRC) enforcement action for violation of the provisions in § 53.050.

Commented [A62]: Staff should revise this to include the purpose and scope of the requirements modeled on part 55 that are in subpart F, including the provision of notice to all persons that manipulate the controls of a commercial nuclear plant that they are subject to this part and may be subject to enforcement action for violations of 53.745. This is likely necessary as criminal penalties apply to that section.

~~**§ 53.010 Frameworks.**~~

~~This part provides two optional frameworks, Framework A and Framework B. The two frameworks are distinct. A license issued under Framework A is subject to the requirements under subpart A, subparts B through K, and Subpart X of this part. A license issued under Framework B is subject to the requirements under subpart A, subparts N through U, and Subpart X of this part. Applicants and licensees subject to the rules in this part must only use the subparts applicable to one framework, except where stated. Consequently, an applicant for a license, certification, or permit may not reference or rely on a license, certification, or permit issued under another framework in this part or another part of this chapter.~~

Subpart A — General Provisions

~~**§ 53.015 Scope.**~~

~~Subpart A provides general provisions applicable to all applicants and licensees subject to the rules of this part.~~

Commented [A63]: Deleted as unnecessary.

§ 53.020 Definitions.

For the purpose of this part:

Act means the Atomic Energy Act of 1954 (68 Stat. 919) including any amendments thereto.

Commented [A64]: In part 50, the term "Act" is defined as being "the Atomic Energy Act of 1954 (68 Stat. 919) including any amendments thereto." That approach is adopted in these edits rather than using "AEA" with or without the citation throughout the regulatory text for part 53.

Anticipated event sequence means event sequences expected to occur one or more times during the life of a commercial nuclear plant. Anticipated event sequences take into account the expected response of all SSCs within the plant, regardless of safety classification.

Applicant means a person applying for a license, permit, or other form of Commission permission or approval under this part.

Certified fuel handler means, for a commercial nuclear plant, either—

(1) A non-licensed operator who has qualified in accordance with a fuel handler training program approved by the Commission; or

(2) A non-licensed operator who demonstrates compliance with the following criteria:

(i) Has qualified in accordance with a fuel handler training program that demonstrates compliance with the same requirements as training programs for non-licensed operators required by § 53.830, and

(ii) Is responsible for decisions on—

(A) Safe conduct of decommissioning activities,

(B) Safe handling and storage of spent fuel, and

(C) Appropriate response to plant emergencies.

Combined license ~~*(COL)*~~ means a combined construction permit ~~(CP)~~ and operating license ~~(OL)~~ with conditions for a commercial nuclear plant issued under this part.

Commercial nuclear plant means a commercial utilization facility consisting of one or more ~~commercial~~ nuclear reactors and associated co-located support facilities, including the collection of buildings, radionuclide sources, and structures, systems, and components ~~(SSCs)~~ for which a license(s) is being sought under this part, that is used for producing power for commercial electric power or other commercial purposes. For the purposes of requirements in this part that reference requirements in ~~10 CFR~~ part 50 of this chapter, a commercial nuclear plant is equivalent to a nuclear power plant.

Commented [A65]: Edited to reflect the fact that the "commercial" nature of these is not limited to the nuclear reactor. By doing this, we can define the term "nuclear reactor" in the same manner as it is defined in 50.2 and avoid introducing another term to the lexicon and necessitating the deeming provision of equivalency between "commercial nuclear reactor" and "nuclear reactor" included in the former definition in this section.

Additionally, the word "utilization" is inserted to rule out production facilities.

~~*Commercial nuclear reactor* means an apparatus, other than an atomic weapon, designed or used to sustain nuclear fission. For the purposes of requirements in this part that reference requirements in 10 CFR part 50, a commercial nuclear reactor is equivalent to a nuclear reactor as defined in § 50.2 of this chapter.~~

Commented [A66]: Replaced with a definition of "nuclear reactor" aligned with the same term in part 50. As discussed in the comment on the definition of "commercial nuclear plant," the nuclear reactor is not by itself commercial.

Commission means the NRC or its duly authorized representatives.

Consensus code or standard means any technical standard that is—

(1) Developed or adopted by a voluntary consensus standard body under procedures that assure that persons having interests within the scope of the standard that are affected by the provisions of the standard have reached substantial agreement on its adoption;

(2) Formulated in a manner that afforded an opportunity for diverse views to be considered; and

(3) Designated by the standards body as a consensus code or standard.

Construction means the activities in paragraph (1) below and does not mean the activities in paragraph (2) below.

(1) Activities constituting construction are those activities credited or relied upon for demonstrating compliance with the safety criteria defined in subpart B of this part that are conducted on-site to build the commercial nuclear plant, including the driving of piles; subsurface preparation; placement of backfill, concrete, or permanent retaining walls within an excavation; installation of foundations; or in-place assembly, erection, fabrication, or testing, which are for—

(i) Safety-related (SR) and non-safety-related but safety-significant (NSRSS) structures, systems, and components (SSCs) of a facility;

(ii) SSCs necessary to comply with 10 CFR part 73; or

(iii) Onsite emergency facilities necessary to comply with § 53.855.

(2) Construction does not include—

(i) Changes for temporary use of the land for public recreational purposes;

(ii) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(iii) Preparation of a site for construction of a facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(iv) Erection of fences and other access control measures;

(v) Excavation;

(vi) Erection of support buildings (such as construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(vii) Building of service facilities (such as paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewage treatment facilities, and transmission lines);

(viii) Procurement or fabrication of components or portions of the proposed facility occurring at locations other than the final, in-place location at the facility; or

(ix) Manufacture of a nuclear power reactor under a manufacturing license under subpart H of this part to be installed at the proposed site and to be part of the proposed facility.

Custom combined license (custom COL) means a COL that does not reference a standard design certification or design certification.

Decommission or *decommissioning* means to remove a plant or site safely from service and reduce residual radioactivity to a level that permits—

(1) Release of the property for unrestricted use and termination of the license; or

(2) Release of the property under restricted conditions and termination of the license.

Defense in depth means inclusion of two or more independent and redundant layers of defense in the design of a facility and its operating procedures to compensate for uncertainties such that no single layer of defense, no matter how robust, is exclusively relied upon. Defense in depth includes, but is not limited to, the use of access controls, physical barriers, redundant and diverse safety functions, and emergency response measures.

Design-basis accidents (DBAs) means postulated event sequences that are used to set functional design criteria and performance objectives for the design of safety-related (SR) structures, systems, and components (SSCs) through deterministic analyses. DBAs are a type of licensing-basis event and are based on the capabilities and reliabilities of SR SSCs needed to mitigate and prevent event sequences, respectively.

Design-basis external hazard level means the level of severity or intensity of an external hazard for which the safety-related structures, systems, and components are designed to withstand with no adverse impact on their capability to perform their safety functions.

Design features means the active and passive structures, systems, and components (SSCs) and the inherent characteristics of those SSCs that contribute to limiting the total effective dose equivalent ~~(TEDE)~~ to individual members of the public during normal operations and prevent or mitigate the consequences of event sequences.

Electric utility means any entity that generates or distributes electricity and that recovers the cost of this electricity, either directly or indirectly, through rates established by the entity itself or by a separate regulatory authority. Investor-owned utilities, including generation or distribution subsidiaries, public utility districts, municipalities, rural electric cooperatives, and State and Federal agencies, including associations of any of the foregoing, are included within the meaning of "electric utility."

Event sequence means a postulated initiating event defined for a set of initial plant conditions followed by system, safety function, and operator successes or failures, and terminating in a specified end state depending on the system, safety function, and operator successes and failures (e.g., prevention of release of radioactive material or release in one of the reactor-specific release categories). An event sequence may include many unique variations of events that are similar in terms of results or end states.

Exclusion area means that area surrounding the reactor, in which the reactor licensee has the authority to determine all activities including exclusion or removal of personnel and property from the area. This area may be traversed by a highway, railroad, or waterway, provided these are not so close to the facility as to interfere with normal operations of the facility and provided appropriate and effective arrangements are made to control traffic on the highway, railroad, or waterway, in case of emergency, to protect the public health and safety. Residence within the exclusion area must normally be prohibited. In any event, residents must be subject to ready removal in case of necessity. Activities unrelated to operation of the reactor may be permitted in an exclusion area under appropriate limitations, provided that no significant hazards to the public health and safety will result.

Fission product release means the amount and composition of radioactive material released to the environment, after accounting for any retention of radionuclides provided by reactor design features.

Functional design criteria means metrics for the performance of structures, systems, and components (SSCs). For safety-related SSCs, these criteria define performance metrics necessary to demonstrate compliance with safety criteria in § 53.210. For non-safety-related but safety-significant SSCs, these criteria define performance metrics necessary to demonstrate compliance with the safety criteria in § 53.220.

Fuel means special nuclear material (SNM) or source material, discrete elements that physically contain SNM or source material, and homogeneous mixtures that contain SNM or source material, intended to or used to create power from nuclear fission in a self-supporting chain reaction in a ~~commercial~~ nuclear ~~plant~~reactor.

Generally licensed reactor operator means any individual licensed under the provisions of § 53.810 to manipulate controls of a self-reliant-mitigation facility and to direct the licensed activities of generally licensed reactor operators.

Interaction-dependent-mitigation facility means a commercial nuclear plant design other than one that demonstrates compliance with the operating and technical characteristics defined under § 53.800.

License, when used in the context of a facility, means a limited work authorization ~~(LWA)~~, construction permit~~CP~~, operating license~~OL~~, early site permit, combined license~~COL~~, or manufacturing license ~~(ML)~~ under this part, or a renewed license issued by the Commission under this part. When used in the context of an operator license, *license* means a license issued by the Commission to perform the

function of an operator, senior operator, or generally licensed reactor operator as defined in this part.

Commented [A67]: Edited to reflect the usage within subpart F.

Licensee means a person who is authorized to conduct activities under a license issued under this part by the Commission.

Licensing-basis events (LBEs) means a collection of event sequences considered in the design and licensing of the commercial nuclear plant. LBEs are unplanned events and include anticipated event sequences, unlikely event sequences, very unlikely event sequences, and design basis accidents.

Licensing basis information means the information contained in regulations, orders, licenses, certifications, or approvals issued by the NRC for a commercial nuclear plant licensed under this part and that information submitted to the NRC by an applicant or licensee in a Safety Analysis Report, program description, or other licensing-related document required under this part.

Load following means operation of a commercial nuclear plant to automatically changing its output to match expected demand in response to externally originated instructions or signals.

Low population zone means the area immediately surrounding the exclusion area which contains residents, the total number and density of which are such that there is a reasonable probability that appropriate protective measures could be taken on their behalf in the event of a serious accident. A permissible population density or total population within this zone is not included in this definition because the situation may vary from case to case. Whether a specific number of people can, for example, be evacuated from a specific area or instructed to take shelter on a timely basis, will depend on many factors such as location, number and size of highways, scope and extent of advance planning, and actual distribution of residents within the area.

Major decommissioning activity means, for a commercial nuclear plant, any activity that results in permanent removal of major radioactive components, permanently modifies the structure of the containment, if applicable, or results in dismantling components for shipment containing greater than class C waste in accordance with § 61.55 of this chapter.

Commented [A68]: Inserted to support the citation in 53.1070.

Manufactured reactor means the essential portions of a nuclear reactor that are manufactured under a~~n~~ manufacturing license~~ML~~ and subsequently transported and incorporated into a commercial nuclear plant under a combined license~~COL~~.

Manufacturing license means a license issued under this part that authorizes the manufacture of a manufactured reactor but not ~~their~~ its construction, installation, or operation.

Non-~~S~~safety-~~R~~related but ~~S~~safety-~~S~~significant (NSRSS) structures, systems, and components (SSCs) means those SSCs ~~which~~that are not SR but are relied on to achieve adequate defense in depth or perform risk-significant functions ~~and warrant special treatment~~.

Commented [A69]: The fact that such SSCs warrant special treatment is a requirement that is laid out in the rules rather than a part of the definition.

Non-~~S~~safety-~~S~~significant ~~(NSS)~~ structures, systems, and components (SSCs) means those SSCs that are not safety-related~~SR~~ or non-safety-related but safety-significant~~NSRSS~~, are not relied on to achieve adequate defense in depth or to perform risk-significant functions, and do not warrant special treatment.

Nuclear reactor means an apparatus, other than an atomic weapon, designed or used to sustain nuclear fission.

Person means—

(1) any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, government agency other than the Commission or the Department, except that the Department shall be considered a person to the extent that

its facilities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974, any State or any political subdivision of, or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and

(2) any legal successor, representative, agent, or agency of the foregoing.

Population center distance means the distance from the reactor to the nearest boundary of a densely populated center containing more than about 25,000 residents.

Probabilistic risk assessment ~~*(PRA)*~~ means a quantitative assessment of the risk associated with plant operation and maintenance that is measured in terms of event sequence occurrence frequencies and consequences.

Programmatic controls means administrative procedures that govern human action in implementing programs and operating, monitoring, and maintaining SSCs and equipment of a commercial nuclear plant. ~~Programmatic controls are specified in an application for a requested activity of the Commission.~~

Prototype plant means a nuclear reactor that is used to test design features. A prototype plant is similar to a first-of-a-kind or standard plant design in all features and size but may include additional safety features to protect the public and the plant staff from the possible consequences of accidents during the testing period.

Quality assurance (QA) means all those planned and systematic actions necessary to ensure that an structure, system, or component~~SSC~~ will perform satisfactorily in service. QA includes quality control, which comprises those QA actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

Reference plant means the specific commercial nuclear plant on which a simulation facility's configuration, system control arrangement, and design data are based. The reference plant may or may not be constructed.

Safety criteria means performance-based metrics that establish a level of safety provided in requirements in §§ 53.210 and 53.220.

Safety function means a purpose served by a design feature, human action, or programmatic control to prevent or mitigate unplanned events and thereby demonstrate compliance with requirements in this part for limiting risks to public health and safety. Safety functions can be performed by any combination of the elements listed above and can be specified at the plant level or at the level of a particular barrier or system. ~~The approach to identifying and addressing safety functions in Frameworks A and B are as follows:~~

~~(1) Within Framework A, the primary safety function is stated to be limiting the release of radioactive materials. Additional safety functions supporting the retention of radioactive materials, such as controlling reactivity, heat generation, heat removal, and chemical interactions, are determined for each reactor design by analyzing a spectrum of unplanned events.~~

Commented [A70]: Deleted as unnecessary due to the requirements proposed in 53.230.

~~(2) Within Framework B, multiple plant-level safety functions are assumed to apply to all reactor designs based on established requirements and historical practices. These fundamental safety functions include the control of reactivity, removal of heat, and limiting the release of radioactive materials. The protection of a specific barrier or system that contributes to meeting plant-level safety criteria may also be referred to as a safety function.~~

Safety-related structures, systems, and components means those structures, systems, and components that are relied upon to meet the safety criteria in § 53.210.

Self-reliant-mitigation facility means a commercial nuclear plant design that demonstrates compliance with the operating and technical characteristics ~~defined under~~of § 53.800.

Severe accident means those events that progress beyond design basis accidents in which substantial damage is done to the reactor core or to any other structure, vessel, or retention system that contains a significant inventory of radiological material, whether or not there are serious offsite consequences.

Commented [A71]: Moved from 53.028. Staff should confirm that this definition supports the usage of the term in 53.1282, 53,1288, and 53.1470 with respect to severe accident mitigation design alternatives for manufacturing licenses and standardization.

Simulation facility means an interface designed to provide a realistic imitation of the operation of a commercial nuclear plant used for the administration of examinations, for training, and/or to demonstrate compliance with experience requirements for applicants or licensees. A simulation facility may rely, in whole or part, upon the physical utilization of the reference plant itself.

Site characteristics means the actual physical, environmental, and demographic features of a site. Site characteristics are specified in an early site permit or in a Preliminary or Final Safety Analysis Report for an limited work authorization~~LWA~~, construction permit~~CP~~, or combined license~~COL~~, as applicable.

Site parameters are the postulated physical, environmental, and demographic features of an assumed site. Site parameters are specified in a standard design approval, standard design certification, or manufacturing license~~ML~~.

Source material means source material as defined in subsection 11z. of the Act and in the regulations contained in part 40 of this chapter.

Special nuclear material (SNM) means: (1) plutonium, uranium-233, uranium enriched in the isotope-233 or in the isotope-235, and any other material which the Commission, pursuant to the provisions of Section 51 of the A~~EA~~ct, determines to be

SNM, but does not include source material; or (2) any material artificially enriched by any of the foregoing, but does not include source material.

Special treatments means those ~~requirements~~items, such as ~~QA~~quality assurance and programmatic controls, that ensure that ~~SR~~safety-related and ~~NSRSS~~non-safety-related but safety-significant structures, systems, and components (SSCs) will provide defense in depth or perform risk-significant functions. The ~~requirements~~special treatments also ensure that the SSCs will perform under the service conditions and with the reliability assumed in the analysis performed ~~in accordance with~~under § 53.450 to demonstrate compliance with the safety criteria in §§ 53.210 and 53.220.

Standard design means a design which is sufficiently detailed and complete to support certification or approval in accordance with subpart H ~~or subpart R~~ of this part, and which is usable under ~~Framework A or Framework B of~~ this part~~, as appropriate,~~ for a multiple number of units or at a multiple number of sites without reopening or repeating the review.

Standard design approval or *design approval* means an NRC staff approval, issued under subpart H ~~or subpart R~~ of this part, of a final standard design for a commercial nuclear plant. The approval may be for either the final design for the entire reactor facility or the final design of major portions thereof.

Standard design certification or *design certification* means a Commission approval, issued under subpart H ~~or subpart R~~ of this part, of a final standard design for a nuclear power facility. This design may be referred to as a certified standard design.

Systems approach to training means a training program that includes the following five elements:

(1) Systematic analysis of the jobs to be performed.

(2) Learning objectives derived from the analysis which describe desired performance after training.

(3) Training design and implementation based on the learning objectives.

(4) Evaluation of trainee mastery of the objectives during training.

(5) Evaluation and revision of the training based on the performance of trained personnel in the job setting.

Total effective dose equivalent ~~(TEDE)~~ means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Unlikely event sequences means event sequences that are not expected to occur in the life of a commercial nuclear plant and are therefore less likely than anticipated event sequences, but are infrequent rather than rare. Unlikely event sequences take into account the expected response of all structures, systems, and components~~SSCs~~ within the plant regardless of safety classification.

Utilization facility means any ~~commercial~~ nuclear reactor other than one designed or used primarily for the formation of plutonium or uranium–233 or a fueled manufactured reactor with at least two independent mechanisms each of which is sufficient to prevent criticality assuming maximum reactivity of the fissile material would be attained from possible fuel configurations, neutron moderation, and neutron reflection from the manufactured reactor and surrounding materials.

Very unlikely event sequences means rare event sequences that are less likely than unlikely event sequences. Very unlikely event sequences take into account the expected response of all structures, systems, and components within the plant regardless of safety classification.

~~§ 53.024 Definitions specific to Framework A.~~

Commented [A72]: Inserted to cure the redundancy between the prior portion of this definition and its comparison with anticipated event sequences.

Commented [A73]: Edited to align with definition (1) of 50.2 and avoid the use of multiple different definitions for the same term.

~~For the purpose of Framework A of this part —~~

~~*Anticipated event sequence* means event sequences expected to occur one or more times during the life of a commercial nuclear plant. Anticipated event sequences take into account the expected response of all SSCs within the plant, regardless of safety classification.~~

~~*Construction* means the activities in paragraph (1) below and does not mean the activities in paragraph (2) below.~~

~~(1) Activities constituting construction are those activities credited or relied upon for demonstrating compliance with the safety criteria defined in subpart B of this part which that are conducted on-site to build the commercial nuclear plant, including the driving of piles; subsurface preparation; placement of backfill, concrete, or permanent retaining walls within an excavation; installation of foundations; or in-place assembly, erection, fabrication, or testing, which are for —~~

~~(i) Safety-related (SR) and non-safety-related but safety-significant (NSRSS) SSCs of a facility;~~

~~(ii) SSCs necessary to comply with 10 CFR part 73; or~~

~~(iii) Onsite emergency facilities necessary to comply with § 53.855.~~

~~(2) Construction does not include —~~

~~(i) Changes for temporary use of the land for public recreational purposes;~~

~~(ii) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;~~

(iii) Preparation of a site for construction of a facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(iv) Erection of fences and other access control measures;

(v) Excavation;

(vi) Erection of support buildings (such as construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(vii) Building of service facilities (such as paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewage treatment facilities, and transmission lines);

(viii) Procurement or fabrication of components or portions of the proposed facility occurring at locations other than the final, in-place location at the facility; or

(ix) Manufacture of a nuclear power reactor under an ML under subpart H of this part to be installed at the proposed site and to be part of the proposed facility.

Design-basis accidents (DBAs) means postulated event sequences that are used to set functional design criteria and performance objectives for the design of SR SSCs through deterministic analyses. DBAs are a type of licensing-basis event (LBE) and are based on the capabilities and reliabilities of SR SSCs needed to mitigate and prevent event sequences, respectively.

Design-basis external hazard level means the level of severity or intensity of an external hazard for which the SR SSCs are designed to withstand with no adverse impact on their capability to perform their safety functions.

Functional design criteria means metrics for the performance of SSCs. For SR SSCs, these criteria define performance metrics necessary to demonstrate compliance

with safety criteria in § 53.210. For NSRSS SSCs, these criteria define performance metrics necessary to demonstrate compliance with the safety criteria in § 53.220.

Licensing-basis events (LBEs) means a collection of event sequences considered in the design and licensing of the commercial nuclear plant. LBEs are unplanned events and include anticipated event sequences, unlikely event sequences, very unlikely event sequences, and DBAs.

Non-Safety-Related but Safety-Significant (NSRSS) SSCs means those SSCs which are not SR but are relied on to achieve adequate defense in depth or perform risk-significant functions and warrant special treatment.

Non-Safety-Significant (NSS) SSCs means those SSCs that are not SR or NSRSS, are not relied on to achieve adequate defense in depth or to perform risk-significant functions, and do not warrant special treatment.

Safety criteria means performance-based metrics that establish a level of safety provided in requirements in §§ 53.210 and 53.220.

Safety-related structures, systems, or components means those SSCs that are relied upon to demonstrate compliance with the safety criteria in § 53.210 and warrant special treatment.

Special treatment means those requirements, such as QA and programmatic controls, that ensure that SR and NSRSS SSCs will provide defense in depth or perform risk-significant functions. The requirements also ensure that the SSCs will perform under the service conditions and with the reliability assumed in the analysis performed in accordance with § 53.450 to demonstrate compliance with the safety criteria in §§ 53.210 and 53.220.

Unlikely event sequences means event sequences that are not expected to occur in the life of a commercial nuclear plant and are therefore less likely than anticipated

event sequences, but are infrequent rather than rare. Unlikely event sequences take into account the expected response of all SSCs within the plant regardless of safety classification.

Very unlikely event sequences means rare event sequences that are not expected to occur in the life of a commercial nuclear plant, are less likely than an unlikely event sequences, and are rare. Very unlikely event sequences take into account the expected response of all SSCs within the plant regardless of safety classification.

§ 53.028 Definitions specific to Framework B.

For the purpose of Framework B of this part—

Anticipated operational occurrences (AOOs) means those conditions of normal operation which are expected to occur one or more times during the life of the commercial nuclear reactor.

Construction means the activities in paragraph (1) below and does not mean the activities in paragraph (2) below.

(1) Activities constituting construction are the driving of piles; subsurface preparation; placement of backfill, concrete, or permanent retaining walls within an excavation; installation of foundations; or in-place assembly, erection, fabrication, or testing, which are for—

(i) SR SSCs, as defined in § 53.028;

(ii) SSCs that are relied upon to mitigate accidents or transients or are used in plant emergency operating procedures;

(iii) SSCs whose failure could prevent SR SSCs from fulfilling their SR function;

(iv) SSCs whose failure could cause a reactor scram or actuation of an SR system;

(v) SSCs necessary to comply with 10 CFR part 73;

(vi) SSCs necessary to comply with § 53.4350; or

(vii) Onsite emergency facilities necessary to comply with § 53.4320.

(2) Construction does not include—

(i) Changes for temporary use of the land for public recreational purposes;

(ii) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(iii) Preparation of a site for construction of a facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(iv) Erection of fences and other access control measures;

(v) Excavation;

(vi) Erection of support buildings (such as construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(vii) Building of service facilities (such as paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewage treatment facilities, and transmission lines);

(viii) Procurement or fabrication of components or portions of the proposed facility occurring at locations other than the final, in-place location at the facility; or

(ix) Manufacture of a manufactured reactor under an ML to be installed at the proposed site and to be part of the proposed facility.

Design bases means that information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values or

ranges of values chosen for controlling parameters as reference bounds for design. These values may be— (1) restraints derived from generally accepted "state of the art" practices for achieving functional goals, or (2) requirements derived from analysis (based on calculation and/or experiments) of the effects of a postulated accident for which a structure, system, or component must demonstrate compliance with its functional goals.

Functional containment means a barrier, or a set of barriers taken together, that effectively limits the physical transport of radioactive material to the environment.

Reactor coolant pressure boundary means, for a light-water reactor, all those pressure-containing components, such as pressure vessels, piping, pumps, and valves, which are—

(1) Part of the reactor coolant system; or

(2) Connected to the reactor coolant system, up to and including any and all of the following:

(i) The outermost containment isolation valve in system piping which penetrates primary reactor containment;

(ii) The second of two valves normally closed during normal reactor operation in system piping which does not penetrate primary reactor containment; and

(iii) The reactor coolant system safety and relief valves.

For nuclear power reactors of the direct cycle boiling water type, the reactor coolant system extends to and includes the outermost containment isolation valve in the main steam and feedwater piping.

Safety-related structures, systems, or components for light-water commercial nuclear reactors means those SSCs that are relied upon to remain functional during and following design-basis events to assure—

~~(1) The integrity of the reactor coolant pressure boundary;~~

~~(2) The capability to shut down the reactor and maintain it in a safe shutdown condition; or~~

~~(3) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in § 53.4730(a)(1)(vi).~~

~~For non-light-water commercial nuclear reactors, *safety-related structures, systems, and components* means those SSCs that are relied on to remain functional during and following design-basis events to assure —~~

~~(1) The capability to perform safety functions determined in accordance with § 53.4730(a)(5)(ii) and (36), including cooling to maintain the integrity of systems and barriers credited in the safety analyses such that these SSCs function as credited;~~

~~(2) The capability to shut down the reactor and maintain it in a safe shutdown condition; or~~

~~(3) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in § 53.4730(a)(1)(vi).~~

~~*Severe accident* means those events that progress beyond the DBAs in which substantial damage is done to the reactor core or to any other structure, vessel, or retention system that contains a significant inventory of radiological material, whether or not there are serious offsite consequences.~~

~~§ 53.030 [Reserved]~~

§ 53.040 Written communications.

(a) *General requirements.* All correspondence, reports, applications, and other written communications from the applicant or licensee to the NRC concerning the

regulations in this part or individual license conditions must be sent either by mail addressed: ATTN: Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland, between the hours of 8:15 a.m. and 4 p.m. eastern time; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, e-mail, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html;* by e-mail to *MSHD.Resource@nrc.gov;* or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. If the communication is on paper, the signed original must be sent. If a submission due date falls on a Saturday, Sunday, or Federal holiday, the next Federal working day becomes the official due date.

(b) *Distribution requirements.* Copies of all correspondence, reports, and other written communications concerning the regulations in this part or individual license conditions, or the terms and conditions of an early site permit or standard design approval, must be submitted to the persons listed below (addresses for the NRC Regional Offices are listed in appendix D to 10 CFR part 20).

(1) *Applications for amendment of permits and licenses, reports, and other communications.* All written communications (including responses to generic letters, bulletins, information notices, regulatory information summaries, inspection reports, and miscellaneous requests for additional information) that are required of or requested from

Commented [A74]: While this section faithfully follows § 50.4 and 52.3, INs, RISs, and RAIs do not require responses.

holders of licenses, permits, and design approvals issued pursuant to this part, must be submitted as follows, except as otherwise specified in paragraphs (b)(2) through (7) of this section: to the NRC's Document Control Desk (if on paper, the signed original), with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector, ~~(~~if one has been assigned to the site of the facility~~)~~ or the place of manufacture of a reactor licensed under this part.

(2) *Applications for permits and licenses, and amendments to applications.* Applications for licenses, permits, and design approvals and amendments to any of these types of applications must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector, ~~(~~if one has been assigned to the facility~~)~~ or the place of manufacture of a reactor licensed under this part, except as otherwise specified in paragraphs (b)(3) through (9) of this section. If the application or amendment is on paper, the submission to the Document Control Desk must be the signed original.

(3) *Acceptance review application.* Written communications required for an application for determination of suitability for docketing must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office. If the communication is on paper, the submission to the Document Control Desk must be the signed original.

(4) *Security plan and related submissions.* Written communications, as defined in paragraphs (b)(4)(i) through (v) of this section, must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office. If the communication is on paper, the submission to the Document Control Desk must be the signed original. Submissions should include the following as appropriate:

(i) Physical security plan;

Commented [A75]: Edited to follow the usage in § 52.3 in order to properly reflect the possibility of assignment of a resident inspector to a place of manufacture of a reactor licensed under this part. This could remain as a parenthetical as it was provided by the staff if the final phrase is moved within the parentheses.

Commented [A76]: Edited to follow the usage in § 52.3 in order to properly reflect the possibility of assignment of a resident inspector to a place of manufacture of a reactor licensed under this part. This could remain as a parenthetical as it was provided by the staff if the final phrase is moved within the parentheses.

(ii) Safeguards contingency plan;

(iii) Cyber security plan;

(iv) Change to security plan, guard training and qualification plan, safeguards contingency plan, or cyber security plan made without prior Commission approval under § 53.1565 ~~or § 53.6065~~; and

(v) Application for amendment of physical security plan, guard training and qualification plan, safeguards contingency plan, or cyber security plan under § 53.1510 ~~or § 53.6010~~.

(5) *Emergency plan and related submissions.* Written communications as defined in paragraphs (b)(5)(i) through (iii) of this section must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector, if one has been assigned to the site of the facility. If the communication is on paper, the submission to the Document Control Desk must be the signed original. Submissions should include the following as appropriate:

(i) Emergency plan;

(ii) Change to an emergency plan under § 53.1565 ~~or § 53.6065~~; and

(iii) Emergency implementing procedures under § 53.855 ~~or § 53.4320~~.

(6) *Updated Final Safety Analysis Report.* An Updated Final Safety Analysis Report (UFSAR) or replacement pages under § 53.1545 ~~or § 53.6045~~ must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector, if one has been assigned to the site of the facility or the place of manufacture of a reactor licensed under this part. Paper copy submissions may be made using replacement pages; however, if a licensee chooses to use electronic submission, all subsequent updates or submissions must be performed electronically on a total replacement basis. If the communication is on paper,

Commented [A77]: Edited to reflect the requirements of § 53.1545(e) for submittals by ML holders. Note that the usage here is consistent with the usage as edited in paragraphs (b)(1) and (2) of this section. Should the decision be made to include the conditional for resident inspector assignment in parentheses in those paragraphs, this paragraphs should be similarly edited for consistency.

the submission to the Document Control Desk must be the signed original. If the communications are submitted electronically, see Guidance for Electronic Submissions to the Commission.

(7) *Quality assurance related submissions.* (i) A change to the Safety Analysis Report quality assurance program (QAP) description under § 53.1565 ~~or § 53.6065~~, or a change to a licensee's NRC-accepted QA topical report under § 53.1565 ~~or § 53.6065~~, must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector, if one has been assigned to the site of the facility or the place of manufacture of a reactor licensed under this part. If the communication is on paper, the submission to the Document Control Desk must be the signed original.

Commented [A78]: Edited to reflect the requirements of § 53.1565(d)(2) for submittals by ML holders. Note that the usage here is consistent with the usage as edited in paragraphs (b)(1) and (2) of this section. Should the decision be made to include the conditional for resident inspector assignment in parentheses in those paragraphs, this paragraphs should be similarly edited for consistency.

(ii) A change to an NRC-accepted QA topical report from non-licensees (i.e., architect/engineers, nuclear steam supply system (NSSS) suppliers, fuel suppliers, constructors, etc.) must be submitted to the NRC's Document Control Desk. If the communication is on paper, the signed original must be sent.

(8) *Certification of permanent cessation of operations.* The licensee's certification of permanent cessation of operations, under subpart G or subpart Q of this part, must state the date on which operations have ceased or will cease, and must be submitted to the NRC's Document Control Desk. This submission must be under oath or affirmation.

(9) *Certification of permanent fuel removal.* The licensee's certification of permanent fuel removal, under subpart G or subpart Q of this part, must state the date on which the fuel was removed from the reactor vessel and the disposition of the fuel, and must be submitted to the NRC's Document Control Desk. This submission must be under oath or affirmation.

(c) *Form of communications.* All paper copies submitted to demonstrate compliance with the requirements set forth in paragraph (b) of this section must be typewritten, printed, or otherwise reproduced in permanent form on unglazed paper. Exceptions to these requirements imposed on paper submissions may be granted for the submission of micrographic, photographic, or similar forms.

(d) *Regulation governing submission.* Licensees, applicants, and holders of standard design approvals submitting correspondence, reports, and other written communications under the regulations of this part are requested but not required to cite whenever practical, in the upper right corner of the first page of the submission, the specific regulation or other basis requiring submission.

§ 53.050 Deliberate misconduct.

(a) Any licensee, holder of a standard design approval, applicant for a standard design certification, applicant for a license, applicant for a standard design approval, employee of a licensee or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or applicant for a license, who knowingly provides to any licensee, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities in this part, may not—

Commented [A79]: Edited to reflect the scope of the corresponding requirement in § 52.4, recognizing that "applicant for a license" would include an "applicant for a permit" due to the definition of the term "license" as including LWAs, CPs, and ESPs, which would make the inclusion of "or permit" redundant.

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or

(2) Deliberately submit to the NRC, a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

(b) A person who violates paragraph (a)(1) or (2) of this section may be subject to enforcement action in accordance with the procedures in subpart B of 10 CFR part 2.

(c) For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows—

(1) Would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

§ 53.060 Employee protection.

(a) Discrimination by a Commission licensee, holder of a standard design approval, an applicant for a license, standard design certification, or standard design approval, a contractor or subcontractor of a Commission licensee, holder of a standard design approval, applicant for a license, standard design certification, or standard design approval, against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in Section 211 of the ERA and in general are related to the administration or enforcement of a requirement imposed under the Act~~EA~~ or the ERA.

(1) The protected activities include but are not limited to—

(i) Providing the Commission or his or her employer information about alleged violations of either of the statutes named in paragraph (a) of this section or possible violations of requirements imposed under either of those statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) of this section or under these requirements if the employee has identified the alleged illegality to the employer;

(iii) Requesting the NRC to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in paragraph (a) of this section; and

(v) Assisting or participating in, or ~~is~~being about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(3) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the ERA or the Act~~EA~~.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraph (a), (e), or (f) of this section by a Commission licensee, a holder of a standard design approval, an applicant for a Commission license, standard design certification, or a standard design approval, or a contractor or subcontractor of a Commission licensee, holder of a standard design approval, or any applicant may be grounds for—

(1) Denial, revocation, or suspension of the license or standard design approval;

(2) Withdrawal or revocation of a proposed or final standard design certification;

(3) Imposition of a civil penalty on the licensee, holder of a standard design approval, or applicant (including an applicant for a standard design certification under this part following Commission adoption of final design certification rule) or a contractor or subcontractor of the licensee, holder of a standard design approval, or applicant; or

(4) Other enforcement action.

(d) Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each holder or applicant for a license or design approval, must prominently post the revision of NRC Form 3, "Notice to Employees," referenced in § 19.11(e)(1) of this chapter. This form must be posted at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted no later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, and for 30 days following license termination.

(2) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate NRC Regional Office listed in appendix D to 10 CFR part 20, via email to *Forms.Resource@nrc.gov*, or by visiting the NRC's online library at *http://www.nrc.gov/reading-rm/doc-collections/forms/*.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to Section 211 of the ERA, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in paragraph (a)(1) of this section including, but not limited to, providing information to the NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

(g) Part 19 of 10 CFR sets forth requirements and regulatory provisions applicable to licensees, holders of a standard design approval, applicants for a license, standard design certification, or standard design approval, and contractors or subcontractors of a Commission licensee, or holder of a standard design approval, and are in addition to the requirements in this section.

§ 53.070 Completeness and accuracy of information.

(a) Information provided to the Commission by a holder of a license, permit, design certification, or standard design approval under this part or an applicant for a license, permit, design certification, or standard design approval under this part, and information required by statute or by the Commission's regulations, orders, license conditions, or terms and conditions of a standard design approval to be maintained by the applicant or the licensee must be complete and accurate in all material respects.

(b) Each applicant for or licensee of a commercial nuclear plant under this part, each holder of a standard design approval under this part, and each applicant for a

standard design certification under this part following Commission adoption of a final design certification regulation, must notify the Commission of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or common defense and security. An applicant, licensee, or holder violates this paragraph only if the applicant, licensee, or holder fails to notify the Commission of information that the applicant, licensee, or holder has identified as having a significant implication for public health and safety or common defense and security. Notification must be provided to the Administrator of the appropriate Regional Office within 2 working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements.

Commented [A80]: As drafted, this paragraph covers holders of operator licenses, senior operator licenses, and generally licensed reactor operators under subpart F. Edited to limit the scope of this paragraph to applicants for and holders of licenses and permits for commercial nuclear plants rather than including those for operators, senior operators, and generally licensed reactor operators, thus reflecting the requirements of 55.9..

§ 53.080 Specific exemptions.

(a) The Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of the regulations of this part, which are authorized by law, will not present an undue risk to the public health and safety, and are consistent with the common defense and security.

(b) The Commission will not consider granting an exemption unless special circumstances are present. Special circumstances are present whenever —

(1) Application of the regulation in the particular circumstances conflicts with other rules or requirements of the Commission;

(2) Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule;

(3) Compliance would result in undue hardship or other costs that are significantly in excess of those contemplated when the regulation was adopted, or that are significantly in excess of those incurred by others similarly situated;

(4) The exemption would result in benefit to the public health and safety that compensates for any decrease in safety that may result from the grant of the exemption;

(5) The exemption would provide only temporary relief from the applicable regulation and the licensee or applicant has made good faith efforts to comply with the regulation; or

(6) There is present any other material circumstance not considered when the regulation was adopted for which it would be in the public interest to grant an exemption. If such condition is relied on exclusively for demonstrating compliance with paragraph (b) of this section, the exemption may not be granted until the Executive Director for Operations has consulted with the Commission.

(c) Any person may request an exemption permitting the conduct of construction activities prohibited by § 53.610 prior to the issuance of a CP. The Commission may grant such an exemption upon considering and balancing the following factors:

(1) Whether conduct of the proposed activities will give rise to a significant adverse impact on the environment and the nature and extent of such impact, if any;

(2) Whether redress of any adverse environment impact from conduct of the proposed activities can reasonably be effective should such redress be necessary;

(3) Whether conduct of the proposed activities would foreclose subsequent adoption of alternatives; and

(4) The effect of delay in conducting such activities on the public interest, including whether the power needs to be used by the proposed facility, the availability of

alternative sources, if any, to meet those needs on a timely basis and delay costs to the applicant and to consumers.

(d) Issuance of such an exemption must not be deemed to constitute a commitment to issue a CP. During the period of any exemption granted pursuant to paragraph (c) of this section, any activities conducted must be carried out in such a manner as will minimize or reduce their environmental impact.

(e) The Commission's consideration of requests for exemptions from requirements of the regulations of other parts in this chapter that are applicable by virtue of this part must be governed by the exemption requirements of those parts.

§ 53.090 Standards for review.

(a) *Common standards*. In determining that a construction permit (CP), operating license (OL), early site permit, combined license (COL), or manufacturing license (ML) ~~in~~under this part will be issued to an applicant, the Commission will be guided by the following considerations:

(1) Except for an early site permit or ML, the processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other technical specifications, or the proposals, in regard to any of the foregoing, collectively provide reasonable assurance that the applicant will comply with the regulations in this chapter, including the regulations in 10 CFR part 20, and that the health and safety of the public will not be endangered.

(2) The applicant for a CP, OL, COL, or ML is technically and financially qualified to engage in the proposed activities in accordance with the regulations in this chapter. However, no consideration of financial qualification is necessary for an electric utility applicant for an OL for a utilization facility of the type described in paragraph (d) of this section or for an applicant for an ML.

(3) The issuance of a CP, OL, early site permit, COL, or ML to the applicant will not, in the opinion of the Commission, be inimical to the common defense and security or to the health and safety of the public.

(4) Any applicable requirements of subpart A of 10 CFR part 51 have been satisfied.

(b) *Additional standards for licenses*. In determining whether a license will be issued to an applicant, the Commission will, in addition to applying the standards set forth in paragraph (a) of this section, consider whether the proposed activities will serve a useful purpose proportionate to the quantities of special nuclear material~~SNM~~ or source material to be utilized.

(c) *Additional standards and provisions affecting licenses ~~and certifications~~ for commercial power*. In addition to applying the standards set forth in paragraphs (a) and (b) of this section, paragraphs (c)(1) through (c)(~~5~~4) of this section apply in the case of a license for a facility for the generation of commercial power. ~~For a design certification under this part, only paragraph (c)(5) of this section applies.~~

(1) The NRC will—

(i) Give notice in writing of each application to the regulatory agency or State as may have jurisdiction over the rates and services incident to the proposed activity;

(ii) Publish notice of the application in trade or news publications as it deems appropriate to give reasonable notice to municipalities, private utilities, public bodies, and cooperatives which might have a potential interest in the utilization ~~or production~~ facility; and

(iii) Publish notice of the application once each week for four consecutive weeks in the *Federal Register*. No license will be issued by the NRC prior to the giving of these notices and until four weeks after the last notice is published in the *Federal Register*.

Commented [A81]: Deleted because design certifications are brought with the scope of paragraph (d) (formerly (c)(5)) of this section by its own terms and would be excluded from the scope of paragraphs (c)(1) through (4) because they are not licenses as defined in 53.020.

Commented [A82]: Deleted because production facilities are outside the scope of this draft part 53.

(2) If there are conflicting applications for a limited opportunity for such license, the Commission will give preferred consideration in the following order: first, to applications submitted by public or cooperative bodies for facilities to be located in high cost power areas in the United States; second, to applications submitted by others for facilities to be located in such areas; third, to applications submitted by public or cooperative bodies for facilities to be located in areas other than high cost power areas; and, fourth, to all other applicants.

(3) The licensee who transmits electric energy in interstate commerce, or sells it at wholesale in interstate commerce, must be subject to the regulatory provisions of the Federal Power Act.

(4) Nothing shall preclude any government agency, now or hereafter authorized by law to engage in the production, marketing, or distribution of electric energy, if otherwise qualified, from obtaining a CP, OL, or COL under this part for a utilization facility for the primary purpose of producing electric energy for disposition for ultimate public consumption.

(~~5~~d) Applications for a design certification, COL, ML, OL, or standard design approval that propose nuclear reactor designs which differ significantly from light-water reactor designs that were licensed before 1997, or use simplified, inherent, passive, or other innovative means to accomplish their safety functions, will be approved only if—

(i)(A) The performance of each safety feature of the design has been demonstrated through either analysis, appropriate test programs, experience, or a combination thereof;

(B) Interdependent effects among the safety features of the design are acceptable, as demonstrated by analysis, appropriate test programs, experience, or a combination thereof; and

Commented [A83]: Staff should insert an appropriate title for this paragraph. Staff should adjust any citations to this paragraph appropriately.

Note that 50.43(e), which forms the basis for this paragraph, may be limited in applicability to Class 103 licenses for the generation of commercial power by the overarching terms of 50.43 and to design certifications for nuclear power facilities by the terms in 52.41. Staff should assess whether the term "commercial power" is broad enough to cover the production of process heat, etc. by a nuclear reactor licensed under 50.22 for industrial purposes rather than commercial purposes.

Commented [A84]: In 50.43(e), which forms the basis for this paragraph, there is a typographic error with a period following the year 1997 rather than a comma and capitalization of the word "Or", resulting in incomplete sentences. Staff should correct this typographic error in 50.43(e) as it has done here in the next administrative rulemaking.

(C) Sufficient data exist on the safety features of the design to assess the analytical tools used for safety analyses over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions; or

(ii) There has been acceptable testing of a prototype plant over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions. If a prototype plant is used to comply with the testing requirements, then the NRC may impose additional requirements on siting, safety features, or operational conditions for the prototype plant to protect the public and the plant staff from the possible consequences of accidents during the testing period.

(de) *Licenses for commercial nuclear plants.* A license will be issued, to an applicant who qualifies, for any one or more of the following: to transfer or receive in interstate commerce, or manufacture, produce, transfer, acquire, possess, or use a ~~production or~~ utilization facility for ~~industrial or~~ commercial purposes. ~~Provided, however, that in the case of a utilization facility which is useful in the conduct of research and development activities of the types specified in Section 31 of the AEA, such facility is deemed to be for industrial or commercial purposes if the facility is to be used so that more than 50 percent of the annual cost of owning and operating the facility is devoted to the production of materials, products, or energy for sale or commercial distribution, or to the sale of services, other than research and development or education or training.~~

§ 53.100 Jurisdictional limits.

No permit, license, standard design approval, or standard design certification under this part shall be deemed to have been issued for activities ~~which~~ that are not under or within the jurisdiction of the United States.

§ 53.110 Attacks and destructive acts.

Commented [A85]: Staff should adjust any citations to this paragraph appropriately.

Commented [A86]: Deleted to reflect that production facilities are outside the scope of this draft part 53.

Commented [A87]: Deleted as the usage in this paragraph is the sole usage of "industrial purposes" for a utilization facility. As described on page 22 of this document, commercial purposes includes purposes such as providing process heat for a variety of industrial applications (e.g., desalination, oil refining, hydrogen production). This renders the term "industrial purposes" in the requirement superfluous.

Commented [A88]: This portion is faithful to the deeming provision of § 50.22 but does not seem to be needed in this draft part 53 due to the limitation in scope to only commercial nuclear plants. Unless the staff desires to change the scope to include non-commercial nuclear plant licensing, this portion should be deleted.

Licensees, applicants for licenses, permits, certifications, and design approvals, and applicants for an amendment to any license, permit, certification, or design approval under this part are not required to provide for design features or other measures for the specific purpose of protection against the effects of—

(a) Attacks and destructive acts, including sabotage, directed against the facility by an enemy of the United States, whether a foreign government or other person; or

(b) Use or deployment of weapons incident to U.S. defense activities.

§ 53.115 Rights related to special nuclear material.

(a) No right to the SNM ~~must~~ will be conferred by a license issued under this part except as may be defined by the license.

Commented [A89]: This corresponds to 50.54(b), which reads "no right to the special nuclear material shall be conferred…." The removal of the use of the word "shall" as a result of plain language efforts is good, but the usage here is better expressed by "will" than by "must".

(b) Neither a license issued under this part, nor any right thereunder, nor any right to utilize or produce SNM may be transferred, assigned, or disposed of in any manner, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission, after securing full information, finds that the transfer is in accordance with the provisions of the Act~~EA (68 Stat. 919)~~ and gives its consent in writing.

§ 53.117 License suspension and rights of recapture.

Any license issued under this part must be subject to suspension and to the rights of recapture of the material or control of the facility reserved to the Commission under Section 108 of the Act~~EA~~ in a state of war or national emergency declared by Congress.

§ 53.120 Information collection requirements: OMB approval.

(a) The NRC has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). The NRC may not conduct or

sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-XXXX.

(b) The approved information collection requirements contained in this part appear in §§ 53.070, 53.080, 53.240, 53.410, 53.420, 53.425, 53.430, 53.440, 53.450, 53.480, 53.500, 53.540, 53.605, 53.610, 53.620, 53.700, 53.710, 53.715, 53.720, 53.730, 53.780, ~~53.785,~~ 53.805, 53.810, 53.815, 53.830, 53.850, 53.855, 53.865, ~~53.870,~~ 53.875, 53.880, ~~53.890,~~ 53.910, 53.1010, 53.1020, 53.1030, 53.1045, 53.1060, 53.1070, 53.1075, 53.1080, 53.1100, 53.1109, 53.1115, 53.1130, 53.1140, 53.1144, 53.1146, 53.1173, 53. 1182, 53.1188, 53.1200, 53.1206, 53.1209, 53.1210, 53.1221, 53.1230, 53.1236, 53.1239, 53.1241, 53.1254, 53.1257, 53,1263, 53.1270, 53.1276, 53.1279, 53.1282, 53.1288, 53.1295, 53.1300, 53.1306, 53.1309, 53.1312, 53.1327, 53.1330, 53.1333, 53.1336, 53.1348, 53.1360, 53.1366, 53.1369, 53.1372, 53.1384, 53.1410, 53.1413, 53.1416, 53.1419, 53.1437, 53.1449, 53.1452, 53.1458, 53.1470, 53.1505, 53.1510, 53.1515, 53.1525, 53.1530, 53.1535, 53.1540, 53.1545, 53.1550, 53.1560, 53.1565, 53.1570, 53.1575, 53.1580, 53.1620, 53.1630, 53.1645, 53.1680, 53.1690, and 53.1720~~, 53.1805, 53.1810, 53.1815, 53.1825, 53.1830, 53.1835, 53.1845, 53.1850, 53.1855, 53.1860, 53.1865, 53.1870, 53.1875, 53.1880, 53.1885, 53.1890, 53.3520, 53.3525, 53.4105, 53.4110, 53.4120, 53.4200, 53.4210, 53.4213, 53.4215, 53.4310, 53.4340, 53.4350, 53.4360, 53.4380, 53.4390, 53.4400, 53.4420, 53.4610, 53.4620, 53.4630, 53.4645, 53.4660, 53.4670, 53.4675, 53.4680, 53.4700, 53.4709, 53.4715, 53.4730, 53.4731, 53.4740, 53.4750, 53.4753, 53.4754, 53.4756, 53.4777, 53.4783, 53.4792, 53.4798, 53.4800, 53.4803, 53.4806, 53.4809, 53.4821, 53.4830, 53.4836, 53.4839, 53.4841, 53.4854, 53.4857, 53.4863, 53.4870, 53.4876, 53.4879, 53.4882, 53.4888, 53.4895, 53.4900, 53.4906, 53.4909, 53.4912, 53.4927, 53.4930,~~

~~53.4933, 53.4936, 53.4948, 53.4960, 53.4966, 53.4969, 53.4972, 53.4984, 53.5010, 53.5013, 53.5016, 53.5019, 53.5037, 53.5049, 53.5052, 53.5058, 53.5070, 53.6005, 53.6010, 53.6015, 53.6025, 53.6030, 53.6035, 53.6040, 53.6045, 53.6050, 53.6052, 53.6054, 53.6060, 53.6065, 53.6070, 53.6075, 53.6080, 53.6320, 53.6330, 53.6340, 53.6345, 53.6380, 53.6390, 53.6420, 53.6605, 53.6610, 53.6615, 53.6625, 53.6330, 53.6635, 53.6645, 53.6650, 53.6655, 53.6660, 53.6665, 53.6670, 53.6675, 53.6680, 53.6685, and 53.6690~~.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. The information collection requirement and the control numbers under which it is approved are as follows:

(1) ~~In §§ 53.765, 53.770, 53.780, and 53.795, NRC Form 396 is approved under control number 3150-0024.~~

~~(2) In §§ 53.775 and 53.795, NRC Form 398 is approved under control number 3150–0090.~~

~~(3)~~ In §§ 53.1640 ~~and 53.6340~~, NRC Form 366 is approved under control number 3150-0104.

(24) In §§ 53.1630 ~~and 53.6330~~, NRC Form 361 is approved under control number 3150-0238.

(35) In §§ 53.1650 ~~and 53.6350~~, IAEA Design Information Questionnaire forms are approved under control number 3150–0056.

(46) In §§ 53.1650 ~~and 53.6350~~, DOC/NRC Form AP–A and associated forms are approved under control numbers 0694–0135.

Subpart B — Technology-Inclusive Safety Requirements

~~§ 53.200 Safety objectives.~~

Commented [A90]: This entire subpart is drafted in the passive voice, which makes it difficult to identify who could be held accountable for a failure to meet the requirements they are phrased as providing. This may be problematic in the application of these as requirements, particularly as they are requirements that could result in criminal penalties for offenders under 53.9010.

~~Each commercial nuclear plant must be designed, constructed, operated, and decommissioned to limit the possibility of an immediate threat to the public health and safety. In addition, additional measures must be taken for each commercial nuclear plant as may be appropriate when considering potential risks to public health and safety. These safety objectives must be carried out by meeting the safety criteria and other requirements identified in this subpart.~~

Commented [A91]: Deleted as unnecessary and to avoid conflict with the AEA.

§ 53.210 Safety criteria for design-basis accidents.

The ~~Design features and programmatic controls must be provided for each commercial nuclear plant such that identification and~~ analyses under § 53.450 of the performance of a commercial nuclear plant for design basis accidents~~DBAs~~ identified under ~~in accordance with~~ § 53.240 must demonstrate the following:

Commented [A92]: Edited to reflect the intent of this section as being to provide safety criteria as discussed in the preamble.

(a) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release would not receive a radiation dose in excess of 25 rem (250 millisieverts (mSv)) total effective dose equivalent (TEDE); and

(b) An individual located at any point on the outer boundary of the low population zone who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (250 mSv) TEDE.[1]

[1] The use of 25 rem TEDE is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

§ 53.220 Safety criteria for licensing-basis events other than design-basis accidents.

(a) The applicant or licensee must identify evaluation criteria for each event or specific category of licensing basis event to determine the acceptability of plant

response to the challenges posed by internal and external hazards to provide an appropriate level of safety.

(b) The ~~Design features and programmatic controls must be provided for each commercial nuclear plant such that identification and~~ analyses under § 53.450 of the performance of a commercial nuclear plant for licensing-basis events (LBEs) other than design basis accidents (DBAs) identified under~~in accordance with~~ § 53.240 demonstrate that~~the following:~~

~~(a) Ensure~~ plant structures, systems, and components~~SSCs~~, personnel, and programs provide the necessary capabilities and maintain the necessary reliability to meet the acceptance criteria identified in paragraph (a) of this section.~~address LBEs other than DBAs in accordance with §§ 53.240 and 53.450(e), and provide measures for defense-in-depth in accordance with § 53.250.; and~~

~~(b) Maintain overall cumulative plant risk from LBEs other than DBAs analyzed in accordance with § 53.450(e) such that the calculated risk to an average individual in the vicinity of the commercial nuclear plant of prompt fatalities remains below five in 10 million years, and the calculated risk to the population in the area near a commercial nuclear plant of cancer fatalities remains below two in 1 million years.~~

§ 53.230 Safety functions.

(a) The primary safety function is limiting the release of radioactive materials from the facility. The holder of a license to operate a commercial nuclear plant under this part ~~and~~ must ~~be~~ maintain~~ed~~ the capability of the plant to perform the primary safety function during normal operation and for licensing-basis events (LBEs) identified under § 53.240 until the Commission terminates the license~~over the life of the plant~~.

(b) The applicant or licensee for a commercial nuclear plant must identify ~~A~~additional safety functions ~~needed~~ to support the retention of radioactive materials

Commented [A93]: Moved here from 53.450(e) to align the identification of safety criteria in the proper location of the regulations.

Commented [A94]: Specific cumulative risk numbers are deleted here consistent with Commission policy expressed in SRM-SECY-89-0102 and reiterated periodically (see, e.g., SRM-SECY-00-0077 and the Commission's affirmation in "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement" that the "safety goals are intended to be applied generically and are not for plant-specific applications." 60 FR 42622, 42628; August 16, 1995).

during LBEs.~~—~~ The additional safety functions may include~~such as~~ controlling reactivity, heat generation, heat removal, and chemical interactions~~— must be identified for each commercial nuclear plant~~ as appropriate to the design.

(c) The primary and additional safety functions ~~are required~~necessary to satisfy the safety criteria defined in §§ 53.210 and 53.220~~, or more restrictive alternative criteria adopted under § 53.470, and~~ must be fulfilled by the design features, human actions, and programmatic controls specified throughout ~~Framework A of~~ this part.

§ 53.240 Licensing-basis events.

(a) The applicant or licensee for a commercial nuclear plant must identify Licensing-basis events (LBEs) ~~must be identified for each commercial nuclear plant and~~for analysis~~zed in accordance with~~under § 53.450 to demonstrate that the safety requirements in this subpart have been satisfied. The LBEs must be identified using insights from the risk evaluation performed under § 53.450 in combination with other generally accepted approaches that have been endorsed or otherwise found acceptable by the NRC for systematically evaluating engineered systems to identify and analyze equipment failures and human errors.

(b) The identified LBEs, ranging from anticipated event sequences to very unlikely event sequences, must collectively address combinations of malfunctions of plant structures, systems, and components (SSCs), human errors, facility hazards, and the effects of external hazards.

(c) The analysis of LBEs must—

(1) Include analysis of one or more design basis accidents~~DBAs in accordance with~~under § 53.450(f);

Commented [A95]: *Passim*, staff has not identified any operational flexibilities that would be gained by adopting alternative criteria under § 53.470. As a result, an applicant or licensee desiring to take advantage of the increased margins under that section would nevertheless need to rely on a specific exemption from whatever requirement the operational flexibilities are desired against. Given that the exemption process would afford an applicant the same opportunity to propose more restrictive alternative criteria as a justification for an exemption to any requirement, there is no need for that section to exist.

(2) Confirm the adequacy of design features and programmatic controls needed to satisfy the safety criteria defined in §§ 53.210 and 53.220~~, or more restrictive alternative criteria adopted under § 53.470~~, and

(3) Establish related functional requirements for plant SSCs, personnel, and programs.

(d) The methodology used to identify, categorize, and analyze LBEs must include a means to identify event sequences that are significant for controlling the risks posed to public health and safety.

§ 53.250 Defense in depth.

(a) Measures must be taken for each commercial nuclear plant to ensure appropriate defense in depth is provided to compensate for uncertainties in the analysis of the safety criteria such that there is reasonable assurance that the safety criteria in this subpart are met over the life of the plant.

(b) The uncertainties that must be addressed under paragraph (a) of this section include those related to the state of knowledge and modeling capabilities, the ability of barriers to limit the release of radioactive materials from the facility during LBEs other than DBAs, the reliability and performance of plant SSCs and personnel, and the effectiveness of programmatic controls.

(c) The safety analysis may not rely upon a single engineered design feature, human action, or programmatic control, no matter how robust, to address the range of LBEs other than DBAs.

§ 53.260 Normal operations.

~~(a)~~ Holders of ~~L~~licensee~~e~~s to operate commercial nuclear plants under ~~Framework A of~~ this part must ~~ensure that normal plant operations do not result in~~control public doses and~~or~~ dose rates in unrestricted areas from normal plant operations~~that~~ to

Commented [A96]: Edited to eliminate coverage of GLROs in this requirement.

meetexceed the limits providedrequirements in Subpart D to 10 CFR part 20 of this chapter.

(b) A combination of design features and programmatic controls must be established such that the estimated TEDE to individual members of the public resulting from normal plant operation is as low as is reasonably achievable in accordance with 10 CFR part 20.

§ 53.270 Protection of plant workers.

(a) Holders of Llicenseeos to operate commercial nuclear plants under Framework A of this part must ensure thatcontrol the radiological dose to plant workers does not exceedto meet the occupational dose limits provided requirements in subpart C to 10 CFR part 20 of this chapter.

(b) A combination of design features and programmatic controls must, to the extent practical, be based upon sound radiation protection principles to achieve occupational doses that are as low as is reasonably achievable in accordance with 10 CFR part 20.

Subpart C — Design and Analysis Requirements

§ 53.400 Design features for licensing-basis events.

(a) Design features must be provided for each commercial nuclear plant such that, when combined with corresponding human actions and programmatic controls, the plant will satisfy the safety criteria defined in §§ 53.210 and 53.220, or more restrictive alternative criteria adopted under § 53.470. and

(b) Design features must ensure thatfulfill the safety functions identified in § 53.230 are fulfilled during licensing-basis eventsLBEs identified under § 53.240.

§ 53.410 Functional design criteria for design-basis accidents.

Commented [A97]: This incorporates the ALARA requirements in part 20.

Commented [A98]: This is unnecessary with the edit to the remainder of this paragraph to refer to the requirements of part 20 rather than the dose limits.

Commented [A99]: Combined with paragraph (a), recognizing that under 53.230(c) design features alone do not fulfill the safety functions.

~~(a)~~ The applicant or licensee for a commercial nuclear plant must define f~~F~~unctional design criteria ~~must be defined~~ for each design feature required by § 53.400 and relied upon to demonstrate compliance with the safety criteria defined in § 53.210.

~~(b) Corresponding human actions and programmatic controls must be identified and implemented in accordance with this and other subparts to achieve and maintain the reliability and capability of SSCs relied upon to satisfy the defined functional design criteria and the safety criteria required in § 53.210, and to maintain consistency with analyses required by § 53.450(f).~~

Commented [A100]: This draft proposed requirement is redundant to the QA requirements and is not a functional design criterion.

§ 53.415 Protection against external hazards.

~~SR SSCs~~Structures, systems, and components (SSCs) categorized as safety-related SSCs under § 53.460 must be protected against or must be designed to withstand the effects of natural phenomena (e.g., earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches) and ~~constructed~~ man-related hazards (e.g., dams, transportation routes, military and industrial facilities) considering an event severity up to the design-basis external hazard levels as determined under § 53.510 without losing the capability to perform the safety functions identified under~~stated in~~ § 53.230. Specific requirements for earthquake engineering are included in § 53.480.

Commented [A101]: Edited to avoid conflict with the definition of "construction" in § 53.024, using the familiar terminology for these types of hazards in part 100.

§ 53.420 Functional design criteria for licensing-basis events other than design-basis accidents.

~~(a)~~ The applicant or licensee for a commercial nuclear plant must define f~~F~~unctional design criteria ~~must be defined~~ for each design feature required by § 53.400 and relied upon to~~—~~

~~(1) Demonstrate compliance with the safety criteria in § 53.220 or more restrictive alternative criteria adopted under § 53.470; and~~

Commented [A102]: Section 53.450(e)(3) requires that the analyses performed for LBEs other than DBAs satisfy the safety criteria in § 53.220. Section 53.450(e)(2) is the paragraph in which evaluation criteria are required to be identified to show that the analyses are acceptable to show an acceptable level of safety. Given that § 53.450(e)(3) establishes the safety criteria of § 53.220 as being needed to show the analyses provide an appropriate level of safety, this reference to § 53.220 is unnecessary.

~~(2) D~~demonstrate compliance with the evaluation criteria in § 53.450(e) ~~or more restrictive alternative criteria adopted under § 53.470~~.

~~(b) Corresponding human actions and programmatic controls must be identified and implemented in accordance with this and other subparts to achieve and maintain the reliability and capability of SSCs relied upon to—~~

~~(1) Satisfy the safety criteria in § 53.220 or more restrictive alternative criteria adopted under § 53.470; and~~

~~(2) Satisfy the evaluation criteria in § 53.450(e) or more restrictive alternate criteria adopted under § 53.470.~~

Commented [A103]: Move up to be part of paragraph (a).

Commented [A104]: This draft proposed requirement is redundant to the QA requirements and is not a functional design criterion.

§ 53.425 Design features and functional design criteria for normal operations.

(a) Design features must be provided for each commercial nuclear ~~plant such that, when combined with corresponding programmatic controls,~~to support the Radiation Protection Program ~~the~~ require~~d~~ments in § 53.~~260(a)~~850 ~~can be met~~.

(b) Functional design criteria must be defined for each design feature relied upon to demonstrate compliance with § 53.~~260(a)~~850.

(c) ~~Corresponding programmatic controls, including monitoring programs, must be identified and implemented to confirm that the criteria in § 53.260(a) are not exceeded.~~

Commented [A105]: The draft proposed requirement here is neither for a design feature nor a functional design criteria. It also duplicates the part 20 requirements.

~~(d)~~ Functional design criteria, including design objectives for dose to the maximally exposed member of the public, must be defined for design features to ~~ensure~~ show that plant ~~SSCs~~ design features and corresponding programmatic controls, including monitoring programs, ~~ensure that~~control liquid, gaseous, and solid wastes ~~are controlled such that the public doses are kept as low as reasonably achievable in accordance with § 53.260(b)~~as required under part 20 of this chapter.[2] A guide for keeping doses to the public as low as is reasonably achievable is that the estimated

annual dose to the maximally exposed member of the public does not exceed 10 mrem total effective dose equivalent. A design objective of maintaining doses below 10 mrem/year should not be construed as a radiation protection standard.

~~[2] A guide for meeting as low as is reasonably achievable in § 53.260(b) is that the estimated annual dose to the maximally exposed member of the public does not exceed 10 mrem TEDE. The design objective of maintaining doses below 10 mrem/year should not be construed as a radiation protection standard.~~

Commented [A106]: This footnote appears to establish a design objective of 10 mrem/year dose to the maximally exposed member of the public. If this is the intent, that should not be accomplished in a footnote but instead in the body of the regulation. See also the comment on § 53.1645 regarding the need for identification of the requirement for the establishment of ALARA design objectives. Staff should confirm that the edits to this paragraph fix these issues.

§ 53.430 Design features and functional design criteria for protection of plant workers.

(a) Design features must be provided for each commercial nuclear plant such that, when combined with corresponding programmatic controls, the requirements in § 53.270~~(a)~~ can be met.

(b) Functional design criteria must be defined for each design feature relied upon to demonstrate compliance with § 53.270~~(a)~~.

~~(c) Corresponding programmatic controls, including monitoring programs, must be identified and implemented to confirm that the worker protection criteria in § 53.270(a) are not exceeded.~~

~~(d) Functional design criteria must be defined for design features to ensure that plant SSCs and corresponding programmatic controls, including monitoring programs, satisfy § 53.270(b).~~

Commented [A107]: This duplicates the requirements of part 20.

§ 53.440 Design requirements.

Commented [A108]: Staff has addressed the construction and operating experience elements of 50.34(f)(3)(i) in 53.610(a)(4) and 53.730(e) respectively. Staff should address the design experience element here.

(a) [Reserved]~~Analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof must demonstrate that each design feature required by § 53.400 meets the defined functional design criteria required by §§ 53.410 and 53.420. This demonstration must consider interdependent effects throughout the commercial nuclear plant and the range of conditions under which the design features required by § 53.400 must function throughout the plant's lifetime.~~

Commented [A109]: This paragraph does not express a design requirement. It is drafted as a demonstration requirement that seems to duplicate the § 53.090(c)(5) (renumbered in these edits as § 53.090(d)) requirements for demonstration of the capabilities of design features. Staff should consolidate these into a single requirement set in an appropriately titled section.

(b) [Reserved]~~The design features required by § 53.400 must, wherever applicable, be designed using generally accepted consensus codes and standards that have been endorsed or otherwise found acceptable by the NRC.~~

(c) The materials used for safety-related (SR) and non-safety-related but safety significant (NSRSS) structures, systems, and components (SSCs) must be qualified for their service conditions over the plant lifetime.

(d) Possible degradation mechanisms related to aging, fatigue, chemical interactions, operating temperatures, effects of irradiation, and other environmental factors that may affect the performance of SR and NSRSS SSCs must be evaluated and used to inform the design~~ and the development of integrity assessment programs under § 53.870.~~

(e)(1) SR and NSRSS SSCs must be designed and located to minimize, consistent with other safety requirements in this part, the probability and effect of fires and explosions.

(2) Noncombustible and fire-resistant materials must be used wherever practical throughout the facility, particularly in locations with SR and NSRSS SSCs.

(3) Fire detection and fire suppression systems of appropriate capacity and capability must be provided and designed to minimize the adverse effects of fires on SR and NSRSS SSCs.

(4) Fire suppression systems must be designed to ensure that their rupture or inadvertent operation does not significantly impair the ability of SR and NSRSS SSCs to perform their safety functions ~~to satisfy~~identified under § 53.230.

(f) Safety and security must be considered together in the design process such that, where possible, security issues are effectively resolved through design and engineered security features.

Commented [A110]: This is discussed in the preamble on page 42 more as guidance than as a requirement (i.e., stating that design features should be designed using generally accepted consensus codes and standards). It is also unclear what the effect of the "wherever applicable" would be on this as a requirement.

Given that the intent of this rulemaking is to facilitate licensing advanced reactors for which consensus codes and standards are not necessarily available, endorsed, or otherwise found acceptable by the NRC, this should be eliminated as a requirement.

Commented [A111]: This appears to be intended to replicate general design criterion 3 from appendix A to part 50. Staff should either clearly articulate the reasons why a developer cannot address the hazards due to fire in its PRA or remove this as a design requirement.

(g) The reactor system and waste stores for each commercial nuclear plant must be capable of ~~achieving and maintaining a subcritical condition~~ reliably controlling reactivity during normal operations and following any LBE identified in accordance with § 53.240.

(h) Each commercial nuclear plant must have a capability to provide long-term cooling of the reactor fuel and waste stores ~~following~~ during normal operations or following any licensing-basis event (LBE) identified in accordance with § 53.240.

(i) The design, analysis, staffing, and programmatic controls for each commercial nuclear plant must consider the number of reactors, waste stores, and other significant inventories of radioactive materials and the associated operating configurations, common systems, system interfaces, and system interactions.

(j)(1) Design features must be provided and related functional design criteria defined such that, with limited use of operator actions, one or more physical barriers are maintained to limit the release of radionuclides from reactor systems, waste stores, or other significant inventories of radioactive materials assuming the impact of a large, commercial aircraft.

(2) The functional design criteria for those design features provided to address the requirements in paragraph (j)(1) of this section must be based on an assessment of the impact of a large, commercial aircraft used for long distance flights in the United States, with aviation fuel loading typically used in such flights, and an impact speed and angle of impact considering the ability of both experienced and inexperienced pilots to control large, commercial aircraft at low altitude representative of a commercial nuclear plant's low profile.[3]

Commented [A112]: Together these two paragraphs seem to address general design criterion 27 from appendix A to part 50 with the requirement for subcriticality exceeding the GDC. If they are retained as requirements, they should be edited as indicated to match the GDC requirement more closely as there has been no articulated reason to impose a more strict requirement on advanced reactors. Note also that as drafted, the requirement to be capable of achieving and maintaining a subcritical condition for the waste stores does not make sense as it would allow for them to actually be critical so long as the capability is maintained.

Commented [A113]: Staff should restart the numbering of footnotes in each section in order to avoid future numbering problems in rulemakings within this part.

(k) Design features and related functional design criteria must be defined such that analyses demonstrate a low risk of permanent injury to the public due to the health effects of the chemical hazards of licensed material.

(l) Measures must be taken during the design of commercial nuclear plants to minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste in accordance with § 20.1406 of this chapter.

(m)(1) Each commercial nuclear plant must include criticality monitoring capabilities meeting the requirements of either § 70.24 of this chapter or paragraph (m)(2) of this section.

(2) In lieu of maintaining a monitoring system capable of detecting criticality as described in § 70.24 of this chapter, criticality accident requirements may be satisfied by—

(i) Demonstrating the sub-criticality of SNM, except when it is inside the reactor and the reactor is being operated, by maintaining k-effective below 0.95 at a 95 percent probability, 95 percent confidence level, under conditions that maximize reactivity for the applicable storage and handling configurations, and

(ii) Providing radiation monitors for fuel storage and associated handling areas when fuel is present to detect excessive radiation levels and to support initiating appropriate safety actions.

(3) While a spent fuel transportation package approved under 10 CFR part 71 of this chapter or spent fuel storage cask approved under 10 CFR part 72 is in the SNM handing or storage area, the requirements in 10 CFR parts 71 or 72, as applicable, and the requirements of the certificate of compliance for that package or cask, are the applicable requirements for the fuel within that package or cask.

(n) *Human factors engineering*

(1) The design of each commercial nuclear plant must reflect state-of-the-art human factors principles for safe and reliable performance in all ~~settings~~ locations that human activities are expected for performing or supporting the continued availability of plant safety or emergency response functions.

(2) In order ~~The design must provide for the capabilities described in § 53.730(b)~~ to ensure the plant staff are able to monitor plant conditions and respond to events, the design must provide for the following capabilities.:

(i) Features for displaying to operating personnel a minimum set of parameters that define the safety status of the plant and are capable of displaying both the full range of important plant parameters and data trends on demand, as well as indicating when process limits are being approached or exceeded;

(ii) Automatic indication of the bypassed and operable status of safety systems;

(iii) Direct indication of SSC status that relates to the ability of the SSC to perform its safety function, such as relief and safety valve position (i.e., open or closed) for barriers important to fulfilling safety functions of with such devices, and ultimate heat sink and cooling system status and availability;

(iv) Instrumentation to measure, record, and display key plant parameters related to the performance of SSCs and the integrity of barriers important to fulfilling safety functions to support operators in monitoring plant conditions and responding to plant events. Examples include temperatures and pressures within important systems or structures, core or fuel system conditions (including possible damage states), temperatures and levels associated with cooling functions, combustible gas concentrations, radiation levels in systems and within structures, and radioactive effluent releases;

(v) Leakage control and detection in the design of systems that pass through barriers important to fulfilling safety functions for the release of radionuclides. An example is an SSC that penetrates a containment structure that might contain radioactive materials that could contribute to the source term during an accident;

(vi) Monitoring of in-plant radiation and airborne radioactivity as appropriate for a broad range of normal operating and accident conditions

(3) The means by which the design and human actions together will achieve the safety requirements of subpart B of this part must be evaluated and used to inform the design and the development of the concept of operations required by § 53.730(c).

(4) A functional requirements analysis and function allocation must be used to ensure that plant design features address how safety functions and functional safety criteria are satisfied, and how the safety functions will be assigned to appropriate combinations of human action, automation, active safety features, passive safety features, or inherent safety characteristics.

(o) *Load following*. The design of a commercial nuclear plant that will operate in a load following mode must include one of the following features capable of immediately refusing demands that could challenge the safe operation of the plant or are otherwise precluded by the plant equipment conditions:

(i) An automatic protection system that utilizes setpoints more conservative than those otherwise credited for the purposes of reactor protection; or

(ii) An automated control system; or

(iii) Provisions to allow operator or senior operator or a generally licensed reactor operator, as appropriate to refuse the demand.

(p) The configuration of structures, systems, and components must provide sufficient access for personnel and equipment to perform inservice inspection and

inservice testing under § 53.880. Shielding must be provided to support the radiation protection of plant personnel when accomplishing the inspections and testing as needed under the radiation protection program required by part 20 of this Chapter.

[3] Changes to the detailed parameters on aircraft impact characteristics set forth in guidance must be approved by the Commission.

§ 53.450 Analysis requirements.

(a) *Requirement to have a ~~probabilistic~~ risk ~~assessment~~evaluation*. An applicant or licensee ~~PRA~~ of ~~each~~a commercial nuclear plant must ~~be~~ perform~~ed~~ a risk evaluation to identify potential failures, susceptibility to internal and external hazards, and other contributing factors to event sequences that might challenge the safety functions identified in § 53.230 and to support demonstrating that ~~each~~ the commercial nuclear plant meets the safety criteria of § 53.220~~, or more restrictive alternative criteria adopted under § 53.470~~.

(b) *Specific uses of analyses*. The ~~PRA~~ risk evaluation in combination with other generally accepted approaches for systematically evaluating engineered systems must be used—

(1) To~~In~~ inform~~ing~~ the selection of the licensing basis events (LBEs)~~, as described in~~under § 53.240, which must be considered in the design to ~~determine~~ achieve compliance with the safety criteria in Subpart B of this part.

(2) To~~For~~ inform~~ing~~ the classification of structures, systems, and components (SSCs) ~~according to their safety significance in accordance with~~under § 53.460 and ~~for~~to identify~~ing~~ the environmental conditions under which the SSCs and operating staff must perform their safety functions.

(3) To~~In~~ evaluat~~e~~ing the adequacy of defense-in-depth measures ~~required in accordance with~~under § 53.250.

(4) To identify and assess all plant operating states where there is the potential for the uncontrolled release of radioactive material to the environment.

(5) To identify and assess events that challenge plant control and safety systems whose failure could lead to the uncontrolled release of radioactive material to the environment. These include internal events, such as human errors and equipment failures, and external events identified in accordance with Subpart D of this part.

(c) *Maintenance and upgrade of ~~analyses~~risk evaluation*. The ~~PRA~~ holder of a license to operate a commercial nuclear plant under this part must ~~be~~ maintain~~ed at least every 5 years~~the risk evaluation until the ~~permanent cessation of~~license no longer authorizes operation~~s~~ of the reactor under § 53.1070. ~~and~~ The licensee must upgrade~~d~~ the risk evaluation as appropriate to its technical adequacy in order to assure that it properly reflects the as-built, as-operated plant ~~in conformance with generally accepted methods, standards, and practices that have been endorsed or otherwise found acceptable by the NRC~~.

(d) *Qualification of analytical codes*. The analytical codes used in modeling plant behavior in analyses of ~~LBEs~~ licensing basis events ~~(including but not limited to thermodynamics, reactor physics, fuel performance, and mechanistic source term codes)~~ must be qualified ~~for~~ over the range of conditions for which they are to be used.

(e) *Analyses of licensing-basis events other than design-basis accidents*. (1) The applicant or licensee for a commercial nuclear power plant ~~Analyses~~ must ~~be~~ perform~~ed~~ analyses for LBEs other than design basis accidents (DBAs). ~~These LBEs must be identified using insights from a~~the PRA in combination with other generally accepted approaches that have been endorsed or otherwise found acceptable by the NRC for systematically evaluating engineered systems to identify and analyze equipment failures and human errors.~~

Commented [A114]: Modified to use a non-breaking space.

Commented [A115]: PRA Technical Adequacy addresses the need for upgrading of a PRA. There may be other needs for other risk evaluation types.

Commented [A116]: Staff should seek specific responses from stakeholders on whether this requirement is necessary in light of the design control quality assurance requirements. If stakeholder feedback indicates that there is broad understanding that this is already required by criterion III of appendix B to part 50 or other similar requirements that would be applicable here, staff should remove this requirement from the rule in order to avoid duplication without value added.

Commented [A117]: Staff should address examples in the guidance.

Commented [A118]: Moved to 53.240(a), which governs identification of LBEs.

(2) [RESERVED] ~~The analysis of LBEs other than DBAs must include definition of evaluation criteria for each event or specific categories of LBEs to determine the acceptability of the plant response to the challenges posed by internal and external hazards to provide an appropriate level of safety~~.

Commented [A119]: Moved to 53.220(a), which governs criteria for analyses of LBEs other than DBAs.

(3) The analyses of LBEs other than DBAs must address event sequences from initiation to a defined end state and be used in combination with other engineering analyses to demonstrate that the functional design criteria required by § 53.420 provide sufficient barriers to the unplanned release of radionuclides to satisfy the evaluation criteria defined for each LBE other than DBAs~~, to satisfy the safety criteria~~ of § 53.220~~,~~ and provide defense in depth as required by § 53.250.

~~(4) The methodology used to identify, categorize, and analyze LBEs must include a means to identify event sequences deemed~~ that are ~~significant for controlling the risks posed to public health and safety.~~

Commented [A120]: Moved to 53.240(d), which governs identification of LBEs.

(f) *Analysis of design-basis accidents*. (1) The analysis of LBEs required by § 53.240 must include analysis of DBAs that address possible challenges to the safety functions identified under~~in accordance with~~ § 53.230. The events selected as DBAs must be those that, if not terminated, have the potential for exceeding the safety criteria in § 53.210.

(2) The DBAs selected must be analyzed using deterministic methods that address event sequences from initiation to a safe stable end state and assume only the SR SSCs identified under~~in accordance with~~ § 53.460 and human actions addressed by the requirements of subpart F of this part are available to perform the safety functions identified in accordance with § 53.230.

(3) The analysis must ~~conservatively~~ demonstrate compliance with the safety criteria in § 53.210.

Commented [A121]: Deleted in order to preserve the status of the safety criteria in 53.210 as setting what is necessary for compliance and to avoid the establishment arbitrary degrees of conservatism that are not defined in the regulations.

(g) *Other required analyses.* Analyses must be performed to assess—

(1) *Fire protection.* Fire protection measures to demonstrate, through inclusion of fires in the analysis of LBEs or by separate analyses, that a fire or explosion in any plant area would not—

(i) Prevent equipment from fulfilling the safety functions identified in accordance with § 53.230, or

(ii) Challenge the safety criteria in §§ 53.210 and 53.220.

(2) *Aircraft impact.* The need for ~~M~~measures ~~provided~~ to protect against aircraft impacts ~~as required by~~under § 53.440(j).

(3) *Dose to members of the public.* Measures taken ~~to satisfy the requirements of~~under § 53.425, including ~~by~~ estimating—

(i) The quantity of each of the principal radionuclides expected to be released annually to unrestricted areas in liquid effluents produced during normal reactor operations and the dose to the maximally exposed member of the public in unrestricted areas.

(ii) The quantities of each of the principal radionuclides of the gases, halides, and particulates expected to be released annually to unrestricted areas in gaseous effluents produced during normal reactor operations and the dose to the maximally exposed member of the public in unrestricted areas.

(iii) The annual external radiation dose in unrestricted areas and the maximally exposed member of the public in unrestricted areas due to direct radiation from contained radiation sources from the commercial nuclear plant during normal reactor operations.

§ 53.460 Safety categorization and special treatments.

(a) Structures, systems, and components (SSCs) must be classified according to their safety significance. The SSC categories must include “Safety-Related” (SR), “Non-Safety-Related but Safety-Significant” (NSRSS), and “Non-Safety-Significant” (NSS), as defined in subpart A of this part.

(b) For SR and NSRSS SSCs, the conditions under which they must perform their safety function in § 53.230 must be identified. Special treatments must be established ~~in accordance with this and other Subparts~~ to provide confidence that the SSCs will perform under the ~~service~~ identified conditions and with ~~the~~ reliability consistent with the analysis performed under~~in accordance with~~ § 53.450 to demonstrate meeting the safety criteria in §§ 53.210 and 53.220~~, or more restrictive alternative criteria adopted under § 53.470~~.

(1) The special treatments for SR SSCs must include meeting the applicable QA requirements ~~from Subpart K of this part~~.

(2) The special treatments for NSRSS SSCs may include meeting selected QA requirements ~~from Subpart K of this part~~ when such treatment is needed to address performance requirements, equipment reliability, or uncertainties.

~~(c) Human actions needed to prevent or mitigate LBEs must be identified, be able to be performed reliably under the postulated environmental conditions, and be addressed by programs established in accordance with Subpart F of this part to provide confidence that those actions will be performed as assumed in the analysis performed in accordance with § 53.450 to demonstrate meeting the criteria in §§ 53.210, 53.220, and 53.450(e), or more restrictive alternative criteria adopted under § 53.470.~~

~~§ 53.470 Maintaining analytical safety margins used to justify operational flexibilities.~~

Commented [A122]: Edited to refer back to the conditions identified under the first sentence of this paragraph and avoid inserting a new term ("service conditions").

Commented [A123]: The subpart A definitions of SR and NSRSS SSCs do not include the safety criteria of 53.220, though they are included in the definition of special treatments. Presumably, SR and NSRSS SSCs can be relied upon to meet 53.220, but this could be better addressed.

Commented [A124]: This paragraph expresses neither a safety categorization nor a special treatment requirement. Human actions are governed under subpart F and analyzed under 53.450 to meet the appropriate criteria.

~~Where an applicant or licensee so chooses, alternative criteria more restrictive than those defined in §§ 53.220 and 53.450(e) may be adopted to support operational flexibilities. In such cases, applicants and licensees must ensure that the functional design criteria of § 53.420, the analysis requirements of § 53.450(e), and identification of special treatment of SSCs and human actions under § 53.460 reflect and support the use of alternative criteria to justify operational flexibilities. Licensees must ensure that measures taken to provide the analytical margins supporting operational flexibilities are incorporated into design features and programmatic controls and are maintained within programs required in other subparts.~~

Commented [A125]: Deleted because there are no operational flexibilities identified that would be granted to an applicant or licensing establishing safety margins. The lack of identified operational flexibilities would result in a need for an exemption to whatever requirement the flexibilities are granted with relation to - these additional margins could be established in the exemption process as a license condition or through some other means.

§ 53.480 Earthquake engineering.

(a) Structures, systems, and components (SSCs) classified as safety-related (SR) or non-safety-related but safety significant (NSRSS) must be able to withstand the effects of earthquakes, commensurate with the safety significance of the SSC, without loss of capability to perform their role in fulfilling the safety functions required by § 53.230.

(b) For the purpose of this section—

Design-Basis Ground Motions (DBGMs) are the vibratory ground motions for which certain SSCs must be designed to remain functional.

Operating basis earthquake (OBE) ground motion is the vibratory ground motion for which those features of the commercial nuclear plant necessary for continued operation without undue risk to the health and safety of the public are designed to remain functional. The OBE ground motion is used in § 53.720.

Response spectrum is a plot of the maximum responses (acceleration, velocity, or displacement) of idealized single-degree-of-freedom oscillators as a function of the

natural frequencies of the oscillators for a given damping value. The response spectrum is calculated for a specified vibratory motion input at the oscillators' supports.

Surface deformation is the distortion of geologic strata on or near the ground surface that occurs by the processes of folding or faulting as a result of various earth forces.~~because of~~ ~~t~~Tectonic surface deformation is associated with~~forces that result from~~ earthquakes.

(c)(1) *Design-Basis Ground Motions.*

(i) The DBGMs must be derived from the Site Ground Motion Response Spectra (GMRS) developed in accordance with § 53.510(c), by taking into consideration the functional design criteria of SSCs in accordance with §§ 53.410 and 53.420. The horizontal component of the DBGM(s) in the free-field at the foundation level of the structures must be an appropriate response spectrum that is determined based on the risk-significance of SSCs and their safety functions. In view of the limited data available on vibratory ground motion of strong earthquakes, it is acceptable that the design response spectra be smoothed spectra.

(ii) The commercial nuclear plant must be designed so that, if the DBGMs occur, the following SSCs ~~must~~ remain functional and within applicable stress, strain, and deformation limits:

(A) SSCs for which functional design criteria are established in accordance with § 53.410 or § 53.420; and

(B) SSCs classified as SR or NSRSS commensurate with safety significance in accordance with § 53.460.

(iii) In addition to seismic loads, applicable concurrent normal operating, functional, and accident-induced loads must be taken into account in the design of the

SR SSCs and, taken into account commensurate with the safety significance~~,~~ of NSRSS SSCs in their design.

(iv) The design of the commercial nuclear plant must take into account the possible effects of seismic-induced ground disruption, such as fissuring, lateral spreads, differential settlement, liquefaction, and landsliding, on the facility foundations.

(v) The SSCs fulfilling the safety functions required by § 53.230 must ~~be demonstrated through design, testing, or qualification methods to~~ be able to fulfill those safety functions during and after the vibratory ground motion associated with the DBGMs as demonstrated through analytical, testing, or qualification methods.

(vi) The evaluation of SSCs required by this section to show they are able to function during and ~~following~~ after earthquake ground motion must take into account soil-structure interaction effects and the expected duration of vibratory motion. It is permissible to design for strain limits in excess of yield strain in some of these ~~SR~~ SSCs ~~during~~ for the DBGMs and under the postulated concurrent loads, provided the necessary safety functions are maintained.

Commented [A126]: The safety functions required by 53.230 include those needed to meet the safety criteria of 53.220, which can be satisfied by NSRSS SSCs. There doesn't appear to be a reason to limit this portion to SR SSCs.

(2) *Operating Basis Earthquake Ground Motion.* The OBE Ground Motion must be characterized by response spectra. The value of the OBE Ground Motion must be set to one-third or less of the DBGMs response spectra.

(3) [Reserved]

(4) *Required Seismic Instrumentation.* Suitable instrumentation must be provided so that the seismic response of commercial nuclear plant SR SSCs or NSRSS SSCs can be evaluated promptly after an earthquake.

(d) *Surface Deformation.*

(1) The potential for surface deformation must be taken into account in the design of the commercial nuclear plant by providing reasonable assurance that in the

event of deformation, ~~the following~~ SSCs classified as SR or NSRSS under § 53.460 will remain functional~~:~~

~~(i) SSCs for which functional design criteria are established in accordance with §§ 53.410 and 53.420; and~~

~~SSCs classified as SR or NSRSS in accordance with § 53.460~~.

(2) In addition to surface deformation induced loads, the design of SSCs must take into account, commensurate with safety significance, seismic loads and applicable concurrent functional and accident-induced loads.

(3) The design provisions for surface deformation must be based on its postulated occurrence in any direction and azimuth and under any part of the commercial nuclear plant, unless evidence indicates this assumption is not appropriate, and must take into account the estimated rate at which the surface deformation may occur.

(e) *Seismically Induced Floods and Water Waves and Other Design Conditions.* Seismically induced floods and water waves from either locally or distantly generated seismic activity and other design conditions determined pursuant to Subpart D must be taken into account in the design of the commercial nuclear plant so as to prevent undue risk to the health and safety of the public.

~~(f) *Analysis.* The analyses required by § 53.450 must address seismic hazards and related SSC responses in determining that the safety criteria defined in § 53.220 will be met.~~

Commented [A127]: 53.450(e)(2) would require this analysis, which is outside the scope of "Earthquake Engineering."

~~(g) *Design criteria, human actions, and programmatic controls.* Functional design criteria, human actions, and programmatic controls needed to address seismic events must be identified and implemented in accordance with this and other subparts to achieve and maintain the performance of SSCs relied upon to satisfy the safety criteria~~

~~in § 53.220 and to maintain consistency with analyses required by § 53.450 when accounting for the site-specific frequencies and magnitudes of earthquakes for a commercial nuclear plant.~~

Commented [A128]: 53.240(b) requires addressing the effects of external hazards as part of the LBE identification process.

Subpart D — Siting Requirements

§ 53.500 General siting and siting assessment.

(a) The siting of each commercial nuclear plant must be supported by assessments of proposed sites such that the design, including design features and programmatic controls corresponding to the site characteristics, satisfies the safety criteria defined in §§ 53.210 and 53.220 ~~or more restrictive alternative criteria adopted under § 53.470~~. The siting assessment must ensure that site characteristics that might contribute to the initiation, progression, or consequences of licensing-basis events (LBEs) analyzed ~~in accordance with~~under §§ 53.450 and 53.480 are identified and mitigated by design features or programmatic controls. The siting assessment must take into consideration the potential adverse impacts that a commercial nuclear plant may have on nearby populations as a result of normal operations or LBEs.

(b) Activities performed to identify site characteristics or otherwise needed to determine site-specific contributors to functional design criteria or analysis assumptions under subpart C of this part must be performed under a quality assurance program that satisfies~~y~~ the applicable special treatment requirements of § 53.460, including, where applicable, the QA requirements from ~~Subpart K of this~~appendix B to part 50 of this chapter.

Commented [A129]: It's not entirely clear that there are any special treatment requirements from 53.460 that would be applicable.

§ 53.510 External hazards.

(a) *General external hazard requirements.* The design-basis external hazard level for the relevant external hazards for a site must be identified and characterized based on site-specific assessments of natural and man-related ~~constructed~~hazards with

the potential to adversely affect plant functions. The external hazard frequencies and magnitudes determined from the site-specific assessments must take into account uncertainties and variabilities in data, models, and methods relied on to characterize the external hazards.

(b) *Definitions.* For the purpose of this section, the following terms mean:

Geological Siting Factors are geological and seismic factors that may affect the design and operation of the proposed commercial nuclear plant.

Ground Motion Response Spectra (GMRS) are the site-specific GMRS resulting from the geologic investigations and evaluations of the site vicinity and region and used to determine design-basis ground motions (DBGMs) for SSCs under § 53.480.

Probabilistic Seismic Hazard Analysis (PSHA) is an analytical methodology that incorporates uncertainty into estimates of an annual frequency of exceedance for a certain ground motion parameter (e.g., peak ground acceleration, peak ground velocity, response spectral values) at a site.

(c) *Geological, seismological, and engineering Investigations*. The investigations required in this paragraph are not considered "construction" as defined in § 53.020. The GMRS for the site must be determined based on the results of investigations of the geological, seismological, and engineering characteristics of the site and its environs and must be characterized by both horizontal and vertical free-field GMRS at the free ground surface. The size of the region to be investigated and the type of data pertinent to the investigations must be determined based on the nature of the region surrounding the site. Data on vibratory ground motion, earthquake recurrence rates, fault geometry and slip rates, and site subsurface material properties must be obtained by reviewing pertinent literature and carrying out field investigations. Uncertainties are inherent in the parameters and models used to estimate the GMRS for the site. The site assessment

must reflect these uncertainties through an appropriate analysis, such as a probabilistic seismic hazard analysis. Each applicant must investigate all geologic and seismic factors (for example, volcanic activity) that may affect the design and operation of the proposed commercial nuclear plant irrespective of whether such factors are explicitly included in this section.

(d) *Geologic ~~and Seismic~~ Siting Factors*. The geologic and seismic siting factors considered for design under §§ 53.415 and 53.480 must include~~, but are not limited to,~~ determination of the potential for surface tectonic and nontectonic deformations, the size and character of seismically induced floods and water waves that could affect a site from either locally or distantly generated seismic activity, soil and rock stability, liquefaction potential, and natural and artificial slope stability.

§ 53.520 Site characteristics.

Site characteristics that might contribute to the initiation, progression, or consequences of ~~LBEs~~ licensing-basis events analyzed ~~in accordance with~~under § 53.450 must be identified, assessed, and considered in the design and analyses required by subpart C of this part.

§ 53.530 Population-related considerations.

Every site must have an exclusion area, a low population zone, and a population center distance as defined in § 53.020.

(a) The offsite radiological consequences estimated by the analyses required by § 53.450(f) must be used in selecting the boundaries of the exclusion area and low population zone.~~to confirm that —~~

~~(1) An individual located at any point on the boundary of the exclusion area for any 2-hour period following onset of the postulated fission product release would not receive a radiation dose in excess of 25 rem (250 mSv) TEDE.~~

Commented [A130]: Deleted to match the term as defined in paragraph (b) of this section.

Commented [A131]: The requirement that "factors … must include" plainly establishes that the list that follows is not a closed list. As a result, the inclusion of the phrase "but are not limited to" is not necessary and highlights the fact that the staff has not fully stated what is necessary to comply with the regulation. Staff should strive to make explicit what it believes is necessary to comply with all draft regulations it provides to the Commission for approval as it is inappropriate to seek a delegation of the Commission's authority to set forth what is required in this manner.

Commented [A132]: This is a verbatim copy of 53.210(a) and is already required to be met under 53.450(f)(3).

~~(2) An individual located at any point on the outer boundary of the low population zone who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (250 mSv) TEDE.~~

Commented [A133]: This provision copies all of 53.210(b) verbatim with the exception of the footnote; 53.450(f)(3) requires meeting 53.210(b), making this redundant.

(b) The population center distance must be at least one and one-third times the distance from the reactor to the outer boundary of the low population zone. The boundary of the population center must be determined upon consideration of population distribution. Political boundaries are not controlling in the calculation of population center distance.

(c) Reactor sites should be located away from very densely populated centers. Areas of low population density are, generally, preferred. However, in determining the acceptability of a particular site located away from a very densely populated center but not in an area of low population density, consideration will be given to safety, environmental, economic, or other factors, which may result in the site being found acceptable.

§ 53.540 Siting interfaces.

Site characteristics must be addressed by the design features, programmatic controls, and supporting analyses used to demonstrate that the safety criteria in §§ 53.210 and 53.220 are met for each commercial nuclear plant. Site characteristics must be such that adequate emergency plans and security plans can be developed and maintained. ~~Changes to site characteristics over the lifetime of a commercial nuclear plant must be considered in the assessments performed under the facility safety program (FSP) required by § 53.890.~~

Subpart E — Construction and Manufacturing Requirements

§ 53.600 Construction and manufacturing – scope and purpose.

This subpart applies to those construction and manufacturing activities authorized by a construction permit~~CP~~, combined license~~COL~~, manufacturing license~~Ml~~, or limited work authorization~~LWA~~ issued under ~~Framework A of~~ this part.

§ 53.605 Reporting of defects and noncompliance.

Each construction permit (CP) and manufacturing license (ML) issued under ~~Framework A of~~ this part is subject to the terms and conditions in this section, and each combined license (COL) issued under ~~Framework A of~~ this part is subject to the terms and conditions in this section until the date that the Commission makes the finding under § 53.1452(g).

(a) *Definitions*. The definitions in § 21.3 of this chapter apply to this section.

(b) *Posting requirements*.(1) ~~Each individual, partnership, corporation, dedicating entity, or other entity~~The holder of a CP, COL, or ML subject to the regulations in this ~~part~~ section must post current copies of this section and the regulations in 10 CFR part 21; Section 206 of the ERA; and procedures adopted under these regulations. These documents must be posted in a conspicuous position on any premises within the United States where the activities subject to the license are conducted.

Commented [A134]: This repeats the error of 50.55(e)(2) of replicating the requirements of 21.6 without adjusting the entities subject to the "regulations in this part" to refer to those subject to 50.55 as setting the scope of the requirement. As a result, this paragraph seeks to expand its scope beyond the limitations of scope in the prefatory paragraph of this section, which is for CPs, MLs, and COLs until the finding under 53.1452(g).

(2) If posting of these regulations or the procedures adopted under them is not practical, the licensee may, in addition to posting Section 206 of the ERA, post a notice ~~which~~ that describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

(c) *Procedures*. The holder of a CP, COL, or ML subject to this section must adopt appropriate procedures to –

(1) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (c)(2) of this section, in all cases within 60 days of discovery, to

identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected.

(2) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from the discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer, or designated person as discussed in paragraph (d)(5) of this section. The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.

(3) Ensure that a director or responsible officer of the holder of a CP, COL, or ML subject to this section is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in paragraph (c)(1) or (c)(2) of this section, if the construction or manufacture of a facility or activity, or a manufactured reactor, or a basic component supplied for such a facility or activity –

Commented [A135]: Inserted because the 21.3 definition of "basic component" does not appear to be broad enough to cover a manufactured reactor due to that being an SSC or part of an SSC. Staff should consider whether a similar insertion is necessary in 50.55(e) and accomplish the change through an administrative rulemaking as appropriate.

(i) Fails to comply with the ActEA or any applicable regulation, order, or license of the Commission relating to a substantial safety hazard;

(ii) Contains a defect; or

(iii) Underwent any significant breakdown in any portion of the quality assurance program (QAP) conducted under the requirements of subpart Kappendix B to this part 50 of this chapter which that could have produced a defect in a basic component or manufactured reactor. These breakdowns in the QAP are reportable whether or not the breakdown actually resulted in a defect in a design approved and released for construction, installation, or manufacture.

(d) R*eporting defects and noncompliance.*

(1) The holder of a CP, COL, or ML subject to this section that obtains information reasonably indicating that the facility or manufactured reactors fails to comply with the ActEA or any applicable regulation, order, or license of the Commission relating to a substantial safety hazard must notify the Commission of the failure to comply through a director, responsible officer, or designated person as discussed in paragraph (d)(5) of this section.

(2) The holder of a CP, COL, or ML subject to this section that obtains information reasonably indicating the existence of any defect found in the construction or manufacture, or any defect found in the final design of a facility or manufactured reactor as approved and released for construction or manufacture, must notify the Commission of the defect through a director, responsible officer, or designated person as discussed in paragraph (d)(5) of this section.

Commented [A136]: Inserted to properly account for the final designs that are approved in MLs. Staff should consider whether a similar insertion is necessary in 50.55(e) and accomplish the change through an administrative rulemaking as appropriate.

(3) The holder of a CP, COL, or ML subject to this partsection, who obtains information reasonably indicating that the QAP has undergone any significant breakdown discussed in paragraph (c)(3)(iii) of this section must notify the Commission of the breakdown in the QAP through a director, responsible officer, or designated person as discussed in paragraph (d)(5) of this section.

(4) When acting as a dedicating entity, the holder of a CP, COL, or ML subject to this section is responsible for identifying and evaluating deviations; reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and maintaining auditable records for the dedication process.

(5) The notification requirements of this paragraph apply to all defects and failures to comply associated with a substantial safety hazard regardless of whether extensive evaluation, redesign, or repair is required to conform to the criteria and bases stated in the Safety Analysis Report, CP, COL, or ML. Evaluation of potential defects

and failures to comply and reporting of defects and failures to comply under this section satisfies the CP holder's, COL holder's, and ML holder's evaluation and notification obligations under 10 CFR part 21, and satisfies the responsibility of individual directors or responsible officers or holders of a CP, COL, or ML subject to this section to report defects, and failures to comply associated with substantial safety hazards under Section 206 of the ERA. The director or responsible officer may authorize an individual to provide the notification required by this section. However, this does not relieve the director or responsible officer of his or her responsibility under this section.

(e) *Notification – timing and where sent*. The notification required by paragraph (d) of this section must consist of –

(1) Initial notification by telephone, facsimile, or e-mail identified in Appendix DA to 10 CFR part ~~73~~20 to the NRC Operations Center within 2 days following receipt of information by the director or responsible ~~corporate~~ officer under paragraph (c)(3) of this section, on the identification of a defect or a failure to comply. If the CP, COL, or ML holder elects to use facsimile, verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in paragraph (c)(2) of this section.

(2) Written notification submitted to the NRC Document Control Desk by an appropriate method listed in § 53.040, with a copy to the appropriate NRC Regional Administrator at the address specified in appendix D to 10 CFR part 20 and a copy to the appropriate NRC resident inspector, if applicable, within 30 days following receipt of information by the director or responsible ~~corporate~~ officer under paragraph (c)(3) of this section, on the identification of a defect or failure to comply.

Commented [A137]: Appendix A to part 73 and appendix D to part 20 both list the same addresses for the Ops Center and the Regional Offices. It isn't entirely clear why we would have a licensee consult those two different appendices in developing or executing their procedures for reporting defects. Edited to harmonize the requirement for simplicity sake.

Note that the notification requirement in 50.55 that this is modeled on only allows for notification by facsimile or telephone. Staff should consider whether email notification is also acceptable and accomplish a change to 50.55(e) to allow it by administrative rulemaking as appropriate.

Commented [A138]: Edited for consistency with paragraph (c)(3).

(f) *Content of notification.* The written notification required by paragraph (e)(2) of this section must clearly indicate that the written notification is being submitted under this section and include the following information, to the extent known.

(1) Name and address of the individual or individuals informing the Commission.

(2) Identification of the facility, the activity, manufactured reactor, or the basic component supplied for the facility or the activity within the United States which contains a defect or fails to comply.

(3) Identification of the firm constructing or manufacturing the facility or manufactured reactor or supplying the basic component which fails to comply or contains a defect.

(4) Nature of the defect or failure to comply and the safety hazard which is created or could be created by the defect or failure to comply.

(5) The date on which the information of a defect or failure to comply was obtained.

(6) In the case of a basic component ~~which~~ that contains a defect or failure to comply, the number and location of these components in use at the facility subject to the regulations in this part.

(7) In the case of a ~~completed~~ manufactured reactor ~~manufactured~~ under ~~Framework A of~~ this part, the entities to which the reactor was supplied.

Commented [A139]: Edited to use the defined term from 53.020.

(8) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(9) Any advice related to the defect or failure to comply about the facility, activity, manufactured reactor, or basic component that has been, is being, or will be given to other entities.

(g) *Procurement documents*. Each holder of a CP, COL, or ML subject to this section must ensure that each procurement document for a facility or a basic component specifies the provisions of 10 CFR part 21 or this section that apply, as applicable.

(h) *Coordination with 10 CFR part 21*. The requirements of this section are satisfied when the defect or failure to comply associated with a substantial safety hazard has been previously reported under 10 CFR part 21, under § 73.71 of this chapter, under this section, or under § 53.1640.

(i) *Records retention*. The holder of a CP, COL, or ML subject to this section must prepare and maintain records necessary to accomplish the purposes of this section, specifically –

(1) Retain procurement documents, which define the requirements that facilities, manufactured reactors, or basic components must satisfy in order to be considered acceptable, for the lifetime of the facility, manufactured reactor, or basic component.

(2) Retain records of evaluations of all deviations and failures to comply under paragraph (c)(1) of this section for the longest of—

(i) Ten years from the date of the evaluation;

(ii) Five years from the date that an early site permit is referenced in an application for a COL; or

(iii) Five years from the date of delivery of a manufactured reactor.

(3) Retain records of all interim reports to the Commission made under paragraph (c)(2) of this section, or notifications to the Commission made under paragraph (d) of this section for the minimum time periods stated in paragraph (i)(2) of this section;

(4) [Reserved]~~Suppliers of basic components must retain records of—~~

Commented [A140]: Suppliers of basic components are not subject to this section but instead must follow the part 21 requirements. Record retention for suppliers of basic components is governed by 21.51 and differs from the periods set forth here and in 50.55(e)(9)(iv). Staff should consider amending 50.55(e) as appropriate using an administrative rulemaking.

~~(i) All notifications sent to affected licensees or purchasers under paragraph (d)(4) of this section for a minimum of 10 years following the date of the notification;~~

~~(ii) The facilities or other purchasers to whom the basic components or associated services were supplied for a minimum of 15 years from the delivery of the basic component or associated services.~~

(5) Maintaining reports in accordance with this section satisfies the recordkeeping obligations under 10 CFR part 21 of the entities, including directors or responsible officers thereof, subject to this section.

§ 53.610 Construction.

(a) ~~*Management and control*~~*Construction experience*. Licensees authorized to construct a commercial nuclear plant must ~~ensure that the following plans, programs, and organizational units are~~ develop~~ed~~ and implement~~ed~~ ~~to manage and control the construction activities:~~

~~(1) Programs to ensure that the construction of a commercial nuclear plant supports the eventual compliance with the design and analysis requirements in subpart C of this part.~~

~~(2) An organization, headed by qualified personnel, responsible for managing, controlling, and evaluating the adequacy of the construction activities.~~

~~(3) Procedures describing the qualifications for personnel in key positions in the licensee's management and control organization and the organizational responsibilities, authority, and interfaces with other parts of the licensee's organization.~~

Commented [A141]: Redundant to QAP.

~~(4) P~~procedures to evaluate the applicability of other national and international construction experience to the planned and ongoing construction activities and to ensure the applicable experience will be provided to those constructing the plant.

~~(5) A fitness-for-duty (FFD) program, under 10 CFR part 26.~~

Commented [A142]: Part 26 is self-executing, rendering this a mere cross-reference. Applicants are already required to submit a description of their FFD under 53.1309(a)(6), for example, making the cross-reference unnecessary.

~~(6)(i) A QAP meeting the requirements of subpart K of this part as required by § 53.460(b).~~

~~(ii) Appropriate programmatic controls to provide special treatment for NSRSS SSCs.~~

~~(7) A radiation protection program, in accordance with 10 CFR part 20, that includes measures for monitoring the dose to individuals working with radioactive materials brought onto the site, as applicable.~~

~~(8) An information security program in accordance with §§ 73.21, 73.22, and 73.23 of this chapter, as applicable.~~

(b) *Construction activities.* No person may begin the construction of a commercial nuclear plant on a site on which the facility is to be operated under ~~Framework A of~~ this part until that person has been issued either a construction permit (CP) or combined license (COL), an early site permit authorizing activities under § 53.1130, or a~~n~~ limited work authorization (LWA) under ~~Framework A of~~ this part.

(1) Licensees must satisfy the following requirements:

(i) [Reserved]. ~~As appropriate, considering the types and quantities of radioactive materials being brought onto the site—~~

~~(A) The licensee must maintain and follow an SNM material control and accounting (MC&A) program, a measurement control program, and other material control procedures that include corresponding record management requirements as required by the provisions of § 70.32 of this chapter. Prior to initial receipt of SNM onsite, the licensee must implement an SNM MC&A Program in accordance with 10 CFR part 74.~~

Commented [A143]: The QAP is required by 53.1309(a)(2)(i), for example. In 50.34(a)(7), the purpose of the QAP is more explicitly addressed as "to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility." That model has worked to date and should be continued as it is understood by industry and other stakeholders.

Commented [A144]: This is self-executing in part 20 without cross-reference. Staff should address this in guidance.

Commented [A145]: *Passim*, none of the content of applications requirements in this subpart (i.e., 53.1146(d) for ESPs, 53.1210(a)(2) for SDAs, 53.1241(a)(4) for DCs, 53.1282(c) for MLs, 53.1309(b) for CPs, 53.1369(e) and (r) for OLs, and 53.1416(a)(5), (a)(19), and (h) for COLs) includes coverage of SGI-M under the information security plans or cyber security. If the staff believes that it is necessary to include coverage of SGI-M, those requirements should be updated.

Commented [A146]: This is self-executing in part 73 without cross-reference. Staff should address this in guidance.

~~(B) Procedures must be in place to receive, possess, use, and store source, byproduct, and SNM in accordance with applicable portions of 10 CFR parts 30, 40, and 70.~~

~~(C) A plant staff training program associated with the receipt of radioactive material must be approved and implemented prior to initial receipt of byproduct, source or SNM (excluding exempt quantities as described in § 30.18 of this chapter).~~

(ii) For construction of a commercial nuclear plant involving multiple reactor units, plans and procedures must be in place to prevent or mitigate potential hazards to the structures, systems, and components ~~SSCs~~ of operating units resulting from construction activities, including the managerial and administrative controls to be used to provide assurance that the limiting conditions for operation of the operating units are not exceeded as a result of construction activities.

(iii) Procedures must be in place prior to the start of construction activities that describe how construction will be controlled so as not to impact other features important to the design, such as dewatering, slope stability, backfill, compaction, and seepage.

(iv) For LWA holders, a plan must be developed for redress of activities performed under the LWA should one of the following situations arise:

(A) LWA work activities are terminated by the holder of the LWA;

(B) The LWA is revoked by the NRC; or

(C) The Commission denies the associated CP or COL application.

(2)~~(i) Onsite fresh fuel must be protected and stored in compliance with § 73.67 of this chapter.~~

~~(ii) Before initial fuel load into the reactor, a cybersecurity program that meets the requirements of § 73.54 or § 73.110 of this chapter, a physical security program that meets the requirements of § 73.55 or § 73.100 of this chapter, and an access~~

Commented [A147]: There is no analog for this as a requirement in part 50, which was successfully used to license and regulate many commercial nuclear plants. Staff should move this to guidance as the cited requirements are self-executing.

Commented [A148]: Staff should move to guidance as the requirements of 73.67 are self-executing.

Commented [A149]: Staff should address the adoption of the draft proposed shift for the initiation of these security requirements in 73.54, 55, and 56 from SECY-22-0052 somewhere in the preamble and explain that the outcomes on that rulemaking will be followed in this one for those sections.

Because all of these requirements are self-executing, staff should move this portion to guidance.

Commented [A150]: The requirements of 73.54 or initiated through 73.55(b)(8) "before fuel is allowed onsite (protected area)" under 73.54(a)(4).

Commented [A151]: The requirements of 73.55 are self-executing and become effective "before fuel is allowed onsite (protected area)" under the current version of and the draft proposed revision to 73.55(a)(4).

~~authorization program that meets the requirements of § 73.56 or § 73.120 of this chapter must be established, as applicable.~~

~~(iii)~~ Fire protection measures must be implemented for work and storage areas (including adjacent fire areas that could affect the work or storage area) before initial receipt of byproduct, source, or non-fuel special nuclear material~~SNM~~ (excluding exempt quantities as described in § 30.18 of this chapter). The fire protection measures for areas associated with new fuel (including all fuel handling, fuel storage, and adjacent fire areas that could affect the new fuel) must be implemented before receipt of fuel. ~~Prior to the receipt of fuel, a formal letter of agreement must be in place with the local fire department specifying the nature of arrangements in support of the fire protection program.~~

(c) ~~*Inspection and acceptance.*~~

~~(1) The licensee must have a process for accepting individual or groups of SSCs upon completion of construction and protecting them from damage or tampering as other construction activities continue.~~

~~(2) The post construction acceptance process must address the inspections, tests, analyses, and acceptance criteria (ITAAC) specified in the COL under § 53.1440 or the equivalent verifications needed to support the issuance of an OL under § 53.1387.~~

~~(d)~~ *Acceptance of a manufactured reactor for construction of a commercial nuclear plant*. Upon delivery to the site, a manufactured reactor may not be used in the construction of a commercial nuclear plant until the COL holder verifies it is in acceptable condition in compliance with the manufacturing license using inspections and tests under its program. These inspections must confirm that all necessary interface requirements between the manufactured reactor and the remaining portions of the commercial nuclear plant are met.

Commented [A152]: The requirements of 73.56 are self-executing and become effective "before fuel is allowed onsite (protected area)" under 73.56(a)(3).

Commented [A153]: This is not required of currently operating reactors and would constrain an applicant for an advanced reactor to reliance on a local fire department rather than having their own. Staff should address this desire in guidance.

Commented [A154]: Redundant to QA requirements and the QAP.

Commented [A155]: Redundant to 53.1449.

Commented [A156]: Redundant to 53.1369(b)(1).

§ 53.615 Application for operating licenses.

(a) *Updating of application*. At or about the time of completion of the construction or modification of the facility, the applicant will file any additional information needed to bring the original application for license up to date and will file an application for an operating license as specified in paragraph (b) of this section.

Commented [A157]: Inserted to provide a requirement for an FSAR submittal corresponding to the 50.55(d) condition on CPs.

(b) Application for operating licenses. The holder of a construction permit for a commercial nuclear plant must, at the time of submission of the final safety analysis report, file an application for an operating license. The application must state the name of the applicant, the name, location and power level, if any, of the facility and the time when the facility is expected to be ready for operation and may incorporate by reference any pertinent information submitted under § 53.1109 with the application for a construction permit.

Commented [A158]: Moved from 53.1124(g)(2) in order to reflect the requirement being in the construction phase. This requirement is fleshed out modeled on 50.30(d), which includes reference to an application for amendment of a license to construct and operate a facility for the issuance of an operating license. That amendment process appears to be a relic of a prior version of combined licensure that is no longer pertinent. Staff should determine whether that portion of 50.30(d) can be removed from the regulation through an administrative rulemaking.

§ 53.620 Manufacturing.

(a) *Management and control*. Holders of manufacturing licenses (MLs) must ensure that the following plans, programs, and organizational units are developed and implemented to manage and control the manufacturing activities within the scope of the ML:

(1) ~~Programs to ensure that the manufacturing of a manufactured reactor or portions of a manufactured reactor complies with the design and analysis requirements in subpart C of this part. The entity with design authority for the manufactured reactor covered by the ML must be identified in the license.~~

Commented [A159]: Redundant to QA requirements and QAP included in application.

Commented [A160]: Moved to 53.1287.

~~(2) An organizational and management structure responsible for managing, controlling, and evaluating the adequacy of the reactor design and manufacturing activities.~~

~~(3) Procedures describing the qualifications for personnel in key positions in the licensee's management and control organization and the organizational responsibilities, authority, and interfaces with other parts of the licensee's organization.~~

~~(4)~~ A program to evaluate the applicability of other national and international design and manufacturing experience to the planned and ongoing manufacturing activities.

~~(5) An FFD program, in accordance with 10 CFR part 26.~~

(~~26~~)~~(i)~~ A quality assurance program (QAP) meeting the requirements of ~~subpart K~~appendix B to~~of this~~ part 50 of this chapter, to be applied to the design, fabrication, ~~construction,~~ and testing of the structures, systems, and components (SSCs) of the manufactured reactor.

~~(ii) Appropriate programmatic controls to provide special treatment measures for NSRSS SSCs.~~

~~(7) A radiation protection program, in accordance with 10 CFR part 20, that includes measures for monitoring the dose to individuals if the manufacturing activities include working with radioactive materials.~~

~~(8) An information security program in accordance with §§ 73.21, 73.22 and 73.23 of this chapter, as applicable.~~

~~(b) *Manufacturing activities.* Holders of MLs must satisfy the following requirements:~~

~~(1) The manufacturing process must be conducted within facilities for which the ML holder has the authority to establish controls on any activity that might affect manufacturing. The licensee must establish access controls to the portions of each facility involved in the manufacturing processes governed by the ML.~~

Commented [A161]: Redundant to QAP.

Commented [A162]: Self-executing without cross-reference. FFD should not be required of ML holders that do not possess SNM as they act essentially the same as providers of basic components.

Commented [A163]: Deleted to reflect that the construction of the manufactured reactor within a commercial nuclear plant would not be accomplished as a manufacturing activity by an ML holder under an ML but instead would be accomplished as a construction activity by a COL holder under a COL. As a result, this QAP would be the QAP of the wrong person for the construction activity.

Commented [A164]: Self-executing under part 20. Staff should move to guidance.

Commented [A165]: Redundant to 53.1282(c) with the exception of the coverage of SGI-M. Staff should determine if SGI-M coverage is necessary and make appropriate changes.

Commented [A166]: This is redundant to the QA requirements to the extent that it covers activities that might affect quality. To the extent that it exceeds activities that might affect quality while still affecting manufacturing it is overreach because there is no supporting justification.

Commented [A167]: There is no articulated basis for requiring access controls to all of these portions in the absence of SNM. It may make sense for an ML holder to accomplish this for business reasons, but we don't have a reason to require it except to the extent that access controls can affect quality - even in that case, the method of protecting quality should be left to the licensee..

~~(2) Manufacturing processes must be performed in accordance with the ML and the referenced codes and standards that have been endorsed or otherwise found acceptable by the NRC.~~

~~(3) A post-manufacturing inspection and acceptance process must be established and implemented before transporting a manufactured reactor or portions of a manufactured reactor for installation at a commercial nuclear plant. The process must consider the results of inspections, tests, and analyses that have been performed and the acceptance criteria that are necessary and sufficient to conclude that manufacturing activities have been completed in accordance with the ML.~~

(b~~c~~) *Loading fuel into a manufactured reactor at the factory*

(1) (i) An ML may include authorization for the loading of fuel into a manufactured reactor at the factory only if the manufactured reactor is configured during its loading and storage to provide at least two independent mechanisms each of which is sufficient to prevent criticality assuming maximum reactivity of the fissile material would be attained from possible fuel configurations, neutron moderation, and neutron reflection from the manufactured reactor and surrounding materials. The Commission has determined that any such fueled manufactured reactor in which these mechanisms have been installed is not a utilization facility as defined in section 11cc. of the Act or § 53.020 until it is installed in its final place of use and the Commission has found that the inspections, tests, and analyses of the ML have been performed and the ML acceptance criteria have been met under § 53.620(f) and the inspections, tests, and analyses in the combined license (COL) that authorized reactor construction have been performed and the COL acceptance criteria have been met under § 53.1452(g); and

(ii) The Commission has determined that, upon a Commission finding with respect to a particular fueled manufactured reactor that the inspections, tests, and

Commented [A168]: This provision is unnecessary in the regulations as the license itself will be enforceable as will and codes and standards incorporated by reference in the ML. Mere referencing of codes and standards should not make them enforceable.

Commented [A169]: While this would be a prudent action for the holder of an ML to take it is redundant to the pre-construction inspection and acceptance proposed for the COL holder in 53.620(f).

analyses in the COL that authorized reactor construction have been performed and the COL acceptance criteria have been are met under § 53.1452(g) that the fueled manufactured reactor is part of a utilization facility and all COL provisions and regulations applicable to the type of commercial nuclear plant for which the Commission has made the finding apply to that fueled manufactured reactor.

(2) If the ML authorizes fuel loading into a manufactured reactor at the factory, the following must be in place prior to the receipt of SNM:

(i) Procedures to receive, transfer, possess, and use source, byproduct, and SNM in accordance with the applicable portions of 10 CFR parts 30, 40 and 70;

(ii) A fire protection program before the initial receipt of byproduct, source, or non-fuel SNM (excluding exempt quantities as described in § 30.18 of this chapter). The fire protection measures for areas associated with fueling a manufactured reactor (including all fuel handling, fuel storage and adjacent areas where a fire could affect the fresh fuel) must be implemented before receipt of fresh fuel at the manufacturer's facility. Prior to the receipt of fuel at the manufacturer's facility, a formal letter of agreement must be in place with the local fire department specifying the nature of arrangements in support of the fire protection program;

(iii) An emergency plan appropriate for responding to the facility-specific hazards of an accidental release of radioactive material and to limit the health effects of the associated chemical hazards of licensed material must be approved and implemented prior to the receipt of byproduct, source, or SNM (excluding exempt quantities as described in § 30.18 of this chapter);

(iv) A plant staff training program associated with the receipt of radioactive material must be approved and implemented before initial receipt of byproduct, source, or SNM (excluding exempt quantities as described in § 30.18 of this chapter).

(v) Security requirements must be implemented for the protection of SNM based on the type, enrichment, and quantity in accordance with 10 CFR part 73, as applicable, and for the protection of Category 1 and Category 2 quantities of radioactive material in accordance with 10 CFR part 37, as applicable.

(vi) Radiation monitoring instrumentation and alarms.

(vii) Measures to prevent criticality accidents under §§ 70.61 and 70.64 of this chapter and to detect potential criticality accidents in accordance with § 53.440(m).

(viii) Procedures, equipment, and personnel qualified to handle fresh fuel, load it into the reactor, monitor the reactivity, and secure the fuel and reactor assembly for shipment.

(ix) A physical security program for the storage of fresh fuel under 10 CFR 73.67.

(x) An MC&A program under 10 CFR part 74.

(3) The storage, movement, and loading of fresh fuel into the manufactured reactor within the manufacturing facility must comply with the requirements of §§ 70.61, 70.62 and 70.64 of this chapter.

(4) The loading or unloading of fresh fuel into or from a manufactured reactor and any changes to the configuration of reactivity-related systems for the manufactured reactor module must be performed by a certified fuel handler meeting the requirements in subpart F.

~~*Control of radioactive materials*. As appropriate considering the types and quantities of radioactive materials being brought into the manufacturing facility—~~

~~(1) Procedures must be in place to receive, transfer, possess, and use source, byproduct, and SNM in accordance with the applicable portions of 10 CFR parts 30, 40 and 70.~~

~~(2) A fire protection program must be established and implemented before the initial receipt of byproduct, source, or non-fuel SNM (excluding exempt quantities as described in § 30.18 of this chapter).~~

~~(3) An emergency plan appropriate for responding to the facility specific hazards of an accidental release of radioactive material and to limit the health effects of the associated chemical hazards of licensed material must be approved and implemented prior to the receipt of byproduct, source, or SNM (excluding exempt quantities as described in § 30.18 of this chapter).~~

~~(4) A plant staff training program associated with the receipt of radioactive material must be approved and implemented before initial receipt of byproduct, source, or SNM (excluding exempt quantities as described in § 30.18 of this chapter).~~

~~(5) Security requirements must be implemented for the protection of SNM based on the type, enrichment, and quantity in accordance with 10 CFR part 73, as applicable, and for the protection of Category 1 and Category 2 quantities of radioactive material in accordance with 10 CFR part 37, as applicable.~~

~~(d) [Reserved]~~

(c~~e~~) *Transportation.*

(1) A holder of an ML may not transport or allow to be removed from the places of manufacture the manufactured reactor ~~or major portions thereof as defined in the ML~~ except to the site of a licensee with a COL. The COL must authorize the construction of a commercial nuclear plant using the manufactured reactor(s).

(2) A holder of an ML must include, in any contract governing the transport of a manufactured reactor ~~or major portions thereof as defined in the ML~~ from the places of manufacture to any other location, a provision requiring that the person or entity

Commented [A170]: The cited requirements would be self-executing or inapplicable to an ML that does not authorize loading fuel into a manufactured reactor.

The need for a fire protection plan at a factory under an ML that doesn't involve radioactive materials would be governed by OSHA requirements.

Commented [A171]: There are no provisions in 53.1270-1295 for licensing the manufacture of major portions of a manufactured reactor.

Commented [A172]: There are no provisions in 53.1270-1295 for licensing the manufacture of major portions of a manufactured reactor.

transporting the manufactured reactor ~~to~~ comply with all NRC-approved shipping requirements in the ML.

(3) Procedures governing the preparation of the manufactured ~~reactor or major portions thereof as defined in the ML~~ for transport and the conduct of the transport must be ~~documented and approved~~implemented prior to transport. ~~The procedures must implement the protective measures and restrictions described in the ML to protect the reactor from potential conditions that would adversely affect the safe operation of a commercial nuclear plant.~~

(4) The packaging and shipping of any fueled manufactured reactor module must be done in compliance with 10 CFR parts 71 and 73.

~~(f) *Acceptance and installation at the site.*~~

~~(1) Installation at the site must follow the regulations in § 53.610.~~

~~(2) Upon arrival at the site, the manufactured reactor or portions of a manufactured reactor may not be installed in its final place of use unless the COL holder performs inspections, using approved procedures, and verifies it is in acceptable condition in compliance with the ML. These inspections must confirm that all necessary interface requirements between the manufactured reactor or portions of a manufactured reactor and the remaining portions of the commercial nuclear plant are met.~~

Subpart F — Requirements for Operation

~~§ 53.700 Operational objectives.~~

~~(a) Each holder of an OL or COL under Framework A of this part must develop, implement, and maintain controls for plant SSCs, responsibilities of plant personnel, and plant programs during the operating life of each commercial nuclear plant such that the requirements defined in subpart B are satisfied. More specifically:~~

Commented [A173]: There are no provisions in 53.1270-1295 for licensing the manufacture of major portions of a manufactured reactor.

Commented [A174]: It is unclear from this draft proposed requirement who the approval authority for the procedures is. The procedures would be required to be submitted to the NRC as part of the application under 53.1279(c)(1), which implies that they would be approved by the NRC prior to issuance of the ML but the discussion here seems to be susceptible to an interpretation that this is the approval by the holder of the ML or some other entity.

Commented [A175]: This is redundant to the requirement for procedures in 53.1279(c)(1) combined with the QA requirements for control of procedures.

Commented [A176]: Redundant to the requirements of an acceptable QAP.

Commented [A177]: This is unnecessary because the installation of a manufactured reactor is "construction."

Commented [A178]: Moved to 53.610(d) because this is not a manufacturing activity but more closely related to construction.

Commented [A179]: This text expresses a requirement to meet other requirements. To the extent that is the case it is unnecessary. To the extent that it implies the need for additional programs, etc., it is insufficiently certain to include as a requirement. The discussion of the general objectives that do not express unique identified requirements should be in the preamble in order to avoid the interpretation that additional requirements are being imposed.

~~(1) Each holder of an OL or COL under Framework A of this part must maintain the capabilities, availability, and reliability of plant SSCs to ensure that the safety functions identified in § 53.230 will be performed if called upon during LBEs.~~

Commented [A180]: This duplicates the QA requirements.

~~(2) Each holder of an OL or COL under Framework A of this part must ensure that plant personnel have adequate knowledge and skills to perform their assigned duties that support the performance of the safety functions identified in § 53.230.~~

Commented [A181]: This duplicates training requirements of 53.830.

~~(3) Each holder of an OL or COL under Framework A of this part must implement plant programs sufficient to ensure that the safety functions identified in § 53.230 will be performed if called upon during normal operations and LBEs.~~

Commented [A182]: This duplicates the QA requirements.

~~(b) [Reserved]~~

§ 53.710 ~~Maintaining capabilities and availability of structures, systems, and components~~Technical specifications and programmatic controls.

~~Controls must be provided for each commercial nuclear plant licensed under Framework A of this part such that the capabilities, availability, and reliability of plant SSCs, when combined with corresponding programmatic controls and human actions, provide that the safety criteria defined in §§ 53.210 and 53.220 will be met.~~

(a) Each operating license or combined license for a commercial nuclear plant under this part must include ~~T~~technical specifications ~~must be developed, implemented, and maintained~~ that define conditions or limitations on plant operations that are necessary to ensure that safety-related (SR) structures, systems, and components (SSCs) can fulfill the safety functions identified ~~in~~under § 53.230 and support meeting the safety criteria of § 53.210. The technical specifications must describe include the following ~~requirements~~items:

Commented [A183]: Edited to reflect the requirements of AEA section 182.

(1) *Inventory Limits* on ~~the inventory of~~ radioactive materials within the reactor system and supporting systems ~~with the potential, individually or~~

~~collectively, to cause a release~~ to prevent exceeding the safety criteria in § 53.210 ~~as a result~~ in the event of a design-basis accident (DBA) ~~analyzed in accordance with § 53.450(f)~~. These limits must be determined based on potential collective releases from the systems.

(2) *Operating limits* for the facility that if exceeded could lead to a failure to perform a required safety function necessary to demonstrate compliance with the safety criteria in § 53.210.

(3) For each SR SSC ~~classified as SR in accordance with § 53.460~~, technical specifications must define—

(i) *Limiting conditions for operation*. Limiting conditions for operation are the lowest functional capability or performance levels of SR SSCs required to ~~ensure~~ prevent exceeding the safety criteria of § 53.210 in the event of a ~~that the~~ DBA~~s analyzed in accordance with § 53.450(f) would not give rise to an immediate threat to the public health and safety as represented by the safety criteria of § 53.210~~. When a limiting condition for operation is not met, the licensee must shut down the plant or follow any remedial action permitted by the technical specifications until the condition can be met.

(ii) *Surveillance requirements*. Surveillance requirements are requirements relating to test, calibration, or inspection to assure that the necessary quality of systems and components is maintained and that the limiting conditions for operation will be met.

(4) *Design elements*. Design elements to be included are those elements of the plant such as materials of construction and geometric arrangements, which, if altered or modified, would have a significant effect on ~~safety~~ the capability of the commercial

Commented [A184]: Deleted because all DBAs are analyzed under 53.450(f).

Commented [A185]: Edited for consistency with paragraph (a) of this section.

Commented [A186]: This omits control of redundant SR SSCs.

nuclear plant to prevent exceeding the safety criteria of § 53.210 and are not covered in categories described in paragraphs (a)(1) through (3) of this section.

(5) *Administrative Controls.* Administrative controls are the provisions relating to organization and management, procedures, recordkeeping, review and audit, and reporting necessary to assure operation of the plant in a safe manner. Administrative controls for commercial nuclear plants subject to §§ 53.800 through 53.820 must address the requirements of § 53.805. Each licensee must submit any reports to the Commission pursuant to approved technical specifications under~~as specified in~~ § 53.040.

(b) Controls on plant operations, including availability controls, must be developed and implemented to ensure that the configurations and special treatments for NSRSS SSCs provide the capabilities, availability, and reliability required to demonstrate compliance with the criteria of §§ 53.220 and 53.450(e). The controls must—

Commented [A187]: How does this address configuration control for SR SSCs required to demonstrate compliance with 53.220?

(1)(i) Identify who within the commercial nuclear plant has authority to make configuration changes;

(ii) Establish processes to make configuration changes to NSRSS SSCs; and

(iii) Establish processes to ensure that all departments of the staff of the commercial nuclear plant affected by the configuration changes are formally notified and approve of the change.

(2) Describe how the special treatments for each NSRSS SSC will be established and maintained over the operating life of the commercial nuclear plant.

§ 53.715 Maintenance, repair, and inspection programs.

(a) ~~Under Framework A,~~Each holder of a license to operate a commercial nuclear plant under this part must develop, implement, and maintain a program to control

maintenance activities and monitor the performance or condition of safety-related (SR) and non-safety-related but safety-significant (NSRSS) structures, systems, and components (SSCs) ~~must be developed, implemented, and maintained~~ to ensure that the safety criteria defined in §§ 53.210 and 53.220 will be met.

(b) Whenever a licensee determines through activities related to maintenance, repair, and inspection of SSCs, the activities under § 53.710, or otherwise that the performance or condition of an NSRSS SSC does not demonstrate compliance with established special treatments or performance goals related to capabilities, availability, or reliability, the licensee must take appropriate corrective action.

(c) Performance and condition monitoring activities and associated goals and preventive maintenance activities must be evaluated at least every 24 months. The evaluations must take into account, where practical, industry-wide operating experience. Adjustments must be made where necessary to ensure that the objective of preventing failures of SSCs through maintenance is appropriately balanced against the objective of minimizing unavailability of SSCs due to monitoring or preventive maintenance.

(d) Before performing maintenance activities (including but not limited to surveillance, post-maintenance testing, and corrective and preventive maintenance), the licensee must assess and manage the increase in risk that may result from the proposed maintenance activities. The scope of the assessment may be limited to SSCs that a risk-informed evaluation process determines are necessary to ensure that the criteria defined in §§ 53.210, 53.220, and 53.450(e) will be met.

§ 53.720 Response to seismic events.

~~Under Framework A, i~~If vibratory ground motion exceeding that of the operating basis earthquake~~OBE~~ Ground Motion determined under § 53.480 or significant plant damage due to vibratory ground motion occurs at a commercial nuclear plant, the

licensee must shut down the ~~commercial nuclear~~ plant. If structures, systems, or components~~SSCs~~ necessary for the safe shutdown of the ~~commercial nuclear~~ plant are not available after the occurrence of this vibratory ground motion, the licensee must consult with the Commission and must propose a plan for the timely, safe shutdown of the ~~commercial nuclear~~ plant. Prior to resuming operations, the licensee must demonstrate to the Commission that those features necessary for continued operation without undue risk to the health and safety of the public or necessary to maintain the licensing basis of the ~~commercial nuclear~~ plant were either not functionally damaged or have been repaired.

§ 53.725 General staffing, training, personnel qualifications, and human factors requirements.

(a) *Two classes of commercial nuclear plants.* Commercial nuclear plants licensed under ~~Framework A or Framework B of~~ this part are either of the class, based upon the similarity of operating and technical characteristics of the plants in the class, of self-reliant-mitigation facilities or of interaction-dependent-mitigation facilities. A commercial nuclear plant is a self-reliant-mitigation facility if the NRC determined as part of its approval of the operating license (OL) or combined license (COL) for that plant that its design demonstrates compliance with the criteria of either § 53.800(a)(1) ~~or~~through (a)(42)~~, as applicable~~. Otherwise, the commercial nuclear plant is an interaction-dependent-mitigation facility.

Commented [A188]: Edited to conform to 53.800(a).

(b) *Purpose and applicability*. The regulations in §§ 53.725 through 53.830 address areas related to staffing, training, personnel qualifications, and human factors engineering for applicants for or holders of OLs or COLs under ~~Frameworks A and B of~~ this part. These regulations are organized as follows:

(1) Sections 53.725 through 53.745 address general requirements for staffing, training, personnel qualifications, and human factors engineering. The regulations within these sections are applicable to all applicants for or holders of OLs or COLs under ~~Frameworks A and B of~~ this part, except where specifically stated otherwise.

(2) Sections 53.760 through 53.78095 address operator and senior operator licensing requirements. The regulations within these sections are applicable to those applicants for or holders of OLs or COLs under ~~Frameworks A and B of~~ this part for interaction-dependent-mitigation facilities that have not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070 ~~or § 53.4670, as applicable~~.

Commented [A189]: Staff should seek stakeholder input on whether this portion of the proposed rule is necessary or if part 55 should be adopted for use of operators and senior operators making the appropriate adaptions necessary to be technology inclusive.

(3) Sections 53.800 through 53.820 address generally licensed reactor operator requirements. The regulations within these sections are in lieu of §§ 53.760 through 53.78095 for by those applicants for or holders of OLs or COLs under ~~Frameworks A and B of~~ this part for self-reliant-mitigation facilities that have not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070 ~~or § 53.4670, as applicable~~.

(4) Section 53.830 provides general personnel training requirements. The regulations within this section are applicable to all applicants for or holders of OLs or COLs under ~~Frameworks A and B of~~ this part.

(c) *Definitions*. ~~When used in §§ 53.725 through 53.830, *applicant* refers to an applicant for an operator or senior operator license; *licensee* refers to the holder of an operator, senior operator, or generally licensed reactor operator license; and *facility licensee* refers to the licensee for the commercial nuclear plant where the applicant would be licensed or the licensee is licensed~~. As ~~also~~ used in §§ 53.725 through 53.830—

Commented [A190]: Staff should determine whether the definitions remaining in this paragraph are appropriately restricted to this portion of part 53 and move those that will not cause unintended consequences to 53.020.

Commented [A191]: Deleted to reflect the use of part 55 for operator licensing.

Automation means a device or system that accomplishes (partially or fully) a function or task.

Auxiliary operator means any individual who operates components of a commercial nuclear plant but does not manipulate controls or direct the manipulation of controls of the plant and is not required to be licensed under the provisions of this part.

Controls when used with respect to a nuclear reactor means apparatus and mechanisms, the manipulation of which directly affects the reactivity or power level of the reactor.

~~*Generally licensed reactor operator* means any individual licensed under the provisions of § 53.810 to manipulate controls of a self-reliant mitigation facility and to direct the licensed activities of generally licensed reactor operators.~~

~~*Interaction-dependent-mitigation facility* means a commercial nuclear plant design other than one that demonstrates compliance with the operating and technical characteristics defined under § 53.800.~~

Commented [A192]: Moved to 53.020 as there are no other uses of this term external to this portion of part 53.

~~*Load following* means a commercial nuclear plant automatically changing its output to match expected demand in response to externally originated instructions or signals.~~

Commented [A193]: Moved to 53.020 in order to allow for reference in the design requirements.

Operator means any individual licensed under the provisions of §§ 53.760 through 53.780~~95~~ to manipulate controls of an interaction-dependent-mitigation facility.

Performance testing means testing conducted to verify a simulation facility's performance as compared to actual or predicted reference plant performance.

~~*Reference plant* means the specific commercial nuclear plant on which a simulation facility's configuration, system control arrangement, and design data are based. The reference plant may or may not be constructed.~~

~~*Self reliant mitigation facility* means a commercial nuclear plant design that demonstrates compliance with the operating and technical characteristics defined under § 53.800.~~

Senior operator means any individual licensed under the provisions of §§ 53.760 through 53.78095 to manipulate controls of an interaction-dependent-mitigation facility and to direct the licensed activities of operators.

~~*Simulation facility* means an interface designed to provide a realistic imitation of the operation of a commercial nuclear plant used for the administration of examinations, for training, and/or to demonstrate compliance with experience requirements for applicants or licensees. A simulation facility may rely, in whole or part, upon the physical utilization of the reference plant itself.~~

~~*Systems approach to training* means a training program that includes the following five elements:~~

~~(1) Systematic analysis of the jobs to be performed.~~

~~(2) Learning objectives derived from the analysis which describe desired performance after training.~~

~~(3) Training design and implementation based on the learning objectives.~~

~~(4) Evaluation of trainee mastery of the objectives during training.~~

~~(5) Evaluation and revision of the training based on the performance of trained personnel in the job setting.~~

(d) Scope. The regulations in §§ 53.725 through 53.830 apply to:

(1) Any individual who manipulates the controls of any commercial nuclear plant licensed under this part,

(2) Any individual designated to be responsible for directing any licensed activity of a senior operator, operator, or generally licensed reactor operator by the holder of a license to operate a commercial nuclear plant under this part.

(c) Any operating license or combined license issued under this part.

§ 53.726 Communications.

~~(a) An applicant or licensee or facility licensee must submit any communication or report required by the regulations contained within §§ 53.725 through 53.830 and must submit any application filed under these regulations to the Commission.~~

~~(b)~~ Each licensee that is required to comply with the requirements of §§ 53.760 through 53.780~~95~~ (i.e., interaction-dependent-mitigation facilities) must notify the appropriate NRC contact within 30 days of the following in regard to a ~~specifically~~ licensed operator or senior operator:

(1) Permanent reassignment from the position for which the licensee has certified the need for a licensed operator or senior operator under § 55.31(a)(3)~~53.775(a)(1)~~ of this chapter;

(2) Termination of any operator or senior operator; or

(3) Permanent disability or illness as required under § 55.25~~53.770~~ of this chapter.

~~**§ 53.728 Completeness and accuracy of information.**~~

~~Information provided to the Commission by an applicant for an operator or senior operator license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee must be complete and accurate in all material respects.~~

§ 53.730 Defining, fulfilling, and maintaining the role of personnel in ensuring safe operations.

Commented [A194]: This is redundant to 53.040 for written communications using the definitions of applicant or licensee in 53.020. Staff should confirm that non-written communications are appropriately covered elsewhere as well.

Note that this differs from 55.5 by omitting much of the information regarding where to send applications and renewal applications.

Commented [A195]: This is redundant to 53.070(a).

Each applicant for or holder of an OL or COL for a commercial nuclear plant under this part must comply with the following:

(a) [Reserved].~~*Human factors engineering design requirements.* The plant design must reflect state-of-the-art human factors engineering principles for safe and reliable performance in all locations that human activities are expected for performing or supporting the continued availability of plant safety or emergency response functions.~~

(b) [Reserved]. ~~*Human system interface design requirements.* The plant design must provide for the following to support operating personnel in monitoring plant conditions and responding to plant events:~~

~~(1) Features for displaying to operating personnel a minimum set of parameters that define the safety status of the plant and are capable of displaying both the full range of important plant parameters and data trends on demand, as well as indicating when process limits are being approached or exceeded;~~

~~(2) Automatic indication of the bypassed and operable status of safety systems;~~

~~(3) Direct indication of SSC status that relates to the ability of the SSC to perform its safety function, such as relief and safety valve position (i.e., open or closed) for barriers important to fulfilling safety functions of with such devices, and ultimate heat sink and cooling system status and availability;~~

~~(4) Instrumentation to measure, record, and display key plant parameters related to the performance of SSCs and the integrity of barriers important to fulfilling safety functions to support operators in monitoring plant conditions and responding to plant events. Examples include temperatures and pressures within important systems or structures, core or fuel system conditions (including possible damage states), temperatures and levels associated with cooling functions, combustible gas~~

~~concentrations, radiation levels in systems and within structures, and radioactive effluent releases;~~

~~(5) Leakage control and detection in the design of systems that pass through barriers important to fulfilling safety functions for the release of radionuclides. An example is an SSC that penetrates a containment structure that might contain radioactive materials that could contribute to the source term during an accident;~~

~~(6) Monitoring of in-plant radiation and airborne radioactivity as appropriate for a broad range of normal operating and accident conditions; and~~

Commented [A196]: Moved to 53.440(n) as these are design requirements that must be addressed prior to the operations phase, for example in design and construction.

~~(7) For self-reliant mitigation facilities, the plant design must also provide the generally licensed reactor operators with the capability to do the following:~~

~~(i) Receive plant operating data, including reactor parameters and information needed for the evaluation of emergency conditions.~~

~~(ii) Immediately initiate a reactor shutdown from their location.~~

~~(iii) Promptly dispatch operations and maintenance personnel.~~

~~(iv) Immediately implement responsibilities under the facility emergency plan, as applicable.~~

(c) *Concept of operations.* A concept of operations that is of sufficient scope and detail to address the following must be provided:

(1) Plant goals;

(2) The roles and responsibilities of operating personnel and automation (or any combination thereof) that are responsible for completing plant functions;

(3) Staffing, qualifications, and training;

(4) The management of normal operations;

(5) The management of off-normal conditions and emergencies;

(6) The management of maintenance and modifications; and

(7) The management of tests, inspections, and surveillances.

(d) *Functional requirements analysis and function allocation*. A functional requirements analysis and a function allocation must be provided that are sufficient to demonstrate compliance with the following:

(1) The functional requirements analysis must address how safety functions and functional safety criteria are satisfied, and

(2) The function allocation must describe how the safety functions will be assigned to human action, automation, active safety features, passive safety features, and/or inherent safety characteristics.

(e) ~~*Programmatic requirements*~~*Operating experience*. A program, during construction and during operation, as applicable, for evaluating and applying operating experience must be developed, implemented, and maintained.

(f) *Staffing plan.* A staffing plan must be developed, implemented and maintained until such time as the permanent cessation of operations and permanent removal of fuel from the reactor vessel has been certified as described under § 53.1070. The staffing plan is subject to the requirements of § 53.1565~~and comply with the~~and the following:

(1) The staffing plan must include a description of how engineering expertise will be available to the on-shift operating personnel during all plant conditions, to assist if they encounter a situation not covered by procedures or training. Engineering expertise includes familiarity with the operation of the plant for which the expertise is provided and one of the following:

(i) A bachelor's degree in engineering, engineering technology, or physical science from an institution accredited by a U.S. Government recognized accrediting body or equivalent; or

(ii) A Professional Engineer's license from a U.S. State or territory.

Commented [A197]: Edited in order to provide some indication of what the programmatic requirements are.

Note that this captures the operating experience portion of 50.34(f)(3)(i) only, omitting the construction and design experience portions. The construction experience portion is captured in 53.610(a)(4). The design experience portion could be captured in 53.440 as suggested in the comments to that section. This has been extended to cover manufacturing experience in 53.620(a)(4).

The specific requests for comment section of this document has been edited to seek stakeholder input on whether there would be synergistic gains in reunifying the various experience evaluation programs into a single program either as an element of or in conjunction with the QA program requirements or elsewhere in the regulations.

(2) Applicants for or holders of OLs or COLs for interaction-dependent-mitigation facilities must include within their staffing plans a description of how the proposed numbers, positions, and qualifications of operators and senior operators across all modes of plant operations will be sufficient to ensure that plant safety functions will be maintained. This description must be supported by human factors engineering analyses and assessments.

(3) Applicants for or holders of OLs or COLs for self-reliant-mitigation facilities must include within their staffing plans a description of how generally licensed reactor operator staffing that is both sufficient to continually monitor the operations of fueled reactors and to provide for a continuity of responsibility for facility operations at all times during the operating phase will be maintained.

(4) Applicants for or holders of OLs or COLs under this part must include within their staffing plans a description of how the numbers, positions, and responsibilities of personnel contained within those plans will adequately support all necessary functions within areas such as plant operations, equipment surveillance and maintenance, radiological protection, chemistry control, fire brigades, engineering, security, and emergency response.

(5) The staffing plan must be approved by the NRC as part of its approval of the OL or COL for the plant. The approved staffing plan is subject to the requirements of § 53.1565 ~~or § 53.6065, as~~ applicable.

(g) *Training, examination, and proficiency programs*. Develop, implement, and maintain programs that comply with the following requirements. These programs must be approved by the NRC as part of its approval of the OL or COL for the plant:

(1) For those applicants for or holders of OLs or COLs for interaction-dependent-mitigation facilities:

(i) The operator licensing initial training program required under § 53.780(a);

(ii) The operator licensing initial examination program required under § 53.780(b);

(iii) The operator licensing requalification program required under § 53.780(c); and

(iv) The operator proficiency program required under § 53.780(g).

(2) For those applicants for or holders of OLs or COLs for self-reliant-mitigation facilities, the generally licensed reactor operator training, examination, and proficiency programs required under § 53.815.

(3) The operator licensing requalification programs required under § 53.780(c) or § 53.815(b) must be implemented upon commencing the administration of initial examinations under the operator licensing examination program required under § 53.780(b) or § 53.815(b), respectively.

§ 53.735 General exemptions.

The regulations in §§ 53.725 through 53.830 do not require a license for an individual who –

(a) Under the direction and in the presence of an operator or senior operator or a generally licensed reactor operator, as appropriate, manipulates the controls of a commercial nuclear plant as a part of the individual's training in ~~a facility licensee's~~ the training program for the commercial nuclear plant as approved by the Commission to qualify for an operator or senior operator license or a generally licensed reactor operator license there, as appropriate, under these regulations; or

(b) Under the direction and in the presence of a senior operator or generally licensed reactor operator, as appropriate, manipulates the controls of a commercial nuclear plant to load or unload the fuel into, out of, or within the reactor vessel while the reactor is not operating.

Commented [A198]: Under part 55, applicants for initial licensing as operators have the option of completing a training program approved by the Commission but are not mandated to do so. Staff should provide an adequate basis for removing that flexibility for operators at advanced reactors, which are expected to have reduced required operator actions and simplified systems that should facilitate operator comprehension under the Commission's "Policy Statement on the Regulation of Advanced Reactors" (73 FR 60612, 60615; October 14, 2008). Absent a suitable justification for removing that flexibility for operator initial training programs, staff should incorporate the flexibilities of 55.31(a)(4) into the application requirements for operator licensing in 53.760.

Commented [A199]: This draft proposed general exemption parallels that of 55.13(b) as it is established for use with light water reactors (LWRs). Staff should seek specific response to comment on whether it is appropriate as a general exemption for commercial nuclear plants that do not use a solid fuel similar to that of an LWR that is loaded, unloaded, or moved into, out of, or within the reactor vessel by means of a crane or other apparatus that requires a different skill set than that of a senior operator, operator, or GLRO (e.g., loading, unloading, or moving fluid fuels within a reactor vessel).

Commented [A200]: This restriction to the general exemption does not appear in 55.13(b). If the staff desires to include the restriction in the regulations for advanced reactors, staff should highlight the difference, explain the basis for the change, and seek specific response to comment on it. Staff should accomplish this in combination with addressing the technology-specific issues of loading, unloading, and moving solid or liquid fuel into, out of, or within the reactor vessel vis-a-vis whether this limitation is appropriate only for fluid fueled reactors where the general exemption could be limited to the reasons under paragraph (a) of this section while it might not be necessary for a solid fueled reactor similar to an LWR.

§ 53.740 ~~Facility licensee requirements — General~~Conditions on Operating and Combined Licenses.

(a) ~~Facility licensees must demonstrate compliance with the requirements of either §§ 53.760 through 53.795 for interaction-dependent-mitigation facilities or §§ 53.800 through 53.820 for self-reliant-mitigation facilities.~~ [Reserved].

Commented [A201]: Deleted as redundant to the applicability provisions in 53.725(b).

(b) ~~The facility licensee must maintain the staffing complement described under its approved facility staffing plan until such time as the permanent cessation of operations and permanent removal of fuel from the reactor vessel has been certified as described under § 53.1070 or § 53.4670, as applicable. The approved staffing plan is subject to the requirements of § 53.1565 or § 53.6065, as applicable.~~ [Reserved].

Commented [A202]: Moved to 53.730(f).

(c) Except as provided under § 53.735, the ~~facility~~ holder of a license~~e~~ to operate a commercial nuclear plant may not permit the manipulation of the controls of ~~a~~the ~~commercial nuclear~~ plant by anyone who is not an operator or senior operator or generally licensed reactor operator at that plant, as appropriate.

(d) ~~Facility~~ Holders of license~~e~~s for interaction-dependent-mitigation facilities that have not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070 ~~or § 53.4670, as applicable,~~ must designate senior operators to be responsible for supervising the licensed activities of operators.

(e) Apparatus and mechanisms other than controls, the operation of which may affect the reactivity or power level of a reactor, must be manipulated only while plant conditions are being monitored by an individual who is an operator or senior operator or a generally licensed reactor operator, as appropriate.

(f)(1) Load following is permitted if ~~at least one of the following is immediately capable of refusing demands when they could challenge the safe operation of the plant or when precluded by the plant equipment conditions:~~—

(i) The actuation of an automatic protection system provided under 53.440(o) is operable~~that utilizes setpoints more conservative than those otherwise credited for the purposes of reactor protection~~; or

(ii) ~~An automated control system;~~ or

~~(iii)~~ An operator or senior operator or a generally licensed reactor operator, as appropriate, is immediately capable of refusing demands that could challenge the safe operation of the plant or are otherwise precluded by the plant equipment conditions.

(2) The provisions of paragraph (e) of this section do not apply to the externally generated instructions or signals during load following operations.

(g)~~(1)~~ Holders of licenses allowing the operation of commercial nuclear plants ~~Facility licensees for interaction-dependent-mitigation facilities~~ must have present during alteration of the core (including fuel loading or transfer) ~~an individual holding~~ a senior operator ~~license~~ or a senior operator with a license limited to fuel handling or a generally licensed reactor operator to directly supervise the activity. ~~and, during this time, the facility licensee~~The individual supervising the alteration of the core must not be assigned other duties ~~to this person~~.

~~(2) Facility licensees for self-reliant-mitigation facilities must have present during alteration of the core (including fuel loading or transfer) an individual holding a generally licensed reactor operator license to directly supervise the activity and, during this time, the facility licensee must not assign other duties to this person.~~

Commented [A203]: Edits have been provided to include the design elements necessary to allow load following in the design requirements in 53.440. Final portion of the prefatory phrase of this requirement has been modified to use an em dash rather than a colon for consistency with the usage in the remainder of the rule text.

Commented [A204]: Restriction inserted in order to reflect that paragraph (e) could apply to the operation of other apparatus and mechanisms that may affect reactivity or power level.

Commented [A205]: Edited to combine paragraphs (g)(1) and (2) and limit applicability to operating plants.

~~(3)~~ The provisions of this paragraph~~s (g)(1) and (2) of this section~~ do not apply to core alterations performed as part of refueling operations while a facility that is capable of online refueling is operating at power.

Commented [A206]: Moved up to combine in paragraph (g).

(h) ~~Facility~~ A licensee~~s~~ may take reasonable action that departs from a license condition or a technical specification (contained in a license issued under this part) in an emergency when this action is immediately needed to protect the public health and safety and no action consistent with license conditions and technical specifications that can provide adequate or equivalent protection is immediately apparent. Such ~~facility~~ licensee action must be approved, as a minimum, by a senior operator or a generally licensed reactor operator, as applicable, or, ~~after~~ at a commercial nuclear plant for which the certifications~~ying~~ ~~the~~of permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070 ~~or § 53.4670, as applicable~~have been submitted, by a certified fuel handler, senior operator, or generally licensed reactor operator, as applicable, prior to taking the action.

§ 53.745 Operator license requirements.

A person must be authorized by a license issued by the Commission to perform the function of an operator, senior operator, or generally licensed reactor operator as defined in this part.

§ 53.760 Operator licensing for interaction-dependent mitigation facilities.

(a) *Applicability*. ~~Sections 53.760 through 53.795~~Part 55 of this chapter addresses operator and senior operator licensing requirements for interaction-dependent mitigation facilities. ~~The regulations within these sections are applicable to those applicants for or holders of OIs or COLs under this part for interaction-dependent mitigation facilities that have not yet certified the permanent cessation of operations and~~

~~permanent removal of fuel from the reactor vessel as described under § 53.1070 or § 53.4670, as applicable.~~

Commented [A207]: This duplicates the provisions of 53.725(b)(2).

(b) ~~Reserved~~The Commission and licensees of interaction-dependent mitigation facilities will use the training, examination, and proficiency programs developed under §§ 53.730(g) and 53.780 in lieu of those specified in part 55.

~~**§ 53.765 Medical requirements.**~~

~~(a) An applicant for an operator or senior operator license must have a medical examination by a physician. An operator or senior operator must have a medical examination by a physician every 2 years.~~

~~(b) To certify the medical fitness of an applicant for an operator or senior operator license, an authorized representative of the facility licensee must complete and sign NRC Form 396, "Certification of Medical Examination by Facility Licensee," which can be obtained by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 301-415-7232, or by visiting the NRC's website at https://www.nrc.gov and selecting forms from the index found on the home page, or by other means provided by the NRC.~~

~~(1) Form NRC 396 must certify that a physician has conducted the medical examination of the applicant as required in paragraph (a) of this section.~~

~~(2) When the medical certification requests a conditional license based on medical evidence, the medical evidence must be submitted on NRC Form 396 to the Commission to enable the Commission to make a determination in accordance with § 53.775(b).~~

~~(c) The facility licensee must document and maintain the results of medical qualifications data, test results, and each operator's or senior operator's medical history for the current license period and provide the documentation to the Commission upon~~

request. The facility licensee must retain this documentation while an individual performs the functions of an operator or senior operator.

§ 53.770 Incapacitation because of disability or illness.

If, during the term of the operator or senior operator license, the licensee develops a permanent physical or mental condition that causes the licensee to fail to demonstrate compliance with the requirements of § 53.775(b)(1)(i), the facility licensee must notify the Commission within 30 days of learning of the diagnosis. For conditions for which a conditional license (as described in § 53.775(b)) is requested, the facility licensee must provide medical certification on Form NRC 396 to the Commission (as described in § 53.765(b)).

§ 53.775 Applications for operators and senior operators.

(a) *How to apply*. (1) The applicant for an operator or senior operator license must—

(i) Complete NRC Form 398, "Personal Qualification Statement - Licensee," which can be obtained by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 301-415-5877, or by visiting the NRC's website at https://www.nrc.gov and selecting forms from the index found on the home page, or by other means provided by the NRC;

(ii) File an original of NRC Form 398, or an equivalent electronic submittal, together with the information required in paragraphs (a)(1)(iii) and (a)(1)(iv) of this section, with the appropriate Regional Administrator.

(iii) Provide evidence that the applicant, as a trainee, has successfully demonstrated competence in manipulating the controls of either the facility for which a license is sought or a simulation facility that demonstrates compliance with the requirements of § 53.780(e). For operators applying for a senior operator license,

certification that the operator has successfully operated the controls of the facility as an operator will be accepted; and

(iv) Provide certification by the facility licensee of medical condition and general health on Form NRC 396, to comply with § 53.765.

(2) The Commission may at any time after the application has been filed, and before the license has expired, require further information under oath or affirmation to enable it to determine whether to grant or deny the application or whether to revoke, modify, or suspend the license.

(3) An applicant whose application has been denied because of a medical condition or their general health may submit a further medical report at any time as a supplement to the application.

(4) Each application and statement must contain complete and accurate disclosure as to all matters required to be disclosed. The applicant must sign statements required by paragraphs (a)(1)(i) and (a)(1)(ii) of this section.

(b) *Disposition of an initial application.* (1) *License approval.* The Commission will approve an initial application if it finds that the following criteria are met:

(i) *Health.* The applicant's medical condition and general health will not adversely affect the performance of assigned operator or senior operator job duties or cause operational errors endangering public health and safety. The Commission will base its finding upon the certification by the facility licensee as detailed in § 53.765(b).

(ii) *Examination.* The applicant has passed the requisite examination in accordance with § 53.780(b). The examination determines whether the applicant for an operator's or senior operator's license has learned to operate a facility competently and safely, and additionally, in the case of a senior operator, whether the applicant has learned to supervise the licensed activities of operators competently and safely.

~~(2) *Conditional license*. If an applicant's general medical condition does not demonstrate compliance with the minimum standards under § 53.775(b)(1)(i), the Commission may approve the application and include conditions in the license to accommodate the medical condition. The Commission will consider the recommendations and supporting evidence of the facility licensee and of the examining physician (provided on Form NRC 396) in arriving at its decision.~~

~~(c) *Re-applications.* (1) An applicant whose application for a license has been denied because of failure to pass the examination may file a new application. The application must be submitted on Form NRC 398 and include a statement signed by an authorized representative of the facility licensee by whom the applicant will be employed that states in detail the extent of the applicant's additional training and remediation since the denial and certifies that the applicant is ready for re-examination.~~

~~(2) An applicant who has passed a portion of the examination and failed another may request in a new application on Form NRC 398 to be excused from re-examination on the portions of the examination that the applicant has passed. The Commission may in its discretion grant the request if it determines that sufficient justification is presented.~~

§ 53.780 Training, examination, and proficiency program.

(a) *Operator licensing initial training program*. (1) A program that is based upon a systems approach to training, as defined by § 53.020~~725(b)~~, ~~must~~ may be utilized ~~for the training of~~ to provide applicants for operator and senior operator licenses with~~. The program must ensure that applicants at the facility will possess~~ the knowledge, skills, and abilities necessary to protect the public health and maintain those plant safety functions specific to the facility design. The program must be approved by the Commission prior to its use for training applicants, as described under § 53.730(g). The

Commented [A208]: Edited to reflect the movement of the definition from 53.725(c) to 53.020.

Commented [A209]: Staff should either justify the basis for eliminating the flexibility available for currently operating reactor licensees to allow applications by individuals using a non-Commission approved initial training program or revise this draft proposed requirement to restore the flexibility.

approved operator licensing initial training program is subject to the requirements of § 53.1565 ~~or § 53.6065, as applicable~~.

(2) The operator licensing initial training program documentation must include the following:

(i) The ~~facility licensee~~holder of the operating license or combined license must maintain records documenting the initial operator licensing training administered and completed by each applicant. The holder of the operating license or combined license~~facility licensee~~ must retain these records during the period in which any trainees subsequently remain licensed as operators or senior operators at the facility.

(ii) [Reserved] ~~Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original, a reproduced copy, or an electronic copy provided that the copy is authenticated by authorized personnel.~~

(b) *Operator licensing initial examination program*. (1) The holder of the operating license or combined license~~facility licensee~~ must establish and implement an examination program for testing a representative sample of the knowledge, skills, and abilities needed to safely perform operator and senior operator duties, as appropriate, to include both the examination methods and criteria to be used to assess passing performance. The program must provide for valid and reliable examinations and be approved by the Commission prior to its use for examining applicants, as described under § 53.730(g). The approved operator licensing initial examination program is subject to the requirements of § 53.1565 ~~or § 53.6065, as applicable~~.

(2) The holder of the operating license or combined license~~facility licensee~~ must submit prepared examinations to the Commission for review and approval in advance of their administration.

Commented [A210]: This draft proposed requirement exceeds the documentation requirements for training of operators and senior operators at currently operating reactors under 55.59(c)(5), which only mandates retention of requalification records until the operator's or senior operator's license is renewed. Staff should justify the basis for this imposition on advanced reactor licensees over what is required of currently operating reactor licensees or eliminate it.

Commented [A211]: As drafted, this proposed requirement would apply to records required throughout part 53. It also appears three times in just this section. Edited to be a single proposed requirement applicable to the section rather than the part.

Commented [A212]: This provision appears to combine the written examination and operating test requirements of part 55 under the name "examination program." This would set up another instance of using similar names that have different meanings between part 53 and part 50/52/53. Staff should clearly explain this in the preamble and seek stakeholder comment on whether it is prudent to set up this difference.

(3) The Commission will either administer an approved examination or allow the holder of the operating license or combined licensefacility licensee to administer the examination. The holder of the operating license or combined licensefacility licensee must ensure that sufficient advance notification is provided to the Commission to either administer the examination or allow for a representative of the Commission to be afforded the opportunity to be present when the holder of the operating license or combined license facility licensee administers the examination.

(4) Graded examination documentation for each applicant must be promptly provided to the Commission for review in making operator licensing decisions.

(5) The operator licensing initial examination program documentation must include the following:

(i) The holder of the operating license or combined licensefacility licensee must maintain records documenting the participation of each operator and senior operator applicant in the a non-NRC-administered initial examination. The records must contain copies of examinations administered, the answers given by the applicant, documentation of the grading of examinations, and documentation of any additional training administered in areas in which an applicant exhibited deficiencies. The holder of the operating license or combined licensefacility licensee must retain these records during the period in which the associated operators or senior operators remain licensed at the facility.

(ii) [Reserved] Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original, a reproduced copy, or an electronic copy provided that the copy is authenticated by authorized personnel.

Commented [A213]: As drafted, this requirement would place the decision responsibility on the NRC as to whether to allow a licensee to administer an examination. This is in contrast to the wording that is used in 55.40, which places that decision responsibility with the licensee. Staff should clearly articulate criteria that would be used in making that decision.

Commented [A214]: Paragraph (b)(3) of this section is phrased as though the default is for administration of the examinations by the Commission with an option to allow a licensee to administer the examination. Given that situation, staff should clarify who grades the examinations and why the licensee would need to provide graded examination documentation to the Commission for Commission-administered examinations. If the staff would be grading those examinations, this proposed requirement should be modified to limit it to licensee-administered examinations.

Commented [A215]: This draft proposed requirement extends the records requirements for the requalification program under 53.59(c)(5) to the initial examination program. This may be appropriate for initial examinations administered by the licensee. The staff should document the basis for imposing this requirement and limit the requirement to licensee-administered examinations.

(c) *Operator licensing requalification program.* (1) A program based upon a systems approach to training, as defined by § 53.020~~725(b)~~, must be utilized for the continuing training of operators and senior operators.

(i) The program must ~~ensure that~~enable operators and senior operators at the facility to maintain the knowledge, skills, and abilities necessary to protect the public health and maintain those plant safety functions specific to the facility design. The program must be conducted for a continuous period not to exceed ~~24 months~~two years in duration.

(ii) The program must be approved by the Commission prior to its use for continuing training, as described under § 53.730(g). The approved operator licensing requalification program is subject to the requirements of § 53.1565 ~~or § 53.6065, as applicable~~.

(2) The following requirements apply to operator licensing requalification programs:

(i) The holder of the operating license or combined license~~facility licensee~~ must propose a requalification examination program for testing, for each requalification period, a sample of the topics included under the systems approach to training, to include both the examination methods and criteria to be used to assess passing performance. The program must provide for valid and reliable examinations and be approved by the Commission prior to its use for examining operators and senior operators, as described under § 53.730(g). The approved requalification examination program is subject to the requirements of § 53.1565 ~~or § 53.6065, as applicable~~.

(ii) The following requirements apply to the requalification examination program:

(A) The holder of the operating license or combined license~~facility licensee~~ must make prepared requalification examinations available to the Commission for review.

Commented [A216]: Edited to reflect the movement of this definition from 53.725(c) to 53.020.

Commented [A217]: The requirements for requalification in 55.59 use "two years" as the limit for the continuous period rather than "24 months."

(B) The holder of the operating license or combined licensefacility licensee must ensure that a representative of the Commission is afforded the opportunity to be present during requalification examination administration.

(C) The holder of the operating license or combined licensefacility licensee must ensure that each operator and senior operator is administered a complete requalification examination on a periodicity not to exceed 24 months. Additionally, the holder of the operating license or combined licensefacility licensee must ensure that any licensed operator or senior licensed operator who either demonstrates unsatisfactory performance on, or fails to complete, the biennial requalification examination is removed from the performance of licensed operator and senior licensed operator duties until such time that any necessary remedial training has been completed and a retake examination has been passed.

(D) The holder of the operating license or combined licensefacility licensee must promptly provide a summary of examination results for each operator and senior operator following the completion of the requalification examination.

(3) The operator licensing requalification program documentation must include the following:

(i) The holder of the operating license or combined licensefacility licensee must maintain records documenting the participation of each operator and senior operator in the requalification program. The records must contain copies of examinations administered, the answers given by the operator or senior operator, documentation of the grading of examinations, and documentation of any additional training administered in areas in which an operator or senior operator exhibited deficiencies. The holder of the operating license or combined licensefacility licensee must retain these records until the operator's or senior operator's license is renewed.

Commented [A218]: Edited to reflect the fact that all "operators" and "senior operators" are licensed as indicated in the definitions of those terms.

Commented [A219]: Staff should clearly state who will designate what remedial training is necessary.

Commented [A220]: This appears to exceed the requirements in 55.59(b), which allows but does not require the Commission to require the completion of additional training. Staff should support this more conservative approach with appropriate justification or match the 55.59(b) approach.

Commented [A221]: Staff should clearly indicate to whom these summaries would be required to be provided. If it is to the NRC, this requirement should identify the meaning of "promptly" and be supported by a justification regarding what the information will be used for.

~~(ii) Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original, a reproduced copy, or an electronic copy provided that the copy is authenticated by authorized personnel.~~

(d) *Examination integrity*. Applicants, operators and senior operators, and holders of operating licenses or combined licenses~~facility licensees~~ must not engage in any activity that compromises the integrity of any application or examination required by §§ 53.760 through 53.7~~95~~80. The integrity of an examination is considered compromised if any activity, regardless of intent, affected, or, but for detection, could have affected the equitable and consistent administration of the examination. This includes activities related to the preparation and certification of applications and all activities related to the preparation, administration, and grading of examinations required by §§ 53.760 through 53.780~~95~~.

(e) *Simulation facilities.* (1) This section addresses the use of a simulation facility for the administration of examinations, for training, or to demonstrate compliance with experience requirements for applicants for operator and senior operator licenses.

(2) Simulation facilities used for training purposes, for demonstrating compliance with experience requirements, or for the conduct of examinations under § 53.780(b) and (c) must demonstrate compliance with the following criteria as they relate to the ~~facility licensee's~~ reference plant:

(i) The simulation facility must be of sufficient scope and fidelity for individuals to acquire and demonstrate the necessary knowledge, skills, and abilities to safely perform operator and senior operator duties.

(ii) The simulation facility must utilize models relating to nuclear, thermal-hydraulic, and other applicable design-specific characteristics that either replicate the

most recent fuel load in the reference ~~commercial nuclear~~ plant or, prior to initial fuel load, replicate the intended initial fuel load for the reference ~~commercial nuclear~~ plant, with the exception of those portions of the simulation facility that utilize the reference plant itself.

(iii) Simulation facility fidelity must be demonstrated so that significant control manipulations are completed without procedural exceptions, simulator performance exceptions, or deviation from the approved training scenario sequence.

(3) Holders of operating licenses or combined licenses~~Facility licensees~~ that maintain a simulation facility that has been approved by the Commission for training purposes, demonstrating compliance with experience requirements, or the conduct of examinations under § 53.780(b) and (c) for the ~~facility licensee's~~ reference plant must:

(i) Conduct performance testing throughout the life of the simulation facility in a manner sufficient to ensure that paragraph (e)(2) of this section is met;

(ii) Retain the results of performance testing for 4 years after the completion of each performance test or until superseded by updated test results;

(iii) Promptly correct modeling and hardware discrepancies and discrepancies identified from scenario validation and from performance testing or provide justification as to why the presence of such discrepancies will not adversely affect simulator performance with respect to the criteria of paragraph (e)(2) of this section;

(iv) Make the results of any uncorrected performance test failures that may exist at the time of the initial license examination or requalification examination available for NRC review, prior to or concurrent with preparations for each initial license examination or requalification examination; and

(v) Maintain the provisions for license application and examination integrity consistent with § 53.780(d).

Commented [A222]: Edited to use the defined term.

Commented [A223]: Staff should clearly articulate what is meant by the term "Promptly" in this requirement or delete it to match the current requirement on operating reactors in 55.46(d)(2). Staff should justify the change from the level of the requirement on currently operating reactors if the term "Promptly" is retained.

(4) A simulation facility must demonstrate compliance with the requirements of paragraphs (e)(2) and (e)(3) of this section for the Commission to accept the simulation facility for conducting initial examinations as described in § 53.780(b), requalification training as described in § 53.780(c), or performing control manipulations that affect reactivity to establish eligibility for an operator or senior operator license as described in § 53.775(a).

(f) *Waiver of examination requirement.* On application, the Commission may waive any or all of the requirements for an examination if it finds that the applicant has demonstrated the required knowledge, skills, and abilities to safely operate the plant, and is capable of continuing to do so. The Commission may make such a finding based on demonstration of the following:

(1) The applicant's actual ~~O~~operating experience at a comparable facility;

(2) ~~Proof of t~~The applicant's past competent and safe performance; and

(3) ~~Proof of t~~The applicant's current qualifications.

(g) *Proficiency.* The ~~facility licensee~~holder of an operating license or combined license must develop, implement, and maintain a proficiency program to ensure that operators and senior operators ~~will~~ who actively perform the functions of an operator or senior operator, respectively, ~~as needed to~~ maintain proficiency with on-shift duties and familiarity with plant status. This program must include those steps ~~that will~~to be taken by an operator or senior operator prior to performing the functions of an operator or senior operator to re-establish proficiency when proficiency~~it~~ cannot be maintained. This program must be approved by the Commission as part of its approval of the OL or COL for the plant. The approved proficiency program is subject to the requirements of § 53.1565 ~~or § 53.6065, as applicable~~.

Commented [A224]: In the preamble, staff explains that the specific criteria of 55.47 for waiver of examination requirements will be shifted to guidance rather than included in the regulations. Of note, the guidance provided for this draft proposed rule, DRO-ISG-2023-01 neither cites 53.780(f) nor provides any information on criteria for waiver of examination requirements. Staff should ensure that the guidance issued for comment in conjunction with this proposed rule reflects the criteria that will be used for approval of waiver requests. Staff should notify the Commission if the criteria will be different from that of 55.47.

Commented [A225]: As drafted, this proposed requirement would not allow the holder of an OL or COL to have an operator or senior operator that does not actively perform the functions of an operator or senior operator. This could be problematic for organizations that have individuals in excess of those actually serving operators or senior operators who are licensed as such. In addition, it would be inconsistent with allowing any operator or senior operator to take family leave for the birth of a child, for example, because of the requirement for the OL/COL holder to "ensure" that they actively perform the functions and maintain proficiency.

(h) *Records*. Each record required by this ~~part~~section must be legible throughout the retention period specified by each Commission regulation. The record may be the original, a reproduced copy, or an electronic copy provided that the copy is authenticated by authorized personnel.

~~§ 53.785 Conditions of operator and senior operator licenses.~~

~~Each operator and senior operator license contains and is subject to the following conditions whether stated in the license or not:~~

~~(a) Neither the license nor any right under the license may be assigned or otherwise transferred.~~

~~(b) The license is limited to the facility for which it is issued.~~

~~(c) The license is limited to those controls of the facility or facilities specified in the license.~~

~~(d) The license is subject to, and the licensee must observe, all applicable rules, regulations, and orders of the Commission.~~

~~(e) The licensee must maintain or re-establish proficiency in accordance with the facility licensee's Commission-approved proficiency program required under § 53.780(g).~~

~~(f) The licensee must be subject to the facility's Commission-approved operator licensing requalification and requalification examination programs required under § 53.780(c).~~

~~(g) The licensee must have a biennial medical examination as described by § 53.765.~~

~~(h) The licensee must notify the Commission within 30 days about a conviction for a felony.~~

~~(i) The licensee must not consume or ingest alcoholic beverages within the protected area of commercial nuclear plants. The licensee must not use, possess, or sell~~

any illegal drugs. The licensee must not perform activities authorized by a license issued under this part while under the influence of alcohol or any prescription, over-the-counter, or illegal substance that could adversely affect his or her ability to safely and competently perform his or her licensed duties. For the purpose of this paragraph, with respect to alcoholic beverages and drugs, the term "under the influence" means the licensee exceeded, as evidenced by a confirmed test result, the lower of the cutoff levels for drugs or alcohol contained in 10 CFR part 26, or as established by the facility licensee. The term "under the influence" also means the licensee could be mentally or physically impaired as a result of substance use including prescription and over-the-counter drugs, as determined under the provisions, policies, and procedures established by the facility licensee for its FFD program, in such a manner as to adversely affect his or her ability to safely and competently perform licensed duties.

(j) Each licensee must participate in the drug and alcohol testing programs as required under 10 CFR part 26.

(k) The licensee must comply with any other conditions that the Commission may impose to protect health or to minimize danger to life or property.

§ 53.790 Issuance, modification, and revocation of operator and senior operator licenses.

(a) *Issuance of operator and senior operator licenses.* If the Commission determines that an applicant for an operator license or a senior operator license demonstrates compliance with the requirements of the AEA and its regulations, it will issue a license in the form and containing any conditions and limitations it considers appropriate and necessary.

(b) *Modification and revocation of operator and senior operator licenses.* (1) The terms and conditions of all operator and senior operator licenses are subject to

amendment, revision, or modification by reason of rules, regulations, or orders issued in accordance with the AEA or any amendments thereto.

(2) Any license may be revoked, suspended, or modified, in whole or in part—

(i) For any material false statement in the application or in any statement of fact required under section 182 of the AEA;

(ii) Because of conditions revealed by the application or statement of fact or any report, record, inspection, or other means that would warrant the Commission to refuse to grant a license on an original application;

(iii) For willful violation of, or failure to observe, any of the terms and conditions of the AEA or the license, or of any rule, regulation, or order of the Commission;

(iv) For any conduct determined by the Commission to be a hazard to safe operation of the facility; or

(v) For the sale, use, or possession of illegal drugs, or refusal to participate in the facility drug and alcohol testing program, or a confirmed positive test for drugs, drug metabolites, or alcohol in violation of the conditions and cutoff levels established by § 53.785(i) or the consumption of alcoholic beverages within the protected area of commercial nuclear plants, or a determination of unfitness for scheduled work as a result of the consumption of alcoholic beverages.

§ 53.795 Expiration and renewal of operator and senior operator licenses.

(a) *Expiration.* (1) Each operator license and senior operator license expires 6 years after the date of issuance, upon termination of employment with the facility licensee, or upon determination by the facility licensee that the licensed individual no longer needs to maintain a license.

(2) If a licensee files an application for renewal or an upgrade of an existing license on Form NRC 398 at least 30 days before the expiration of the existing license, it

does not expire until disposition of the application for renewal or for an upgraded license has been finally determined by the Commission. Filing by mail will be deemed to be complete at the time the application is postmarked

(b) *Renewal.* (1) The applicant for renewal of an operator license or senior operator license must—

(i) Complete and sign Form NRC 398 and include the number of the license for which renewal is sought.

(ii) File an original of NRC Form 398 as specified in § 53.726.

(iii) Provide written evidence of the applicant's experience under the existing license and the approximate number of hours that the licensee has operated the facility.

(iv) Provide a statement by an authorized representative of the facility licensee that during the effective term of the current license the applicant has satisfactorily completed the requalification program for the facility for which operator or senior operator license renewal is sought.

(v) Provide evidence that the applicant has discharged the license responsibilities competently and safely. The Commission may accept as evidence of the applicant's having met this requirement a certificate of an authorized representative of the facility licensee or holder of an authorization by which the licensee has been employed.

(vi) Provide certification by the facility licensee of medical condition and general health on Form NRC 396, to comply with § 53.765.

(2) The license will be renewed if the Commission finds that—

(i) The medical condition and the general health of the licensee continue to be such as not to cause operational errors that endanger public health and safety. The Commission will base this finding upon the certification by the facility licensee as described in § 53.765(b).

~~(ii) The licensee –~~

~~(A) Is capable of continuing to competently and safely assume licensed duties;~~

~~(B) Has successfully completed a requalification program that has been approved by the Commission as required by § 53.780(c); and~~

~~(C) Has passed the requalification examinations as required by § 53.780(c).~~

~~(iii) There is a continued need for an operator to operate or for a senior operator to supervise operators at the facility designated in the application.~~

~~(iv) The past performance of the licensee has been satisfactory to the Commission. In making its finding, the Commission will include in its evaluation information such as notices of violations or letters of reprimand in the licensee's docket.~~

§ 53.800 ~~Facility licensees for s~~Self-reliant-mitigation facilities.

(a) A commercial nuclear plant is a self-reliant-mitigation facility if the NRC determined as part of its approval of the OL or COL for that plant that its design demonstrates compliance with criteria (a)(1) though (a)(~~5~~4) of this section. A self-reliant-mitigation facility is of a class, based upon the similarity of operating and technical characteristics of the plants in the class, such that its licensee must comply with the requirements of §§ 53.800 through 53.820 in lieu of those in §§ 53.760 through 53.78095.

(1) ~~The following safety performance criteria of either Framework A or B of this part, as applicable, must be met without reliance upon human action for credited event mitigation:~~

~~(i) Under Framework A of this part, the safety criteria of §§ 53.210 and 53.220 and, if applicable, any alternative criteria used in accordance with § 53.470.~~

~~(ii) Under Framework B of this part, the safety assessment performed under § 53.4730(a)(1)(vi) and the criteria of § 53.4730(a)(34)(ii) for.~~

~~(A) Additionally, those commercial nuclear plants performing alternative evaluations for risk insights must further demonstrate that the qualification of § 53.4730(a)(34)(ii) will also be met without reliance upon credited human actions.~~

~~(B) [Reserved]~~

~~(2)~~ The results of ~~a probabilistic risk analysis or, as permitted by § 53.4730(a)(34), an alternative evaluation for risk insights~~the risk evaluation under ~~, must demonstrate that the evaluation criteria for the events analyzed in accordance with~~ § 53.450 must demonstrate that the evaluation criteria in §§ 53.210 and 53.220 ~~in Framework A or § 53.4730 in Framework B~~ will be met without reliance on human actions to achieve acceptable event mitigation.

(2~~3~~) The functional requirements analysis and function allocation performed under § 53.730(d) must demonstrate that functions required for safety are not reliant upon credited human action.

(3~~4~~) The plant response to events analyzed under~~in accordance with~~ § 53.450 in ~~Framework A of this part or § 53.4730 in Framework B of this part~~ must rely exclusively on safety features and characteristics that will neither be rendered unavailable by credible human errors of commission or omission nor credibly require manual human operation in response to equipment failures. Compliance with this paragraph may be achieved through the use of structures, systems, and components~~SSCs~~ that function through inherent characteristics or that have engineered protections against human failures.

(4~~5~~) The plant design must provide for a layered defense-in-depth approach that is not dependent upon any single barrier or credited human action.

(b) [Reserved]

§ 53.805 ~~Facility licensee requirements~~ Conditions of licenses for commercial nuclear plants related to generally licensed reactor operators.

(a) ~~Licensees~~ Holders of operating licenses or combined licenses for self-reliant-mitigation facilities that have not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070 ~~or § 53.4670, as applicable,~~ must ~~demonstrate compliance with the following requirements:~~

(1) Ensure that, in addition to being qualified to perform~~ing~~ those items identified by the facility-specific systems approach to training conducted under § 53.815, generally licensed reactor operators are qualified to safely and competently—

(i) Perform administrative tasks, including compliance with technical specifications, and perform operability determinations;

(ii) Implement maintenance and configuration controls;

(iii) Comply with radioactive release limitations;

(iv) Understand plant operating data, including reactor parameters, and evaluate emergency conditions;

(v) Initiate a reactor shutdown from necessary locations;

(vi) Dispatch and direct operations and maintenance personnel;

(vii) Implement any applicable responsibilities under the facility emergency plan; and

(viii) Make required notifications to local, State, participating Tribal and Federal authorities.

(2) [Reserved] ~~Develop, implement, and maintain facility technical specifications that provide the necessary administrative controls to ensure the implementation of these requirements.~~

Commented [A226]: As drafted, the term "licensees for self-reliant-mitigation facilities" under 53.725(c) would mean generally licensed reactor operators for such facilities rather than the holder of the operating licenses or combined licenses for the facilities. Even with the edits in this document the term "licensees for self-reliant-mitigation facilities" is too broad because it could include CP holders and COL holders before the finding.

Commented [A227]: Edited to use a terminal em dash for the line and eliminate the phrase "demonstrate compliance with the following requirements." The use of that phrase has the potential to complicate the development of "contrary to" statements in enforcement if it becomes necessary to do so. It would also be awkward to be evaluating the demonstration of compliance rather than the actual compliance.

Commented [A228]: Moved to 53.710(a)(5).

(3) Develop, implement, and maintain the generally licensed reactor operator training, examination, and proficiency programs required under § 53.815.

(4) Ensure that generally licensed reactor operators are subject to the facility's generally licensed reactor operator training, examination, and proficiency programs required under § 53.815. Ensure that generally licensed reactor operators are subject to and comply with the applicable programmatic requirements for plant personnel required under 10 CFR parts 26 and 73. An individual that is not in compliance with any of these programs is not qualified to be in a position that may involve the manipulation of the controls of the commercial nuclear plant.

(5) Report annually to the NRC the identity of all generally licensed reactor operators at the commercial nuclear plant, including all additions and deletions since the previous report.

(6) Ensure that the ~~facility design~~commercial nuclear plant continues to meet the criteria of § 53.800.

(b) [Reserved]

§ 53.810 Generally licensed reactor operators.

(a) A general license to manipulate the controls of a self-reliant-mitigation facility and to direct the licensed activities of generally licensed reactor operators is hereby issued to any individual employed in a position that may involve the manipulation of the controls of that self-reliant-mitigation facility and who observes the restrictions of this section.

(b) A generally licensed reactor operator must ~~observe~~ comply with the operating procedures and other conditions specified in the license authorizing operation of the facility.

(c) The general license is limited to the ~~facility or facilities~~commercial nuclear plant(s) at which the operator is employed.

(d) ~~The Commission will suspend the general license on an individual basis for violations of any provision of the Act~~EA or any rule or regulation issued thereunder ~~whenever the Commission deems such suspension desirable, including—~~

~~(1) For willful violation of, or failure to observe, any of the terms and conditions of the Act~~EA or the general license, or of any rule, regulation, or order of the Commission;

~~(2) For any conduct determined by the Commission to be a hazard to safe operation of the facility~~commercial nuclear plant; ~~or~~

~~(3) For the sale, use, or possession of illegal drugs, or refusal to participate in the facility drug and alcohol testing program, or a confirmed positive test for drugs, drug metabolites, or alcohol in violation of the conditions and cutoff levels established by § 53.810(f) or the consumption of alcoholic beverages within the protected area of commercial nuclear plants, or a determination of unfitness for scheduled work as a result of the consumption of alcoholic beverages.~~

Commented [A229]: Moved to paragraph (f) of this section in order to place the potential for suspension of the general license under subparagraph (3) of this provision after the license condition prohibiting the activities identified in subparagraph (3).

~~(e)~~ The Commission may require information from a generally licensed reactor operator to determine whether a general license should be revoked or suspended with respect to that operator.

(~~f~~e) The generally licensed reactor operator must not consume or ingest alcoholic beverages within the protected area of commercial nuclear plants, or power reactors, or the controlled access area on non-power utilization facilities. The generally licensed reactor operator must not use, possess, or sell any illegal drugs. The generally licensed reactor operator must not perform activities requiring a general license while under the influence of alcohol or any prescription, over-the-counter, or illegal substance that could adversely affect his or her ability to safely and competently perform these activities. For

the purpose of this paragraph, with respect to alcoholic beverages and drugs, the term "under the influence" means the generally licensed reactor operator exceeded, as evidenced by a confirmed test result, the lower of the cutoff levels for drugs, drug metabolites, or alcohol contained in 10 CFR part 26, or as established by the ~~facility licensee~~holder of the operating license or combined license. The term "under the influence" also means the generally licensed reactor operator could be mentally or physically impaired as a result of substance use including prescription and over-the-counter drugs, as determined under the provisions, policies, and procedures established by the ~~facility licensee~~holder of the operating license or combined license for its fitness for duty~~FFD~~ program, in such a manner as to adversely affect his or her ability to safely and competently perform generally licensed reactor operator duties.

(f) The Commission will suspend the general license on an individual basis for violations of any provision of the Act or any rule or regulation issued thereunder whenever the Commission deems such suspension desirable, including—

(1) For willful violation of, or failure to observe, any of the terms and conditions of the Act or the general license, or of any rule, regulation, or order of the Commission;

(2) For any conduct determined by the Commission to be a hazard to safe operation of the commercial nuclear plant; or

(3) For the sale, use, or possession of illegal drugs, or refusal to participate in the facility drug and alcohol testing program, or a confirmed positive test for drugs, drug metabolites, or alcohol in violation of the conditions and cutoff levels established by § 53.810(f) or the consumption of alcoholic beverages within the protected area of commercial nuclear plants, or power reactors, or the controlled access area on non-power utilization facilities, or a determination of unfitness for scheduled work as a result of the consumption of alcoholic beverages

(g) The generally licensed reactor operator must notify the Commission within 30 days about a conviction for a felony.

§ 53.815 Generally licensed reactor operator training, examination, and proficiency programs.

(a) *Applicability*. The requirements of this section apply to each ~~licensee~~ holder of an operating license or combined license for a self-reliant-mitigation facility that has not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070 or § 53.4670, as applicable.

(b) *Requirements*. (1) The licensee must develop, implement, and maintain training and examination programs that demonstrate compliance with the requirements of paragraphs (b)(2) through (b)(3) of this section.

(2) The training program must provide for both the initial and continuing training of generally licensed reactor operators and be derived from a systems approach to training as defined in this part.

(3)(i) The training program must incorporate the instructional requirements necessary to provide qualified generally licensed reactor operators to operate and maintain the facility in a safe manner in all modes of operation. The training program must comply with the ~~facility~~ license for the commercial nuclear plant, including all technical specifications and applicable regulations. The ~~facility licensee~~holder of the operating license or combined license must periodically evaluate and revise the training program as appropriate to reflect industry experience and relevant changes, including changes to the ~~facility~~commercial nuclear plant, procedures, regulations, and QA requirements. ~~Facility licensee management~~The holder of the operating license or combined license must periodically review the training program for effectiveness.

(ii) The training program must ~~ensure~~ enable th~~eat~~ generally licensed reactor operators to acquire~~have~~ and maintain the necessary knowledge, skills, and abilities.

(iii) The training program must include the generally licensed reactor operator manipulating the controls of either the ~~facility~~ commercial nuclear plant or a simulation facility that demonstrates compliance with the requirements of § 53.815(e).

(iv) The training program must include an initial examination program for testing a representative sample of the knowledge, skills, and abilities needed to safely perform generally licensed reactor operator duties, to include both the examination methods and criteria to be used to assess passing performance. The ~~facility licensee~~holder of the operating license or combined license must provide the opportunity for a representative of the Commission to be present during initial examination administration.

(v) The training program must include a requalification examination program for testing a sample of the topics included under the systems approach to training, to include the examination methods and criteria to be used to assess passing performance. The requalification examination program must specify an appropriate periodicity for administering a complete requalification examination to each generally licensed reactor operator, and the holder of the operating license or combined license~~facility licensee~~ must provide the opportunity for a representative of the Commission to be present during requalification examination administration.

(A) The holder of the operating license or combined license~~facility licensee~~ must ensure that any generally licensed reactor operator who either demonstrates unsatisfactory performance on, or fails to complete, the requalification examination is removed from the performance of generally licensed reactor operator duties until such time that any necessary remedial training has been completed and a retake examination has been passed.

(B) [Reserved]

(vi) The training program must be approved by the Commission prior to its use, as described under § 53.730(g). The examination program must provide for valid and reliable examinations and must be approved by the Commission prior to ~~their~~ its use, as described under § 53.730(g). The approved programs are subject to the requirements of § 53.1565 ~~or § 53.6065, as applicable~~.

Commented [A230]: Under 53.730(g), as drafted by the staff, it is the examination program that must be approved by the Commission prior to use rather than the individual examinations.

(c) *Records.* The following is required regarding the documentation of the generally licensed reactor operator training and examination programs:

(1) Sufficient records must be maintained by the holder of the operating license or combined license~~facility licensee~~ to maintain the integrity of the programs and kept available for NRC inspection to verify the adequacy of the programs.

(2) The holder of the operating license or combined license ~~facility licensee~~ must maintain records documenting the participation of each generally licensed reactor operator in the training and examination programs. The records must contain copies of examinations administered, the answers given by the generally licensed reactor operator, documentation of the grading of examinations, and documentation of any additional training administered in areas in which a generally licensed reactor operator exhibited deficiencies. The holder of the operating license or combined license~~facility licensee~~ must retain these records while the associated generally licensed reactor operators remain employed at the facility.

(3) Each record required by this part must be legible throughout the retention period. The record may be the original, a reproduced copy, or an electronic copy provided that the copy is authenticated by authorized personnel.

(d) *Examination integrity.* Generally licensed reactor operators and ~~facility licensees~~holders of operating licenses and combined licenses must not engage in any

activity that compromises the integrity of any examination conducted under the generally licensed reactor operator training and examination programs. The integrity of an examination is considered compromised if any activity, regardless of intent, affected, or, but for detection, could have affected the equitable and consistent administration of the examination. This includes all activities related to the preparation, administration, and grading of examinations.

(e) *Simulation facilities.* (1) Simulation facilities used for training purposes, for maintaining proficiency, or for the conduct of examinations must demonstrate compliance with the following criteria as they relate to the ~~facility licensee's~~ reference plant:

(i) The simulation facility must be of sufficient scope and fidelity for individuals to acquire and demonstrate the necessary knowledge, skills, and abilities to safely perform generally licensed reactor operator duties.

(ii) The simulation facility must utilize models relating to nuclear, thermal-hydraulic, and other applicable design-specific characteristics that either replicate the most recent fuel load in the reference ~~commercial nuclear~~ plant or, prior to initial fuel load, replicate the intended initial fuel load for the reference ~~commercial nuclear~~ plant, with the exception of those portions of the simulation facility that utilize the reference plant itself.

(iii) Simulator fidelity must be demonstrated so that significant control manipulations are completed without procedural exceptions, simulator performance exceptions, or deviation from the approved training scenario sequence.

(2) ~~Facility licensees~~Holders of operating licenses and combined licenses that maintain a simulation facility for training purposes, for maintaining proficiency, or for the conduct of examinations must—

(i) Conduct performance testing throughout the life of the simulation facility in a manner sufficient to ensure that paragraph (e)(1) of this section is met;

(ii) Retain the results of performance testing for 4 years after the completion of each performance test or until superseded by updated test results;

(iii) Promptly correct modeling and hardware discrepancies and discrepancies identified from scenario validation and from performance testing or provide justification for why the presence of such discrepancies will not adversely affect the criteria of paragraph (e)(1) of this section;

(iv) Make the results of any uncorrected performance test failures that may exist at the time of an inspection available for NRC review; and

(v) Maintain the provisions for examination integrity consistent with § 53.815(d).

(f) *Waiver of examination requirement*. The ~~facility licensee~~holder of an operating license or combined license may waive any or all of the requirements for an examination in accordance with the facility licensee's Commission-approved generally licensed reactor operator training and examination programs.

(g) *Proficiency*. The holder of the operating license or combined license~~facility licensee~~ must develop, implement, and maintain a proficiency program to ~~ensure~~ allow that generally licensed reactor operators ~~will~~ to maintain proficiency regarding position functions and familiarity with plant status. This program must include those steps that will be taken in order to re-establish proficiency when it cannot be maintained.

§ 53.820 Cessation of individual applicability.

The general license ceases to be applicable on an individual basis once a generally licensed reactor operator is no longer being employed in a position that may involve the manipulation of the controls of the self-reliant mitigation facility.

§ 53.830 Training and qualification of commercial nuclear plant personnel.

(a) This section addresses personnel training requirements. The regulations within this section are applicable to all applicants for or holders of O~~l~~Ls or COLs under this part.

(b) Prior to fuel load, each holder of an operating or COL under this part must, with sufficient time to provide trained and qualified personnel to operate the ~~facility~~commercial nuclear plant, establish, implement, and maintain a training program that demonstrates compliance with the requirements of paragraphs (c) and (d) of this section.

(c) The training program must be derived from a systems approach to training as defined in this part and must provide, at a minimum, for the training and qualification of the following categories of commercial nuclear plant personnel:

(1) Supervisors (e.g., shift supervisors);

(2) Technicians (e.g., maintenance, chemistry, and radiological); and

(3) Other appropriate operating personnel (e.g., auxiliary operators, certified fuel handlers, and individuals who provide engineering expertise to on-shift operating personnel).

(d) The training program must incorporate the instructional requirements necessary to provide qualified personnel to operate components of a commercial nuclear plant and maintain the ~~facility~~ commercial nuclear plant in a safe manner in all modes of operation. The training program must be developed to be in compliance with the facility license, including all technical specifications and applicable regulations.

(1) The training program must be periodically evaluated and revised as appropriate to reflect industry experience and relevant changes, including changes to the ~~facility~~commercial nuclear plant, procedures, regulations, and QA requirements. The

training program must be periodically reviewed ~~by facility licensee management~~ for effectiveness.

(2) Sufficient records must be maintained by the holder of the operating license or combined license~~facility licensee~~ to maintain program integrity and kept available for NRC inspection to verify the adequacy of the training program.

§ 53.845 Programs.

(a) The required plant programs under ~~Framework A of~~ this part ~~must~~ include ~~but are not necessarily limited to~~ the programs described in the following sections of this subpart. Licensees may combine, separate, and otherwise organize programs and related documents as appropriate for the technologies and organizations associated with the commercial nuclear plant.

(b) [Reserved]~~In addition to the programs described in the following sections, programs must be provided for each commercial nuclear plant, if necessary, to ensure that the performance of design features and human actions are consistent with the analyses performed under §§ 53.450 and 53.730 and that the plant will demonstrate compliance with the safety criteria defined in §§ 53.210 and 53.220~~.

Commented [A231]: This paragraph is redundant to the requirement for administrative controls in the technical specifications that would be required under 53.710(a)(5) and (c)(5) and the controls for NSRSS SSCs under 53.710(b).

§ 53.850 Radiation protection.

~~(a) Each holder of an OL or COL under Framework A of this part must develop, implement, and maintain a Radiation Protection Program for operations that is commensurate with the scope and extent of licensed activities under this part and includes measures for limiting and monitoring radioactive plant effluents and limiting and monitoring the dose to individuals working with radioactive materials in accordance with 10 CFR part 20.~~

Commented [A232]: This is redundant to the requirements of part 20, which would be made applicable by the conforming changes proposed in 20.1002. Including this as a requirement here while omitting it from subpart G runs the risk of unintended consequences by conveying to the uninformed reader that part 20 is made applicable during the operations phase by this section rather than by its own terms and that no radiation protection program is required for a commercial nuclear plant no longer in the operations phase.

Staff should limit the codification of requirements contained elsewhere in the Commission's regulations and are self-executing to the content of applications requirements where appropriate for programs that will be reviewed as a part of an approval process for the license. If review is not necessary as part of the approval process for the license, the reference to these programs should be moved to guidance or left for industry to address in industry-controlled guidelines.

~~(b)~~ Each holder of an operating license~~OL~~ or combined license~~COL~~ under ~~Framework A of~~ this part must develop, implement, and maintain a program for the

control of radioactive effluents and for keeping the doses to members of the public from radioactive effluents as low as is reasonably achievable. The program must be ~~contained in an Offsite Dose Calculations Manual (ODCM), must be~~ implemented by procedures~~,~~ and must include remedial actions to be taken whenever the program limits are exceeded. ~~The ODCM must—~~

~~(1) Contain the methodology and parameters used in the calculation of offsite doses resulting from radioactive gaseous and liquid effluents, in the calculation of gaseous and liquid effluent monitoring alarm and trip setpoints, and in the conduct of the radiological environmental monitoring program; and~~

~~(2) Contain the radioactive effluent controls and radiological environmental monitoring activities, and descriptions of the information that should be included in the Annual Radiological Environmental Operating and Radioactive Effluent Release Reports required by § 53.1645.~~

Commented [A233]: Staff should move to guidance or justify the reasons for including these prescriptive items in part 53 when they are absent from parts 50 and 52.

~~(c) Each licensee under Framework A of this part must develop, implement, and maintain a Process Control Program that identifies the administrative and operational controls for solid radioactive waste processing, process parameters, and surveillance requirements sufficient to ensure compliance with the requirements of 10 CFR part 20, 10 CFR part 61, and 10 CFR part 71.~~

Commented [A234]: Staff should move to guidance.

§ 53.855 Emergency preparedness.

~~(a)~~ Each holder of an operating license~~OL~~ or combined license~~COL~~ under this part must ~~develop~~ have an emergency response plan ~~which must contain information needed to demonstrate compliance with the requirements in~~under appendix E to 10 CFR part 50 and § 50.47 of this chapter.

Commented [A235]: This draft proposed requirement appears to be misplaced due to the limitation of 50.47(a) that had been included in the draft proposed 53.855(b), which would prevent issuing a license authorizing operation of the commercial nuclear plant without the emergency response plan. As a result, the development of the plan, which is the sole proposed requirement in this paragraph, would have taken place prior to the operation phase that is the subject of this subpart.

Staff should evaluate whether it is appropriate to include requirements to "develop" programs that are intended to be in place throughout the entirety of the operations phase in this subpart rather than during the application or construction phase and propose revisions to account for the natural progression of a commercial nuclear plant through its review, approval, construction, and operation phases.

~~(b) No initial operating license, initial combined license, or early site permit that includes complete and integrated emergency plans will be issued under of this part~~

~~unless a finding is made by the NRC, in accordance with § 50.47 of this chapter, that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency~~.

§ 53.860 Security and fitness for duty programs.

(a) *Physical ~~P~~protection ~~P~~program*. Each holder of an operating license (OL) or combined license (COL) under ~~Framework A of~~ this part must ~~develop, implement, and maintain~~have a physical protection program ~~demonstrating compliance with~~under the following requirements:

(1) The licensee must implement security requirements for the protection of SNM based on the type, enrichment, and quantity in accordance with 10 CFR part 73, as applicable, and implement security requirements for the protection of Category 1 and Category 2 quantities of radioactive material in accordance with 10 CFR part 37, as applicable; and

(2) The licensee must ~~demonstrate compliance with the provisions set forth in~~develop, implement, and maintain a physical protection program for SNM based on the type, enrichment, and quantity under either § 73.55 or § 73.100 of this chapter, unless the licensee performs a site-specific analysis, including identification of target sets, to show that the need for physical protection of SNM is met through design and engineered safety features under § 53.440(f) of this part by demonstrating that the radiological consequences from a design basis threat initiated event involving the loss of engineered systems for decay heat removal and possible breaches in physical structures surrounding the reactor, spent fuel, and other inventories of radioactive materials result in offsite doses below the values in § 53.210. The analysis must assume that licensee mitigation and recovery actions, including any operator actions, are unavailable or ineffective. The licensee must maintain the analysis until the

Commented [A236]: Deleted as redundant to the requirements in 50.47(a). Note that the limitation also applies to initial combined licenses under part 52 and there is no corresponding repetition of the limitation in that part. In addition, the limitation of this paragraph cannot apply during the operational phase that is the subject of this subpart because it would prevent the issuance of the required OL or COL and the ESP would not permit operations.

Commented [A237]: As drafted, paragraph (a)(1) would have required a licensee to develop, implement, and maintain a physical security program under part 73 regardless of the outcome of the analysis in paragraph (a)(2)(ii) with respect to the criterion of paragraph (a)(2)(i). Having developed, implemented, and being in the state of maintaining such a program, a licensee performing an analysis under paragraph (a)(2)(ii) to demonstrate that the criterion of paragraph (a)(2)(i) would merely be relieved of the need to demonstrate that the physical security program under part 73 complies with the provisions of either 73.55 or 73.100. That is to say, the sole benefit of meeting the criterion would be relief from a requirement for demonstration of compliance while there would nevertheless be a requirement to develop, implement, and maintain the program under part 73.

This section is edited to make the need for development, implementation, and maintenance of a physical security program under part 73 contingent on the status of the optional analysis with respect to the criterion.

Commented [A238]: As discussed in the comment on 53.855, the requirement to develop this program seems misplaced because it would be necessary to accomplish the development and implementation prior to the operations phase. Staff should evaluate the appropriate location for this set of requirements.

permanent cessation of operations and permanent removal of fuel from the reactor vessel is certified as described under § 53.1070.~~demonstrates compliance with the following criterion:~~

~~(i) The radiological consequences from a design basis threat initiated event involving the loss of engineered systems for decay heat removal and possible breaches in physical structures surrounding the reactor, spent fuel, and other inventories of radioactive materials result in offsite doses below the values in § 53.210.~~

~~(ii) The applicant must perform a site-specific analysis, including identification of target sets, to demonstrate that the criterion in § 53.860(a)(2)(i) is satisfied. The analysis must assume that licensee mitigation and recovery actions, including any operator actions, are unavailable or ineffective. The licensee must maintain the analysis until the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070.~~

(b) *Fitness for ~~D~~duty*. Each holder of an OL or COL under ~~Framework A of~~ this part must develop, implement, and maintain a~~n~~ fitness for duty~~FFD~~ program ~~that demonstrates compliance with the requirements in~~under 10 CFR part 26.

Commented [A239]: As discussed in the comment on 53.855(a), the requirement to develop this program seems misplaced because it would be necessary to accomplish the development and implementation prior to the operations phase. Staff should evaluate the appropriate location for this set of requirements.

(c) *Access ~~A~~authorization*. Each holder of an OL or COL under ~~Framework A of~~ this part must develop, implement, and maintain an access authorization program ~~that demonstrates compliance with the requirements in~~under § 73.120 of this chapter if the criterion in § 53.860(a)(2)~~(i)~~ is satisfied, or the requirements in § 73.56 of this chapter if the criterion is not satisfied.

Commented [A240]: As discussed in the comment on 53.855(a), the requirement to develop this program seems misplaced because it would be necessary to accomplish the development and implementation prior to the operations phase. Staff should evaluate the appropriate location for this set of requirements.

(d) *Cyber security*. Each holder of an OL or COL under ~~Framework A of~~ this part must develop, implement, and maintain a cyber security program ~~that demonstrates compliance with the requirements in~~under § 73.54 or § 73.110 of this chapter.

Commented [A241]: As discussed in the comment on 53.855(a), the requirement to develop this program seems misplaced because it would be necessary to accomplish the development and implementation prior to the operations phase. Staff should evaluate the appropriate location for this set of requirements.

(e) *Information ~~S~~security*. Each holder of an OL or COL under ~~Framework A of~~ this part must develop, implement, and maintain an information protection system ~~that demonstrates compliance with the requirements of~~under §§ 73.21, 73.22, and 73.23 of this chapter, as applicable.

§ 53.865 Quality assurance.

Each holder of an operating license~~OL~~ or combined license~~COL~~ under ~~Framework A of~~ this part must develop, implement, and maintain a quality assurance program (QAP) ~~in accordance with subpart K~~under appendix B to part 50 of this ~~part~~chapter. ~~A written QAP manual must be developed and used to guide the conduct of the program in accordance with generally accepted consensus codes and standards that have been endorsed or otherwise found acceptable by the NRC.~~

~~**§ 53.870 Integrity assessment programs.**~~

~~Each holder of an OL or COL under Framework A of this part must develop, implement, and maintain an integrity assessment program to monitor, evaluate, and manage—~~

~~(a) The effects of plant aging on SR and NSRSS SSCs. The program may refer to surveillances, tests, and inspections conducted for specific SSCs in accordance with other requirements in this part or conducted in accordance with applicable consensus codes and standards endorsed or otherwise found acceptable by the NRC;~~

~~(b) Cyclic or transient load limits to ensure that SR and NSRSS SSCs are maintained within the applicable design limits; and~~

~~(c) Degradation mechanisms related to chemical interactions, operating temperatures, effects of irradiation, and other environmental factors to ensure that the capabilities, availability, and reliability of SR and NSRSS SSCs demonstrate compliance with the functional design criteria of §§ 53.410 and 53.420~~.

Commented [A242]: As discussed in the comment on 53.855(a), the requirement to develop this program seems misplaced because it would be necessary to accomplish the development and implementation prior to the operations phase. Staff should evaluate the appropriate location for this set of requirements.

Commented [A243]: As discussed in the comment on 53.855(a), the requirement to develop this program seems misplaced because it would be necessary to accomplish the development and implementation prior to the operations phase. Staff should evaluate the appropriate location for this set of requirements.

Commented [A244]: This is more prescriptive than the requirements in part 50 or 52. In addition, it would be an improper incorporation by reference of unnamed codes and standards in the regulations.

Commented [A245]: This paragraph would impose requirements for an aging management program on advanced reactors during the initial term of operation. This is an additional imposition on advanced reactors in this part that does not exist in part 50 or part 52 and is therefore in conflict with Commission direction to regulate advanced reactors no more strictly than currently operating reactors.

§ 53.875 Fire protection.

(a)(1) Each holder of an operating license (OL) or combined license (COL) under ~~Framework A of~~ this part must have a fire protection plan that describes the overall fire protection program for the facility; identifies the various positions within the licensee's organization that are responsible for the program; states the authorities that are delegated to each of these positions to implement those responsibilities; and outlines the plans for fire protection, fire detection and suppression capability; and limitation of fire damage.

(2) The fire protection plan must also describe specific features necessary to implement the program described in paragraph (a)(1) of this section such as the following: administrative controls and personnel requirements for fire prevention and manual fire suppression activities; automatic and manually operated fire detection and suppression systems; and the means to limit fire damage to ~~SR and NSRSS SSCs~~structures, systems, and components (SSCs) so that the capability to demonstrate compliance with the requirements of § 53.210 is ensured.

(b)~~(1)~~ Each holder of an OL or COL under ~~Framework A of~~ this part must develop a performance-based or deterministic fire protection program that demonstrates compliance with the safety criteria outlined in §§ 53.210 and 53.220, related safety functions outlined in § 53.230, and defense in depth as outlined in § 53.250 with specific fire protection measures related to fire prevention, fire detection, and fire suppression.

~~(2) The fire protection program must comply with the following:~~

~~(i) SR and NSRSS SSCs must be designed, located, and maintained to minimize, consistent with other safety requirements, the probability and effect of fires and explosions.~~

~~(ii) Noncombustible and fire-resistant materials must be used wherever practical throughout the facility, particularly in locations with SR and NSRSS SSCs.~~

~~(iii) Fire detection and fire suppression systems of appropriate capacity and capability must be provided and designed and maintained to minimize the adverse effects of fires on SR and NSRSS SSCs.~~

~~(iv) Fire suppression systems must be designed and maintained to ensure that their rupture or inadvertent operation does not significantly impair the ability of SR and NSRSS SSCs to perform their safety functions to satisfy § 53.230.~~

Commented [A246]: This merely repeats the draft proposed requirements of 53.440(e).

§ 53.880 Inservice inspection and inservice testing.

(a) Each holder of an OL or COL under ~~Framework A of~~ this part must develop, implement, and maintain a program for inservice inspection (ISI) and inservice testing (IST) ~~prior to receiving an OL or COL~~. ~~The ISI/IST programs must, wherever applicable, be in accordance with generally accepted consensus codes and standards that have been endorsed or otherwise found acceptable by the NRC.~~ The ISI/IST program must ~~include all inspections and tests required by the codes and standards used in the design and~~ be supplemented by risk insights that identify the most important SSCs to plant safety. The types of testing and inspections and their frequency should be informed by risk insights to maintain the reliability and performance of SSCs consistent with the associated design and analyses activities involving those SSCs. Risk insights must also be used to determine when to conduct the inspections and tests (e.g., full power, shutdown, refueling) to minimize risk to the plant workers and the public. ~~The ISI/IST program must be documented in a written manual and managed by qualified personnel reporting to the Plant Manager.~~

Commented [A247]: As discussed in the comment on 53.855(a), the requirement to develop this program seems misplaced because it would be necessary to accomplish the development and implementation prior to the operations phase. Staff should evaluate the appropriate location for this set of requirements.

Commented [A248]: As drafted, this sentence would limit the requirement to maintain the ISI/IST programs to "prior to receiving an OL or COL".

Commented [A249]: Staff should address the use of codes and standards in guidance or identify them with sufficient specificity to meet the OFR requirements for incorporation by reference in the regulations. Note that as drafted, this would require inclusion of all inspections and tests required by the codes and standards used in the design without regard to any limitations and conditions the NRC determines necessary for those codes and standards to be acceptable.

Commented [A250]: This prescriptive draft proposed requirement is not imposed upon currently operating reactors.

(b) Prior to plant operation, baseline inspections and testing must be performed using the same techniques as will be used for future inspections and testing. The results

Commented [A251]: This is outside the scope of the operations phase, which is the subject of subpart F.

of these inspections and testing must be used as benchmarks for evaluating the results of future inspections and testing. ~~Sufficient room and support must be provided to accommodate the personnel, ISI/IST equipment, and shielding necessary to perform the inspections and testing.~~ Acceptance criteria for determining whether corrective action is needed must be developed ~~(or taken from the codes and standards used in the design)~~ for evaluating the results of the inspections and testing. ~~The results of the inspections and testing must be provided to the Plant Manager who is responsible for determining what, if any, corrective action is needed and when it should be taken.~~ The ISI/IST results and corrective actions must be documented and the documentation retained ~~for the life of the plant~~until certification by the licensee of permanent cessation of operation and removal of fuel from the reactor vessel under § 53.1070.

Commented [A252]: Moved to 53.440(p).

Commented [A253]: Staff should address in guidance. Note that the development of acceptance criteria can be done by reference to codes and standards without a need for this parenthetical note in the regulation.

Commented [A254]: The allocation of responsibilities to particular individuals in the organization of the commercial nuclear plant is prescriptive and should be left to the licensee to decide as a part of their ISI/IST program or QA program development.

Commented [A255]: Staff should evaluate whether retention of these records should be required beyond the date of the certifications under 53.1070 in order to support reasonable assurance that the SSCs relied upon for safe decommissioning of the plant will be able to perform any necessary safety functions during decommissioning and make appropriate edits.

~~**§ 53.890 Facility safety program.**~~

~~(a) Each holder of an OL or COL under Framework A of this part must develop, implement, and maintain an FSP that includes a risk-informed, performance-based process to identify new or revised internal or external hazards to the facility and performance issues related to plant SSCs, programmatic controls, and human actions; assess changes in the risks posed to the public from the commercial nuclear plant; and, when appropriate, consider measures to mitigate or eliminate the resulting risks.~~

~~(b)(1) Each licensee must implement risk reduction measures as may be appropriate when considering potential risks to public health and safety, technology changes, economic costs, operating experience, new or revised hazard assessments, or other factors included in the FSP plan required by paragraph (c) of this section.~~

~~(2) Each licensee must develop, implement, and maintain a process to routinely assess potential changes in contributors to plant risks and identify when to assess potential risk reduction measures related to internal and external events, identified~~

hazards, or other specific contributors to the overall cumulative risk from unplanned events. The process must, at a minimum, assess potential risk reduction measures when—

(i) The estimated frequency-weighted cumulative dose to nearby populations increases by 5 person-rem due to a new or revised hazard or could be decreased by 5 person-rem by a risk reduction measure; and

(ii) There is a significant reduction in or possibility to significantly increase the calculated margins between the frequency and consequences of LBEs and the evaluation criteria in § 53.450(e) or more restrictive alternate criteria adopted under § 53.470.

(3) Possible risk reduction measures for commercial nuclear plants whose licenses refer to certified designs or MLs must also follow the change control and reporting provisions of subpart I related to changes to standardized designs. Licensees need not pursue risk reduction measures under this section if the only cost-effective measures would require a license amendment or exemption under subpart I due to references to a certified design or ML.

(c)(1) Each licensee subject to this section must adopt and implement an FSP under paragraph (b) of this section by using a written FSP plan that, at a minimum, describes the facility or facilities covered by the plan; facility environs that influence the assessments; and how the FSP addresses the role of and operating experience with SSCs, personnel, and programmatic controls supporting the safety functions required by § 53.230.

(2) Each FSP plan must also describe—

(i) The methods used to identify and analyze current, new, or novel technologies that will mitigate or eliminate internal or external hazards and resulting risks from the release of radioactive materials;

(ii) The licensee's overall safety philosophy and intended safety culture to be practiced by its management, employees, and contractors;

(iii) The required participants in the FSP, which will include managers, employees, and contractors that directly support facility operations; maintain, inspect, or change plant SSCs or programmatic controls; or assess potential risk reduction measures;

(iv) The FSP-related training program; and

(v) Periodic reviews of the effectiveness of the FSP and its implementation.

(d) The NRC will review the FSP plan as part of the applications for an OL or COL under subpart H. Approval of an FSP plan under Framework A of this part does not constitute approval of the specific actions the licensee will implement under its FSP plan pursuant to this section and must not be construed as establishing an NRC standard regarding those specific actions.

(e) Updates and revisions to the FSP plan must be provided biennially or more frequently in accordance with § 53.1560 and the licensee must obtain NRC approval of a proposed change in accordance with § 53.1565 if its implementation requires an exemption from the requirements in this section.

§ 53.910 Procedures and guidelines.

(a) Each holder of an OL or COL under Framework A of this part must have a program for developing, implementing, and maintaining an integrated set of procedures, guidelines, and related supporting activities to support normal operations and respond to possible unplanned events.

(b) The program required by paragraph (a) of this section must include but is not limited to development, implementation, maintenance, and supporting activities of procedures and guidelines for the following:

(1) Plant operations;

(2) Maintenance activities under § 53.715;

(3) Program requirements under this subpart F of this part;

(4) Emergency operating procedures, if developed to address the role of human actions in responding to LBEs;

(5) Accident management guidelines, if developed to address the role of human actions in responding to LBEs;

(6) Procedures for each area in which licensed SNM is handled, used, or stored to protect personnel upon the sounding of a criticality alarm required by § 53.440(m); and

(7) Procedures that describe how the licensee will address the following areas if the licensee is notified of a potential aircraft threat:

(i) Verification of the authenticity of threat notifications;

(ii) Maintenance of continuous communication with threat notification sources;

(iii) Contacting all onsite personnel and applicable offsite response organizations;

(iv) Onsite actions necessary to enhance the capability of the facility to mitigate the consequences of an aircraft impact;

(v) Measures to reduce visual discrimination of the site relative to its surroundings or individual buildings within the protected area;

(vi) Dispersal of equipment and personnel, as well as rapid entry into site protected areas for essential onsite personnel and offsite responders who are necessary to mitigate the event; and

~~(vii) Recall of site personnel.~~

Subpart G — Decommissioning Requirements

§ 53.1000 Scope and purpose.

This subpart defines the requirements related to decommissioning for applicants for, or holders of, an operating license~~OL~~ or combined license~~COL~~ under this part~~Framework A~~. ~~The requirements related to maintaining financial assurance for decommissioning are in §§ 53.1010 through 53.1060. The requirements for transitioning from operations to decommissioning and for the release of property and termination of the license are in §§ 53.1070 through 53.1080.~~

§ 53.1010 Financial assurance for decommissioning.

(a) This section establishes requirements for indicating to the NRC how an applicant for or holder of an operating license (OL) or combined license (COL) under ~~Framework A of~~ this part will provide reasonable assurance that funds will be available for the decommissioning process. Reasonable assurance consists of a series of steps as provided in paragraph (b) of this section and §§ 53.1020, 53.1030 and 53.1040. Funding for the decommissioning of commercial nuclear plants may also be subject to the regulation of Federal or State government agencies (e.g., Federal Energy Regulatory Commission (FERC) and State Public Utility Commissions (PUCs)) that have jurisdiction over rate regulation. The requirements of this subpart, in particular § 53.1020, are in addition to, and not a substitution for, other requirements, and are not intended to be used by themselves or by other agencies to establish rates.

(b) Each applicant for an OL or COL under ~~Framework A of~~ this part must prepare a ~~plan and an associated~~ decommissioning report that ~~ensures and~~ documents ~~that~~ how adequate funding will be available to decommission the facility. ~~Each holder of an OL or COL must implement and maintain the plan.~~

Commented [A256]: This section duplicates requirements from a variety of other places, including but not limited to appendix B to part 50, subpart F of this part, and administrative controls in technical specifications. Staff should address the need for this type of listing, which does not attempt to be comprehensive in this draft section, in guidance.

Commented [A257]: Deleted as unnecessary. Additionally, these sentences mischaracterize the effects of 53.1045 and 53.1060.

Commented [A258]: Because the plan is not submitted and reviewed there is no reason to require it. The requirements that follow for submittal of updated decommissioning reports certifying the status will accomplish what is necessary.

(1)~~(i)~~ Before the Commission issues an OL under ~~Framework A of~~ this part, the applicant must submit an updated the decommissioning report to certify that it has provided financial assurance for decommissioning in the amount proposed in the application and approved by the NRC ~~in accordance with~~under § 53.1020.

~~(ii) No later than 30 days after the Commission issues the notice of intended operation under § 53.1452 for a COL under Framework A of this part, the licensee must update the decommissioning report to certify that it has provided financial assurance for decommissioning in the amount proposed in the application and approved by the NRC in accordance with § 53.1020.~~

Commented [A259]: Deleted because this duplicates 53.1060(b).

(2) The amount of financial assurance for decommissioning to be provided must be based on a site-specific cost estimate for decommissioning the facility ~~in accordance with~~under § 53.1020.

(3) The amount of financial assurance for decommissioning to be provided must be adjusted annually using a rate at least equal to that stated in § 53.1030.

(4) The amount of financial assurance for decommissioning to be provided must be covered by one or more of the methods described in § 53.1040 as acceptable to the NRC. ~~A copy of the financial instrument obtained to satisfy the requirements of § 53.1040 must be submitted to the NRC as part of the application for an OL under Framework A of this part; however, an applicant for or holder of a COL need not obtain such financial instrument or submit a copy to the Commission except as provided in § 53.1060(b).~~

Commented [A260]: Moved to 53.1366(b).

Commented [A261]: Unnecessary as the submittal requirement has been moved to content of applications and the submittal requirement in 53.1060(b) is independent of this paragraph.

§ 53.1020 Cost estimates for decommissioning.

Cost estimates for decommissioning must be site-specific. Site-specific decommissioning cost estimates (DCEs) must account for the engineering, labor, equipment, transportation, disposal, and related charges needed to support termination

of the license. They must include the costs for decontaminating structures, systems, and components ~~SSCs~~ and the site environs; removal of contaminated components and materials from the plant and the site environs; disposal of removed components and materials in appropriate facilities; and any other activities supporting the release of the property and termination of the license. They must also address the approach to annual adjustments required by § 53.1030. Finally, site-specific DCEs must include plans for adjusting levels of funds assured for decommissioning to demonstrate that a reasonable level of assurance will be provided that funds will be available when needed to cover the cost of decommissioning.

§ 53.1030 Annual adjustments to cost estimates for decommissioning.

Each applicant for or holder of an OL or COL under ~~Framework A of~~ this part must annually adjust the cost estimate for decommissioning to account for escalation in ~~labor, energy, and waste burial~~ costs. Applicants or ~~l~~licensees may elect to use either a site-specific adjustment factor that addresses the estimated contributions and escalation of costs of decommissioning or a generic adjustment factor equal to 0.65 L + 0.13 E + 0.22 B, where L and E are escalation factors for labor and energy, respectively, and are to be taken from regional data of U.S. Department of Labor Bureau of Labor Statistics and B is an escalation factor for waste burial and is to be taken from NRC report NUREG-1307, "Report on Waste Burial Charges."~~,~~ The site-specific adjustment factor must be approved as part of the ~~plan and associated~~ decommissioning report required by § 53.1010, ~~in paragraph (a) of this section or~~and must be at least equal to the generic adjustment factor ~~in paragraph (b) of this section~~.

~~(a) A site-specific adjustment factor must address the estimated contributions and escalation of costs for the following aspects of decommissioning:~~

~~(1) Labor, materials, and services;~~

Commented [A262]: Edited to improve consistency because these descriptors of the costs do not match the things that must be accounted in the cost estimates under 53.1020 and the factors in paragraph (a) of this section. While labor, energy, and waste burial cost escalation factors are used in the generic adjustment factor of paragraph (b), which matches the minimum adjustment factor of 50.75(c)(2), the site-specific adjustment factors under paragraph (a) address additional costs.

Commented [A263]: As drafted, this proposed requirement would not set a generic adjustment factor. Instead, it would set a minimum adjustment factor because of the use of the phrase "must be at least." The corresponding wording used in 50.75 (c)(2) is similar to this wording but distinct because it doesn't identify anything as a "generic adjustment factor" but instead merely sets a minimum for adjustment factors to use.

This section is edited to address this issue.

~~(2) Energy and waste transportation; and~~

~~(3) Radioactive waste burial or other disposition.~~

~~(b) A generic adjustment factor must be at least equal to 0.65 L + 0.13 E + 0.22 B, where L and E are escalation factors for labor and energy, respectively, and are to be taken from regional data of U.S. Department of Labor Bureau of Labor Statistics and B is an escalation factor for waste burial and is to be taken from NRC report NUREG-1307, "Report on Waste Burial Charges."~~

§ 53.1040 Methods for providing financial assurance for decommissioning.

Financial assurance for decommissioning is to be provided by the following methods.

(a) *Prepayment*. Prepayment is the deposit made preceding the start of operation or the transfer of a license under § 53.1570 into an account segregated from licensee assets and outside the administrative control of the applicant or licensee and its subsidiaries or affiliates of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, or Government fund with payment by certificate of deposit, deposit of government or other securities, or other method acceptable to the NRC. This trust, escrow account, Government fund, or other type of agreement must be established in writing and maintained at all times in the United States with an entity that is an appropriate State or Federal government agency, or an entity whose operations in which the prepayment deposit is managed are regulated and examined by a Federal or State agency. An applicant or licensee that has prepaid funds ~~based on a site-specific cost estimate under § 53.1020~~ may take credit for projected earnings on the prepaid decommissioning trust funds, using up to a 2 percent annual real rate of return through the time of termination of the license. An applicant or licensee may use a credit of

Commented [A264]: Section 50.75 does not mandate consideration of the aspects listed here in the development of a site-specific adjustment factor. Staff should address these in guidance.

Commented [A265]: As drafted, this proposed requirement would not set a generic adjustment factor. Instead, it would set a minimum adjustment factor because of the use of the phrase "must be at least." The corresponding wording used in 50.75 (c)(2) is similar to this wording but distinct because it doesn't identify anything as a "generic adjustment factor" but instead merely sets a minimum for adjustment factors to use.

This section is edited to address this issue.

Commented [A266]: Edited throughout this section to reflect that it is applicable to applicants as well as licensees.

Commented [A267]: This clause is unnecessary because all part 53 licensees must use a site-specific cost estimate.

Note that the term "applicant" is omitted throughout 50.75(e) in similar places (i.e., all paragraphs except for 50.75(e)(1)(iii)(C)). Staff should correct 50.75(e) in an administrative rulemaking.

greater than 2 percent if the licensee's rate-setting authority has specifically authorized a higher rate. Actual earnings on existing funds may be used to calculate future fund needs.

(b) *External sinking fund*. An external sinking fund is a fund established and maintained by setting funds aside periodically in an account segregated from licensee assets and outside the administrative control of the applicant or licensee and its subsidiaries or affiliates in which the total amount of funds would be sufficient to pay decommissioning costs. An external sinking fund may be in the form of a trust, escrow account, or Government fund, with payment by certificate of deposit, deposit of Government or other securities, or other method acceptable to the NRC. This trust, escrow account, Government fund, or other type of agreement must be established in writing and maintained at all times in the United States with an entity that is an appropriate State or Federal government agency, or an entity whose operations in which the external sinking fund is managed are regulated and examined by a Federal or State agency. An applicant or licensee ~~that has collected funds based on a site-specific cost estimate under § 53.1020~~ may take credit for projected earnings on the external sinking funds using up to a 2 percent annual real rate of return from the time of future funds' collection through the time of termination of the license. An applicant or licensee may use a credit of greater than 2 percent if the licensee's rate-setting authority has specifically authorized a higher rate. Actual earnings on existing funds may be used to calculate future fund needs. An applicant or licensee whose rates for decommissioning costs cover only a portion of these costs may make use of this method only for the portion of these costs that are collected in one of the manners described in this paragraph. This method may be used as the exclusive mechanism relied upon for providing financial assurance for decommissioning in the following circumstances:

(1) By an applicant or licensee that recovers, either directly or indirectly, the estimated total cost of decommissioning through rates established by "cost of service" or similar ratemaking regulation. Public utility districts, municipalities, rural electric cooperatives, and State and Federal agencies, including associations of any of the foregoing, that establish their own rates and are able to recover their cost of service allocable to decommissioning, are deemed to satisfy this condition.

(2) By an applicant or licensee whose source of revenues for its external sinking fund is a "non-bypassable charge," the total amount of which will provide funds estimated to be needed for decommissioning pursuant to § 53.1020, § 53.1060, or § 53.1575.

(c) *A surety method, insurance, or other guarantee method*.

(1) These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended, or, if written for a specified term, such as 5 years, must be renewed automatically, unless 90 days or more prior to the renewal day the issuer notifies the NRC, the beneficiary, and the applicant or licensee of its intention not to renew. The surety or insurance must also provide that the full- face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the applicant or licensee fails to provide a replacement acceptable to the NRC within 30 days after receipt of notification of cancellation.

(ii) The surety or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the NRC. An acceptable trustee includes an appropriate State or Federal government agency or an

entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(2) A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A to 10 CFR part 30.

(3) For commercial companies that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix C to 10 CFR part 30. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in appendix D to 10 CFR part 30. A guarantee by the applicant or licensee may not be used in any situation in which the applicant or licensee has a parent company holding majority control of voting stock of the company.

(d) *Funding method for Federal licensees*. For a Federal applicant or licensee, a statement of intent containing a cost estimate for decommissioning and indicating that funds for decommissioning will be obtained when necessary.

(e) *Contractual funding method*. Contractual obligation(s) on the part of an applicant's or licensee's customer(s), the total amount of which over the duration of the contract(s) will provide the applicant's or licensee's total share of uncollected funds estimated to be needed for decommissioning pursuant to § 53.1020, § 53.1060, or § 53.1575. To be acceptable to the NRC as a method of decommissioning funding assurance, the terms of the contract(s) must include provisions that the buyer(s) of electricity or other products will pay for the decommissioning obligations specified in the contract(s), notwithstanding the operational status either of the licensed plant to which the contract(s) pertains or force majeure provisions. All proceeds from the contract(s) for

decommissioning funding will be deposited to the external sinking fund. The NRC reserves the right to evaluate the terms of any contract(s) and the financial qualifications of the contracting entity or entities offered as assurance for decommissioning funding.

(f) *Other funding mechanisms*. Any other mechanism, or combination of mechanisms, that provides, as determined by the NRC upon its evaluation of the specific circumstances of each licensee submittal, assurance of decommissioning funding equivalent to that provided by the mechanisms specified in paragraphs (a) through (e) of this section. Applicants or ~~L~~licensees who do not have sources of funding described in paragraph (b) of this section may use an external sinking fund in combination with a guarantee mechanism, as specified in paragraph (c) of this section, provided that the total amount of funds estimated to be necessary for decommissioning is assured.

(g) Licensees that are not "electric utilities" as defined in § 53.020 that use prepayment or an external sinking fund to provide financial assurance must provide in the terms of the arrangements governing the trust, escrow account, or Government fund, used to segregate and manage the funds that—

(1) The trustee, manager, investment advisor, or other person directing investment of the funds—

(i) Is prohibited from investing the funds in securities or other obligations of the licensee or any other owner or operator of any commercial nuclear plant or their affiliates, subsidiaries, successors or assigns, or in a mutual fund in which at least 50 percent of the fund is invested in the securities of a licensee or parent company whose subsidiary is an owner or operator of a foreign or domestic commercial nuclear plant. However, the funds may be invested in securities tied to market indices or other non-nuclear sector collective, commingled, or mutual funds, provided that no more than 10

Commented [A268]: Moved here from 53.1045(b) because these are required terms of prepayment or external sinking fund arrangements rather than limitations on uses of the funds.

percent of trust assets may be indirectly invested in securities of any entity owning or operating one or more commercial nuclear plants.

(ii) Is obligated at all times to adhere to a standard of care set forth in the trust, which either shall be the standard of care, whether in investing or otherwise, required by State or Federal law or one or more State or Federal regulatory agencies with jurisdiction over the trust funds, or, in the absence of any such standard of care, whether in investing or otherwise, that a prudent investor would use in the same circumstances. The term "prudent investor," shall have the same meaning as set forth in FERC's "Regulations Governing Nuclear Plant Decommissioning Trust Funds" at 18 CFR 35.32(a)(3), or any successor regulation.

(2) The licensee, its affiliates, and its subsidiaries are prohibited from being engaged as investment manager for the funds or from giving day-to-day management direction of the funds' investments or direction on individual investments by the funds, except in the case of passive fund management of trust funds where management is limited to investments tracking market indices.

(3) The trust, escrow account, Government fund, or other account used to segregate and manage the funds may not be amended in any material respect without written notification to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the proposed effective date of the amendment. The licensee must provide the text of the proposed amendment and a statement of the reason for the proposed amendment. The trust, escrow account, Government fund, or other account may not be amended if the person responsible for managing the trust, escrow account, Government fund, or other account receives written notice of objection from the Director, Office of

Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period.

(4) Except for withdrawals being made under § 53.1045(a) or for payments of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, no disbursement or payment may be made from the trust, escrow account, Government fund, or other account used to segregate and manage the funds until written notice of the intention to make a disbursement or payment has been given to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the date of the intended disbursement or payment. The disbursement or payment from the trust, escrow account, Government fund or other account may be made following the 30-working day notice period if the person responsible for managing the trust, escrow account, Government fund, or other account does not receive written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period. Disbursements or payments from the trust, escrow account, Government fund, or other account used to segregate and manage the funds, other than for payment of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, are restricted to decommissioning expenses or transfer to another financial assurance method acceptable under this section until final decommissioning has been completed. After decommissioning has begun and withdrawals from the decommissioning fund are made under paragraph (a) of this section, no further notification need be made to the NRC.

(h) Licensees that are "electric utilities" under § 53.020 that use prepayment or an external sinking fund to provide financial assurance must include a provision in the terms of the trust, escrow account, Government fund, or other account used to segregate and manage funds that except for withdrawals being made under § 53.1045 or for payments of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, no disbursement or payment may be made from the trust, escrow account, Government fund, or other account used to segregate and manage the funds until written notice of the intention to make a disbursement or payment has been given the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the date of the intended disbursement or payment. The disbursement or payment from the trust, escrow account, Government fund or other account may be made following the 30-working day notice period if the person responsible for managing the trust, escrow account, Government fund, or other account does not receive written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period. Disbursements or payments from the trust, escrow account, Government fund, or other account used to segregate and manage the funds, other than for payment of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, are restricted to decommissioning expenses or transfer to another financial assurance method acceptable under this section until final decommissioning has been completed. After decommissioning has begun and withdrawals from the

Commented [A269]: Moved here from 53.1045(c) because these are required terms of prepayment or external sinking fund arrangements rather than limitations on uses of the funds.

decommissioning fund are made under paragraph (a) of this section, no further notification need be made to the NRC.

(ii) A licensee that is not an "electric utility" under § 53.020 and using a surety method, insurance, or other guarantee method to provide financial assurance must provide that the trust established for decommissioning costs to which the surety or insurance is payable contains in its terms the requirements in paragraphs (b)(1), (2), (3), and (4) of this section.

Commented [A270]: Moved here from 53.1045(d) because these are required terms of trusts rather than limitations on uses of the funds.

§ 53.1045 Limitations on the use of decommissioning trust funds.

(a)(1) Decommissioning trust funds may be used by licensees if—

(i) The withdrawals are for expenses for decommissioning activities consistent with the definition of decommission or decommissioning in § 53.020;

(ii) The expenditure would not reduce the value of the decommissioning trust below an amount necessary to place and maintain the reactor in a safe storage condition if unforeseen conditions or expenses arise; and

Commented [A271]: In 50.82(a)(8)(i) and 52.110(h)(1)(ii), the semicolon is misplaced after the word "and" rather than after the word "arise." Staff should correct this in the next administrative rulemaking.

(iii) The withdrawals would not inhibit the ability of the licensee to complete funding of any shortfalls in the decommissioning trust needed to ensure the availability of funds to ultimately release the site and terminate the license.

(2) Initially, 3 percent of the amount determined in accordance with § 53.1020 may be used for decommissioning planning. For licensees that have submitted the certifications required under § 53.1070 and commencing 90 days after the NRC has received the post-shutdown decommissioning activities report (PSDAR) required by § 53.1060, an additional 20 percent may be used. An updated site-specific DCE must be submitted to the NRC prior to the licensee using any funding in excess of these amounts.

(b) Licensees that are not "electric utilities" as defined in § 53.020 that use prepayment or an external sinking fund to provide financial assurance must provide in the terms of the arrangements governing the trust, escrow account, or Government fund, used to segregate and manage the funds that—

(1) The trustee, manager, investment advisor, or other person directing investment of the funds—

(i) Is prohibited from investing the funds in securities or other obligations of the licensee or any other owner or operator of any commercial nuclear plant or their affiliates, subsidiaries, successors or assigns, or in a mutual fund in which at least 50 percent of the fund is invested in the securities of a licensee or parent company whose subsidiary is an owner or operator of a foreign or domestic commercial nuclear plant. However, the funds may be invested in securities tied to market indices or other non-nuclear sector collective, commingled, or mutual funds, provided that no more than 10 percent of trust assets may be indirectly invested in securities of any entity owning or operating one or more commercial nuclear plants.

(ii) Is obligated at all times to adhere to a standard of care set forth in the trust, which either shall be the standard of care, whether in investing or otherwise, required by State or Federal law or one or more State or Federal regulatory agencies with jurisdiction over the trust funds, or, in the absence of any such standard of care, whether in investing or otherwise, that a prudent investor would use in the same circumstances. The term "prudent investor," shall have the same meaning as set forth in FERC's "Regulations Governing Nuclear Plant Decommissioning Trust Funds" at 18 CFR 35.32(a)(3), or any successor regulation.

(2) The licensee, its affiliates, and its subsidiaries are prohibited from being engaged as investment manager for the funds or from giving day-to-day management

Commented [A272]: Moved to 53.1040.

direction of the funds' investments or direction on individual investments by the funds, except in the case of passive fund management of trust funds where management is limited to investments tracking market indices.

(3) The trust, escrow account, Government fund, or other account used to segregate and manage the funds may not be amended in any material respect without written notification to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the proposed effective date of the amendment. The licensee must provide the text of the proposed amendment and a statement of the reason for the proposed amendment. The trust, escrow account, Government fund, or other account may not be amended if the person responsible for managing the trust, escrow account, Government fund, or other account receives written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period.

(4) Except for withdrawals being made under paragraph (a) of this section or for payments of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, no disbursement or payment may be made from the trust, escrow account, Government fund, or other account used to segregate and manage the funds until written notice of the intention to make a disbursement or payment has been given to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the date of the intended disbursement or payment. The disbursement or payment from the trust, escrow account, Government fund or other account may be made following the 30-working day notice period if the person

responsible for managing the trust, escrow account, Government fund, or other account does not receive written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period. Disbursements or payments from the trust, escrow account, Government fund, or other account used to segregate and manage the funds, other than for payment of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, are restricted to decommissioning expenses or transfer to another financial assurance method acceptable under § 53.1040 until final decommissioning has been completed. After decommissioning has begun and withdrawals from the decommissioning fund are made under paragraph (a) of this section, no further notification need be made to the NRC.

(c) Licensees that are "electric utilities" under § 53.020 that use prepayment or an external sinking fund to provide financial assurance must include a provision in the terms of the trust, escrow account, Government fund, or other account used to segregate and manage funds that except for withdrawals being made under paragraph (a) of this section or for payments of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, no disbursement or payment may be made from the trust, escrow account, Government fund, or other account used to segregate and manage the funds until written notice of the intention to make a disbursement or payment has been given the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the date of the intended disbursement or payment. The disbursement or payment from the trust, escrow account, Government fund or other

~~account may be made following the 30-working day notice period if the person responsible for managing the trust, escrow account, Government fund, or other account does not receive written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period. Disbursements or payments from the trust, escrow account, Government fund, or other account used to segregate and manage the funds, other than for payment of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, are restricted to decommissioning expenses or transfer to another financial assurance method acceptable under § 53.1040 until final decommissioning has been completed. After decommissioning has begun and withdrawals from the decommissioning fund are made under paragraph (a) of this section, no further notification need be made to the NRC.~~

~~(d) A licensee that is not an "electric utility" under § 53.020 and using a surety method, insurance, or other guarantee method to provide financial assurance must provide that the trust established for decommissioning costs to which the surety or insurance is payable contains in its terms the requirements in § 53.1045(b)(1), (2), (3), and (4).~~

§ 53.1050 NRC oversight.

The NRC reserves the right to take the following steps in order to ensure a licensee's adequate accumulation of decommissioning funds: review, as needed, the rate of accumulation of decommissioning funds and, either independently or in cooperation with FERC and the licensee's State PUC, take additional actions as appropriate on a case-by-case basis, including modification of a licensee's schedule for the accumulation of decommissioning funds.

§ 53.1060 Reporting and recordkeeping requirements.

(a) Each holder of an operating license (OL) under ~~Framework A of~~ this part or holder of a combined license (COL) under ~~Framework A of~~ this part after the date that the Commission has made the finding under § 53.1452(g) must report, at least once every 2 years, by March 31, on the status of its certification of decommissioning funding for each ~~reactor~~ commercial nuclear plant or part of a ~~reactor~~ plant that it owns. The information in this report must include, at a minimum, the amount of decommissioning funds estimated to be required ~~pursuant to~~under §§ 53.1020 and 53.1030; the amount of decommissioning funds accumulated to the end of the calendar year preceding the date of the report; a schedule of the annual amounts remaining to be collected; the assumptions used regarding rates of escalation in decommissioning costs, rates of earnings on decommissioning funds, and rates of other factors used in funding projections; any contracts upon which the licensee is relying ~~pursuant to~~under § 53.1040(e); any modifications occurring to a licensee's ~~current~~ method of providing financial assurance since the last submitted report; and any material changes to trust agreements. If any of the preceding items is not applicable, the licensee should so state in its report. Any licensee for a plant that is within 5 years of the projected end of its operation, or where conditions have changed such that it will close within 5 years (before the end of its licensed life), or that has already closed (before the end of its licensed life), or that is involved in a merger or an acquisition must submit this report annually.

Commented [A273]: Deleted to reflect that the licensee's current method of providing financial assurance would be the result of modifications to that licensee's prior method of providing financial assurance rather than modifications to the current method.

(b) Each holder of a COL under ~~Framework A of~~ this part must, 2 years before and 1 year before the scheduled date for initial loading of fuel, submit a report to the NRC containing a certification updating the decommissioning cost estimates (DCEs) and a copy of the financial instrument to be used to satisfy § 53.1040. No later than 30 days after the Commission publishes notice in the *Federal Register* under § 53.1452(a), the

licensee must submit an updated decommissioning report ~~required under § 53.1010(b)(1)(ii)~~, including a copy of the financial instrument obtained to satisfy § 53.1040.

(c) Each licensee must keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Commission. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Commission considers important to decommissioning consists of—

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when significant contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored and of locations of possible inaccessible contamination such as buried pipes ~~which~~ that may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee must substitute appropriate records of available information concerning these areas and locations.

(3) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(4) Records of—

(i) The licensed site area, as originally licensed and any revisions, which must include a site map and any acquisition or use of property outside the originally licensed site area for the purpose of receiving, possessing, or using licensed materials;

(ii) The licensed activities carried out on the acquired or used property; and

(iii) The release and final disposition of any property recorded in paragraph (c)(4)(i) of this section, the historical site assessment performed for the release, radiation surveys performed to support release of the property, submittals to the NRC made ~~in accordance with~~under § 53.1070, and the methods employed to ensure that the property met the radiological criteria of subpart E of 10 CFR part 20 at the time the property was released.

(d) Each holder of an OL or COL under ~~Framework A of~~ this part must at or about 5 years prior to the projected end of operations submit a preliminary DCE which includes an up-to-date assessment of the major factors that could affect the cost to decommission.

(e) Prior to or within 2 years following permanent cessation of operations, the licensee must submit a post shutdown decommissioning activities report (PSDAR) to the NRC, and a copy to the affected State(s). The PSDAR must contain a description of the planned decommissioning activities along with a schedule for their accomplishment, a discussion that provides the reasons for concluding that the environmental impacts associated with site-specific decommissioning activities will be bounded by appropriate previously issued environmental impact statements, and a site-specific DCE, including the projected cost of managing irradiated fuel.

(f) For decommissioning activities that delay completion of decommissioning by including a period of storage or surveillance, the licensee must provide a means of

adjusting cost estimates and associated funding levels over the storage or surveillance period.

(g) After submitting its site-specific DCE required by paragraph (e) of this section, and until the licensee has completed its final radiation survey and demonstrated that residual radioactivity has been reduced to a level that permits termination of its license, the licensee must annually submit to the NRC, by March 31, a financial assurance status report. The report must include the following information, current through the end of the previous calendar year:

(1) The amount spent on decommissioning, both cumulative and over the previous calendar year, the remaining balance of any decommissioning funds, and the amount provided by other financial assurance methods being relied upon;

(2) An estimate of the costs to complete decommissioning, reflecting any difference between actual and estimated costs for work performed during the year, and the decommissioning criteria upon which the estimate is based;

(3) Any modifications occurring to a licensee's current method of providing financial assurance since the last submitted report; and

(4) Any material changes to trust agreements or financial assurance contracts.

(5) If the sum of the balance of any remaining decommissioning funds, plus earnings on such funds calculated at not greater than a 2 percent real rate of return, together with the amount provided by other financial assurance methods being relied upon, does not cover the estimated cost to complete the decommissioning, the financial assurance status report must include additional financial assurance to cover the estimated cost of completion.

(h) After submitting its site-specific DCE required by paragraph (e) of this section, the licensee must annually submit to the NRC, by March 31, a report on the status of its

funding for managing irradiated fuel. The report must include the following information, current through the end of the previous calendar year:

(1) The amount of funds accumulated to cover the cost of managing the irradiated fuel;

(2) The projected cost of managing irradiated fuel until title to the fuel and possession of the fuel is transferred to the Secretary of Energy; and

(3) If the funds accumulated do not cover the projected cost, a plan to obtain additional funds to cover the cost.

§ 53.1070 Termination of license.

For each holder of an operating license (OL) or combined license (COL) under ~~Framework A of~~ this part—

(a)(1) When the licensee has determined to permanently cease operations the licensee must, within 30 days, submit a written certification to the NRC, consistent with the requirements of § 53.040(b)(8);

~~(2) When appropriate to support decommissioning activities and the eventual permanent removal of fuel from the reactor vessel, the licensee must develop defueled technical specifications by reviewing the operational technical specifications and determining which specifications no longer apply during decommissioning and which ones should remain applicable. The licensee must make the appropriate submittals to the NRC in accordance with § 53.1510 to request changes to the technical specifications; and~~

(~~3~~2)~~(i)~~ Once fuel has been permanently removed from the reactor vessel, the licensee must submit a written certification to the NRC that meets the requirements of § 53.040(b)(9); and

Commented [A274]: Staff should move this suggestion to guidance as there is no justification proposed for requiring these actions. They do appear to be sensible to expect a licensee to take, but are not required under part 50 or 52.

~~(ii) The licensee must establish and maintain staffing consisting of certified fuel handlers, as defined under § 53.020, and other non-licensed personnel with appropriate qualifications, and in sufficient numbers, to ensure support for facility operations and radiological control activities, as required by the facility defueled technical specifications. These personnel must be subject to the training requirements of § 53.830.~~

Commented [A275]: Moved to 53.1075.

(b) Upon docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessel, or when a final legally effective order to permanently cease operations has come into effect, the license issued under ~~Framework A of~~ this part no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor vessel.

(c) Decommissioning will be completed within 60 years of permanent cessation of operations. Completion of decommissioning beyond 60 years will be approved by the Commission only when necessary to protect public health and safety. Factors that will be considered by the Commission in evaluating an alternative that provides for completion of decommissioning beyond 60 years of permanent cessation of operations include unavailability of waste disposal capacity and other site-specific factors affecting the licensee's capability to carry out decommissioning, including presence of other nuclear facilities at the site.

(d)(1) ~~Prior to or within 2 years f~~Following ~~permanent cessation of operations, the licensee must submit a PSDAR and site-specific DCE in accordance with § 53.1060(e).~~

~~(2) The NRC must notice~~ receipt of the post shutdown decommissioning activities report (PSDAR) submitted under § 53.1060(e), The NRC must~~and~~ make the PSDAR publicly available and publish notice of its availability for public comment in the *Federal Register*. The NRC must also schedule a public meeting readily accessible to individuals in the vicinity of the licensee's facility ~~upon receipt of the PSDAR~~. The NRC must publish

a notice in the *Federal Register* and in a forum, such as local newspapers, that is readily accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.

(e) Licensees must not perform any major decommissioning activities, as defined in § 53.020, until 90 days after the NRC has received the licensee's PSDAR submittal and until certifications of permanent cessation of operations and permanent removal of fuel from the reactor vessel, as required under paragraph (a) of this section, have been submitted.

Commented [A276]: Staff should confirm that the insertion of a definition for "major decommissioning activity" in 53.020 accurately reflects that activity.

(f) Licensees must not perform any ~~decommissioning~~ activities~~, as defined in § 53.020,~~ that—

(1) Foreclose release of the site for possible unrestricted use;

(2) Result in significant environmental impacts not previously reviewed; or

(3) Result in there no longer being reasonable assurance that adequate funds will be available for decommissioning.

Commented [A277]: Edited to reflect that there is no definition of "decommissioning activities" in 53.020. Extrapolating from the definition provided in 53.020 for "decommission or decommissioning" to infer what "decommissioning activities" are reveals that any activities that would fall under paragraph (f)(1) would be incompatible with that definition and therefore not "decommissioning activities."

This error occurs in 50.82(a)(6) and 52.110(f), which similarly cite decommissioning activities as defined in 50.2 and 52.1 respectively without an underlying definition being provided in those sections. Staff should correct 50.82(a)(6) and 52.110(f) in an administrative rulemaking.

(g) In taking actions permitted under § 53.1540 following submittal of the PSDAR, the licensee must notify the NRC in writing, and send a copy to the affected State(s), before performing any decommissioning activity inconsistent with, or making any significant schedule change from, those actions and schedules described in the PSDAR, including changes that increase the decommissioning cost by more than 20 percent from the previously provided DCE.

(h) Licensees may use decommissioning trust funds consistent with the limitations of § 53.1045(a). Licensees must report on the status of decommissioning trust funds consistent with the requirements of § 53.1060.

(i) Licensees must submit an application for termination of license in accordance with § 53.1070. The application for termination of license must be accompanied or preceded by a license termination plan to be submitted for NRC approval.

(1) The license termination plan must be a supplement to the Final Safety Analysis Report (FSAR) or equivalent and must be submitted at least 2 years before termination of the license date.

(2) The license termination plan must include—

(i) A site characterization;

(ii) Identification of remaining dismantlement activities;

(iii) Plans for site remediation;

(iv) Detailed plans for the final radiation survey;

(v) A description of the end use of the site, if restricted;

(vi) An updated site-specific estimate of remaining decommissioning costs;

(vii) A supplement to the environmental report, pursuant to § 51.53 of this chapter, describing any new information or significant environmental change associated with the licensee's proposed termination activities; and

(viii) Identification of parts, if any, of the facility or site that were released for use before approval of the license termination plan.

(3) ~~The NRC shall notice~~Following receipt of the license termination plan, the NRC must ~~and~~ make the license termination plan publicly available and publish notice of its availability for public comment in the *Federal Register*. The NRC ~~shall~~ must also schedule a public meeting readily accessible to individuals in the vicinity of the licensee's facility upon receipt of the license termination plan. The NRC ~~shall~~ must publish a notice in the *Federal Register* and in a forum, such as local newspapers, that is readily

accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.

(j) If the license termination plan demonstrates that the remainder of decommissioning activities will be performed in accordance with the regulations in this chapter, will not be inimical to the common defense and security or to the health and safety of the public, and will not have a significant effect on the quality of the environment and after notice to interested persons, the Commission ~~shall~~ will approve the plan, by license amendment, subject to such conditions and limitations as it deems appropriate and necessary and authorize implementation of the license termination plan.

(k) The Commission ~~shall~~will terminate the license if it determines that—

(1) The remaining dismantlement has been performed in accordance with the approved license termination plan, and

(2) The final radiation survey and associated documentation, including an assessment of dose contributions associated with parts released for use before approval of the license termination plan, demonstrate that the facility and site have met the criteria for decommissioning in subpart E of 10 CFR part 20.

§ 53.1075 Program requirements during decommissioning.

(a) Licensees that have submitted the certifications required under § 53.1070 must maintain a decommissioning fire protection program to address the potential for fires that could cause the release or spread of radioactive materials.

(1) The objectives of the decommissioning fire protection program are to

(i) Reasonably prevent these fires from occurring;

(ii) Rapidly detect, control, and extinguish those fires that do occur and that could result in a radiological hazard; and

(iii) Ensure that the risk of fire-induced radiological hazards to the public, environment, and plant personnel is minimized.

(2) The licensee must assess the decommissioning fire protection program on a regular basis. The licensee must revise the decommissioning fire protection program documentation as appropriate throughout the various stages of facility decommissioning.

(3) The licensee may make changes to the decommissioning fire protection program without NRC approval if these changes do not reduce the effectiveness of fire protection for SSCs that could result in a radiological hazard, taking into account the decommissioning plant conditions and activities.

(b) The licensee must establish and maintain staffing consisting of certified fuel handlers, as defined under § 53.020, and other non-licensed personnel with appropriate qualifications, and in sufficient numbers, to ensure support for facility operations and radiological control activities. These personnel must be subject to the training requirements of § 53.830. ~~[Reserved]~~

§ 53.1080 Release of part of a commercial nuclear plant or site for unrestricted use.

(a) Prior written NRC approval is required to release part of a commercial nuclear plant or site for unrestricted use at any time before receiving approval of a license termination plan. Section 53.1060 specifies recordkeeping requirements associated with partial release. Holders of an operating license~~OL~~ or combined license~~COL~~ under ~~Framework A of~~ this part seeking NRC review and approval must—

(1) Evaluate the effect of releasing the property to ensure that—

(i) The dose to individual members of the public does not exceed the limits and standards of subpart D of 10 CFR part 20;

(ii) There is no reduction in the effectiveness of emergency planning or physical security;

(iii) Effluent releases remain within license conditions;

(iv) The environmental monitoring program and offsite dose calculation manual are revised to account for the changes;

(v) The siting criteria of subpart D of this part continue to be met; and

(vi) All other applicable statutory and regulatory requirements continue to be met.

(2) Perform a historical site assessment of the part of the commercial nuclear plant or site to be released; and

(3) Perform surveys adequate to demonstrate compliance with the radiological criteria for unrestricted use specified in § 20.1402 of this chapter for impacted areas.

(b) For release of non-impacted areas, the licensee may submit a written request for NRC review and approval of the release if a license amendment is not otherwise required. The request submittal must include—

(1) The results of the evaluations performed in accordance with paragraphs (a)(1) and (a)(2) of this section;

(2) A description of the part of the commercial nuclear plant or site to be released;

(3) The schedule for release of the property;

(4) The results of the evaluations performed in accordance with § 53.1540; and

(5) A discussion that provides the reasons for concluding that the environmental impacts associated with the licensee's proposed release of the property will be bounded by appropriate previously issued environmental impact statements.

(c) After receiving a request from the licensee for NRC approval of the release of a non-impacted area, the NRC ~~shall~~must—

(1) Determine whether the licensee has adequately evaluated the effect of releasing the property as required by paragraph (a)(1) of this section;

(2) Determine whether the licensee's classification of any release areas as non-impacted is adequately justified; and

(3) If determining that the licensee's submittal is adequate, inform the licensee in writing that the release is approved.

(d) For release of impacted areas, the licensee must submit an application for amendment of its license for the release of the property. The application must include—

(1) The information specified in paragraphs (b)(1) through (b)(3) of this section;

(2) The methods used for and results obtained from the radiation surveys required to demonstrate compliance with the radiological criteria for unrestricted use specified in § 20.1402; and

(3) A supplement to the environmental report, under § 51.53 of this chapter, describing any new information or significant environmental change associated with the licensee's proposed release of the property.

(e) After receiving a license amendment application from the licensee for the release of an impacted area, the NRC ~~shall~~must—

(1) Determine whether the licensee has adequately evaluated the effect of releasing the property as required by paragraph (a)(1) of this section;

(2) Determine whether the licensee's classification of any release areas as non-impacted is adequately justified;

(3) Determine whether the licensee's radiation survey for an impacted area is adequate; and

(4) If determining that the licensee's submittal is adequate, approve the licensee's amendment application.

(f) The NRC ~~shall~~must publish notice receipt of the release approval request or license amendment application in the *Federal Register* and make the approval request or license amendment application available for public comment. Before acting on an approval request or license amendment application submitted in accordance with this section, the NRC ~~shall~~must conduct a public meeting readily accessible to individuals in the vicinity of the licensee's facility for the purpose of obtaining public comments on the proposed release of part of the commercial nuclear plant or site. The NRC ~~shall~~must publish a document in the *Federal Register* and in a forum, such as local newspapers, which is readily accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.

Subpart H — Licenses, Certifications, and Approvals

§ 53.1100 Filing of application for licenses, certifications, or approvals; oath or affirmation.

(a) *Serving of applications*.

(1) Each filing of an application for a standard design approval, standard design certification, or license under ~~Framework A of~~ this part, and any amendments to the applications, must be submitted to the NRC under § 53.040, as applicable.

(2) Each applicant for a construction permit (CP), early site permit, combined license (COL), or manufacturing license (ML) under ~~Framework A of~~ this part must, upon notification by the presiding officer designated to conduct the public hearing required by the Act~~EA~~, update the application and serve the updated copies of the application or parts of it, eliminating all superseded information, together with an index of the updated application, as directed by presiding officer. Any subsequent amendment to the application must be served on those served copies of the application and must be

submitted to the NRC as specified in § 53.040, as applicable.

(3) The applicant must make a copy of the updated application available at the public hearing for the use of any other parties to the proceeding and must certify that the updated copies of the application contain the current contents of the application submitted in accordance with the requirements under ~~Framework A of~~ this part.

(4) At the time of filing an application, the Commission will make available at the NRC Web site, http://www.nrc.gov, a copy of the application, subsequent amendments, and other records pertinent to the matter that is the subject of the application for public inspection and copying.

(5) The serving of copies required by this section must not occur until the application has been docketed under § 2.101(a) of this chapter. Copies must be submitted to the Commission, as specified in § 53.040, as applicable, to enable the Director, Office of Nuclear Reactor Regulation to determine whether the application is sufficiently complete to permit docketing.

(b) *Oath or affirmation*. Each application for a standard design approval, standard design certification, or license, including, whenever appropriate, a CP or early site permit, or amendment of it, and each amendment of each application must be executed in a signed original by the applicant or duly authorized officer thereof under oath or affirmation.

(c) [Reserved]

(d) [Reserved]

(e) *Filing fees*. Each application for a standard design approval, standard design certification, or commercial nuclear plant license under ~~Framework A~~ this part, including, whenever appropriate, a CP, COL, OL, ML, or early site permit, other than a license exempted from 10 CFR part 170, must be accompanied by the fee prescribed in

10 CFR part 170. No fee will be required to accompany an application for renewal, amendment, or termination of a CP, OL, COL, or ML, except as provided in § 170.21 of this chapter.

(f) *Environmental report*. An application for a CP, OL, early site permit, design certification, COL, or ML for a commercial nuclear plant must be accompanied by an environmental report required under subpart A of 10 CFR part 51.

§ 53.1101 Requirement for license.

Except as provided in § ~~53.1120~~50.11 of this chapter, no person within the United States may transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, or use any utilization facility except as authorized by a license issued by the Commission.

Commented [A278]: In the course of this rulemaking, staff should determine whether the act of "transfer[ring] ... in interstate commerce" is bounded by the act of "transfer[ring]" included in the list that follows this and make appropriate adjustments to the wording of this as a requirement. If the prohibition of transfer of a utilization facility as provided by the latter use of the term is sufficient to encompass the prohibition of transfer of a utilization facility in interstate commerce, staff should make conforming changes to 50.10(b) as well.

§ 53.1103 Combining applications and licenses.

(a) An applicant may combine ~~several~~ more than one application~~s~~ in one application for different kinds of licenses under the regulations in this chapter.

Commented [A279]: Edited to reflect the plain language definition of "several" being "an indefinite number more than two and fewer than many." This would allow combination of two applications rather than only three or more.

The usage in 50.30 is distinct from this because of the phrasing as "his several applications" and more aptly fits with the definition of "several" as "existing apart; separate'; distinct; individual."

(b) The Commission may combine in a single license the activities of an applicant which would otherwise be licensed separately.

§ 53.1106 Elimination of repetition.

An applicant may incorporate by reference in its application information contained in previous applications, statements, or reports filed with the Commission, provided, however, that such references are clear and specific.

§ 53.1109 Contents of applications; general information.

Each application must include, unless otherwise indicated in this subpart—

(a) Name of applicant;

(b) Address of applicant;

(c) Description of business or occupation of applicant;

(d)(1) If applicant is an individual, the citizenship of applicant;

(2) If applicant is a partnership, the name, citizenship and address of each partner and the principal location where the partnership does business;

(3) If applicant is a corporation or an unincorporated association, the following information:

(i) The State where it is incorporated or organized and the principal location where it does business;

(ii) The names, addresses and citizenship of its directors and of its principal officers; and

(iii) Whether it is owned, controlled, or dominated by an alien, a foreign corporation, or foreign government, and if so, give details; or

(4) If the applicant is acting as agent or representative of another person in filing the application, identify the principal and furnish information required under this paragraph with respect to such principal;

(e) The ~~class and~~ type of license applied for, the use to which the facility will be put, the period of time for which the license is sought, and a list of other licenses, except operator's licenses, issued or applied for in connection with the proposed facility;

Commented [A280]: Deleted as unnecessary due to the limitation of part 53 to class 103 licenses.

(f) [Reserved]

(g)(1) If the application is for an operating license (OL) or combined license (COL) for a commercial nuclear plant, or if the application is for an early site permit for a commercial nuclear plant and contains plans for coping with emergencies under § 53.1146(b)(2)(ii), radiological emergency response plans of State, local, and participating Tribal governmental entities in the United States that are wholly or partially within the plume exposure pathway emergency planning zone (EPZ),[41] and the plans of State governments wholly or partially within the ingestion pathway EPZ.[5] If the

Commented [A281]: Edited to restart footnote numbering for individual sections.

application is for an early site permit that, under § 53.1146(b)(2)(i), proposes major features of the emergency plans describing the EPZs, then the descriptions of the EPZs must demonstrate compliance with the requirements of this paragraph. Generally, the plume exposure pathway EPZ for a commercial nuclear plant must consist of an area about 10 miles (16 km) in radius and the ingestion pathway EPZ must consist of an area about 50 miles (80 km) in radius. The exact size and configuration of the EPZs surrounding a particular commercial nuclear plant must be determined in relation to the local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. The size of the EPZs also may be determined on a case-by-case basis for gas-cooled reactors and for reactors with an authorized power level less than 250 megawatt (MW) thermal. The plans for the ingestion pathway must focus on such actions as are appropriate to protect the food ingestion pathway.

(2) [Reserved]

(h) [Reserved]

(i) A list of the names and addresses of such regulatory agencies as may have jurisdiction over the rates and services incident to the proposed activity, and a list of trade and news publications which circulate in the area where the proposed activity will be conducted and which are considered appropriate to give reasonable notice of the application to those municipalities, private utilities, public bodies, and cooperatives, which might have a potential interest in the facility; and

(j) If the application contains Restricted Data or ~~other defense~~classified National Security information, confirmation that all Restricted Data and ~~other defense~~classified National Security information are separated from the unclassified information.

(k) [Reserved]

Commented [A282]: Edited to use the defined term in part 95 rather than "defense information" as used in 50.33(j). The usage in 50.33(j) dates back to the AEC amendment of that section on January 19, 1956 (21 FR 355, 357) and was not changed with the promulgation of part 95 (45 FR 14476; March 5, 1980) after the establishment of the NRC and the 1975 reissuance of the former AEC regulations. This aligns with the usage in 53.1115.

Staff should change the usage in 50.33(j) to reflect the establishment of part 95 and its definition in 95.5 of the term "classified National Security Information" rather than the undefined term "other defense information" in the next administrative rulemaking.

[14] EPZs are discussed in NUREG–0396, EPA 520/1–78–016, "Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light-Water Nuclear Power Plants," December 1978.

~~[5] If the State, local, and participating Tribal emergency response plans have been previously provided to the NRC for inclusion in the facility docket, the applicant need only provide the appropriate reference to meet this requirement.~~

Commented [A283]: Deleted as redundant to 53.1106, "Elimination of repetition."

§ 53.1112 Environmental conditions.

(a) Each construction permit (CP), early site permit, and combined license (COL) under ~~Framework A of~~ this part may include conditions to ~~address~~ protect the environment~~al issues~~ during construction. These conditions are to be set out in an attachment to the license, which is incorporated in and made a part of the license. These conditions will be derived from information contained in the environmental report submitted pursuant to § 51.50 of this chapter, as analyzed and evaluated in the NRC record of decision, and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirement for the protection of the nonaquatic environment.

Commented [A284]: Edited to parallel the wording in 50.36b and harmonize with the final sentence of this paragraph.

(b) Each license authorizing operation of a commercial nuclear plant~~, including a COL,~~ under ~~Framework A of~~ this part, and each license for a commercial nuclear plant ~~for which the certification of permanent cessation of~~that no longer authorizes operation~~s~~ of the reactor ~~required~~ under § 53.1070 ~~has been~~ submitted may include conditions to ~~address~~ protect the environment~~al issues~~ during operation and

Commented [A285]: Deleted as unnecessary due to the definition of combined license in 53.020.

Commented [A286]: Edited to reflect the potential for removal of the authority to operate the reactor when an final legally effective order to permanently cease operations comes into effect under 53.1070. Staff should consider whether a similar change is appropriate in 50.36b to reflect the similar provisions in 50.82(a)(2) and whether such a change can be accomplished in an administrative rulemaking.

decommissioning. These conditions are to be set out in an attachment to the license, which is incorporated in and made a part of the license. These conditions will be derived from information contained in the environmental report or the supplement to the environmental report submitted under §§ 51.50 and 51.53 of this chapter as analyzed and evaluated in the NRC record of decision, and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data and any conditions and monitoring requirement for the protection of the nonaquatic environment.

§ 53.1115 Agreement limiting access to classified information.

As part of its application and in any event before the receipt of Restricted Data or classified National Security Information or the issuance of a license or standard design approval under ~~Framework A of~~ this part, or before the Commission has adopted a final standard design certification rule under ~~Framework A of~~ this part, the applicant must agree in writing that it will not permit any individual to have access to or any facility ~~or~~ to possess Restricted Data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. The agreement of the applicant becomes part of the license or standard design approval.

§ 53.1118 Ineligibility of certain applicants.

Any person who is a citizen, national, or agent of a foreign country, or any corporation, or other entity which the Commission knows or has reason to believe is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government, will be ineligible to apply for and obtain a license.

~~**§ 53.1120 Exceptions and exemptions from licensing requirements.**~~

~~Nothing in this part must be deemed to require a license for—~~

Commented [A287]: The comma after "attachment to the license" is omitted from the corresponding sentence in 50.36b(b). Staff should determine whether a comma is appropriate in this sentence, which is identical in both paragraph (a) and (b) of this section and either include a comma here or delete the comma from the sentence in paragraph (a) of this section. Staff should similarly correct the appropriate paragraph in 50.36b in the next administrative rulemaking.

Commented [A288]: Edited to match the wording used in 52.54(c) for the parallel wording of the requirement as made applicable to design certificate applicants in the 2007 part 52 rulemaking. This also matches the discussion on the subject in the preamble for that rulemaking at 72 FR 49352, 49399; August 28, 2007 (upper right column). In that rulemaking, the word "or" was omitted between "have access to" and "any facility" in 50.37 due to a drafting error. (73 FR 49352, 49493). This edit restores the wording of the text of this portion of the requirement to the pre-2007 wording.

Staff should correct the omission in 50.37 in the next administrative rulemaking.

~~(a) The manufacture, production, or acquisition by the Department of Defense of any utilization facility authorized pursuant to section 91 of the AEA, or the use of such facility by the Department of Defense or by a person under contract with and for the account of the Department of Defense;~~

~~(b) Except to the extent that the Department of Energy facilities of the types subject to licensing pursuant to section 202 of the ERA are involved —~~

~~(1)(i) The processing, fabrication or refining of SNM or the separation of SNM, or the separation of SNM from other substances by a prime contractor of the Department of Energy under a prime contract for —~~

~~(A) The performance of work for the Department of Energy at a United States government-owned or controlled site;~~

~~(B) Research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or~~

~~(C) The use or operation of a utilization facility in a United States owned vehicle or vessel; or~~

~~(ii) The processing, fabrication or refining of SNM of the separation of SNM, or the separation of SNM from other substances by a prime contractor or subcontractor of the Commission or the Department of Energy under a prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety; or~~

~~(2)(i) The construction or operation of a utilization facility for the Department of Energy at a United States government-owned or controlled site, including the transportation of the utilization facility to or from such site and the performance of~~

~~contract services during temporary interruptions of such transportation; or the construction or operation of a utilization facility for the Department of Energy in the performance of research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof; or the use or operation of a utilization facility for the Department of Energy in a United States government-owned vehicle or vessel; provided that such activities are conducted by a prime contractor of the Department of Energy under a prime contract with the Department of Energy; or~~

~~(ii) The construction or operation of a utilization facility by a prime contractor or subcontractor of the Commission or the Department of Energy under his prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety; or~~

~~(c) The transportation or possession of any utilization facility by a common or contract carrier or warehouse employee in the regular course of carriage for another or storage incident thereto.~~

Commented [A289]: Deleted as unnecessary in light of the provisions of 50.11 with conforming changes.

§ 53.1121 Public inspection of applications.

Applications and documents submitted to the Commission in connection with applications may be made available for public inspection ~~in accordance with~~under the provisions of ~~the regulations contained in 10 CFR~~ part 2 of this chapter.

§ 53.1124 Relationship between ~~sections~~licenses, certifications, and approvals.

(a) ~~*Limited work authorization.* An application for an LWA under Framework A of this part may be submitted as part of an application for an early site permit, CP, or COL under Framework A of this part as required in § 53.1130(a)(2).~~

~~(b) *Early site permit.* (1) A holder of an early site permit may request an LWA.~~

~~(2) An application for a CP or COL under Framework A of this part may, but need not, reference an early site permit.~~

~~(c)~~ *Standard design certifications and standard design approvals*. (1) An application for a standard design certification or standard design approval under ~~Framework A of~~ this part may, but need not, reference an operating license (OL) or custom combined license (COL) under ~~Framework A of~~ this part that is essentially the same as the information supporting the standard design for which certification or approval is being requested.

~~(d) *Standard design certification.* An application for a standard design certification under Framework A of this part may, but need not, reference an OL or custom COL under Framework A of this part that is essentially the same as the standard design for which certification is being requested.~~

(2) An application for a construction permit (CP), OL, or COL may, but need not, reference a standard design certification or standard design approval issued under this part. In the absence of a demonstration that an entity other than the one originally sponsoring and obtaining a standard design certification is qualified to supply a design, the Commission will entertain an application for a CP, OL, or COL that references a standard design certification issued under this part only if the entity that sponsored and obtained the certification supplies the design for the applicant's use.

(~~b~~e) *Manufacturing licenses*. ~~(1)~~ An application for a COL under this part may reference a manufactured reactor manufactured under a~~n~~ manufacturing license (ML) issued under ~~Framework A of~~ this part may ~~only~~ to be transported to and installed at a construction site for ~~which~~ a commercial nuclear plant~~COL under Framework A of this part has been issued~~. An application for an OL under this part may not reference a manufactured reactor.

Commented [A290]: Deleted because these paragraphs provide no limitations on the relationships between the application types and the references to other types is explicitly addressed elsewhere.

Commented [A291]: The word "respectively" is deleted because it serves no purpose in the sentence.

Commented [A292]: Edited to parallel the discussion on the subject provided by the staff in paragraph (g) of this section and to avoid the inference that referencing a standard design certification or approval is a prerequisite to also referencing an early site permit.

Commented [A293]: Edited to reflect that the purpose of this section is to implement the relationship restrictions between the licensing, certification, and approval types rather than to forbid the actual installation of manufactured reactors.

The requirement that prevents installation of manufactured reactors at commercial nuclear plants under OLs is 53.620(e)(1).

(2) An ML applicant under Framework A of this part may reference a standard design certification or a standard design approval under Framework A of this part in its application.

(f) *Construction permit.* An application for a CP may, but need not, reference a standard design certification or standard design approval issued under Framework A of this part, respectively, and may also reference an early site permit issued under Framework A of this part. In the absence of a demonstration that an entity other than the one originally sponsoring a standard design certification is qualified to supply a design, the Commission will entertain an application for a CP that references a standard design certification issued under Framework A of this part only if the entity that sponsored the certification supplies the design for the applicant's use.

(g) *Operating license.* (1) An application for an OL under Framework A of this part may, but need not, reference an early site permit, standard design certification, or standard design approval issued under Framework A of this part. In the absence of a demonstration that an entity other than the one originally sponsoring a standard design certification is qualified to supply a design, the Commission will entertain an application for an OL that references a standard design certification issued under Framework A of this part only if the entity that sponsored the certification supplies the design for the applicant's use.

(2) The holder of a CP must, at the time of submission of the FSAR, file an application for an OL.

(h) *Combined licenses.* An application for a COL under Framework A of this part may, but need not, reference an early site permit, standard design certification, standard design approval, or ML issued under Framework A of this part. In the absence of a demonstration that an entity other than the one originally sponsoring and obtaining a

Commented [A294]: The word "respectively" is deleted because it serves no purpose in the sentence.

Commented [A295]: Edited to parallel the discussion on the subject provided by the staff in paragraph (g) of this section and to avoid the inference that referencing a standard design certification or approval is a prerequisite to also referencing an early site permit.

Commented [A296]: Moved to paragraph (a)(2).

Commented [A297]: Combined with paragraph (f), moved to paragraph (a)(2) for simplicity and to more succinctly state the only restriction provided by these paragraphs.

Commented [A298]: Moved to 53.615(b), fleshed out with the details from 50.30(d), and combined with an insertion of a paragraph modeled on 50.55(d) to avoid setting a trap for the unwary of a submittal requirement in the section on relationship between sections.

~~standard design certification is qualified to supply a design, the Commission will entertain an application for a COL that references a standard design certification issued under Framework A of this part only if the entity that sponsored the certification supplies the design for the applicant's use.~~

Commented [A299]: Combined with paragraph (f), moved to paragraph (a)(2) for simplicity and to more succinctly state the only restriction provided by these paragraphs.

§ 53.1130 Limited work authorizations.

(a) *Request for limited work authorization*. (1) Any person to whom the Commission may otherwise issue either a license or permit related to a commercial nuclear plant may request a~~n~~ limited work authorization (LWA) allowing that person to perform the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, and installation of the foundation, including placement of concrete, any of which are for a~~n~~ structure, system, or component (SSC) of the facility for which either a construction permit (CP) or combined license (COL) is otherwise required under § 53.610 of this part.

(2) An application for an LWA may be submitted as part of a complete application for a CP or COL in accordance with § 2.101(a)(1) through (a)(5) of this chapter, or as a partial application in accordance with § 2.101(a)(9) of this chapter. An application for an LWA by the holder of an early site permit must be submitted as a complete application in accordance with § 2.101(a)(1) through (a)(4) of this chapter.

(3) The application must include—

(i) A Safety Analysis Report required by § 53.1146, § 53.1309 or § 53.1416, as applicable, a description of the activities requested to be performed, and the design and construction information otherwise required by the Commission's rules and regulations to be submitted for a CP or COL under ~~Framework A of~~ this part but limited to those portions of the facility that are within the scope of the LWA.~~;~~

~~(A)~~ The Safety Analysis Report must demonstrate that activities conducted under

Commented [A300]: Moved up to prior paragraph.

the LWA will be conducted in compliance with the technically relevant Commission requirements in 10 CFR chapter I applicable to the design of those portions of the facility within the scope of the LWA;

~~(B) [Reserved]~~

(ii) An environmental report in accordance with § 51.49 of this chapter; and

(iii) A plan for redress of activities performed under the LWA, should limited work activities be terminated by the holder, or the LWA be revoked by the NRC or upon effectiveness of the Commission's final decision denying the associated CP or COL application, or the early site permit for the site is not referenced in an application for a CP or COL while the permit remains valid, as applicable.

Commented [A301]: Inserted to address the need for redress of limited work accomplished under an early site permit that is not referenced in a CP or COL application as contemplated under 53.1161. Staff should address the lack of this explicit need in 52.25 in a future rulemaking.

(b) *Issuance of limited work authorization*. (1) The Director, Office of Nuclear Reactor Regulation may issue an LWA only after—

(i) The NRC staff issues the final environmental impact statement for the LWA ~~in accordance with~~under subpart A of ~~10 CFR~~ part 51 of this chapter;

(ii) The presiding officer makes the finding in § 51.105(c) or § 51.107(d) of this chapter, as applicable;

(iii) The Director determines that the applicable standards and requirements of the Act~~E~~EA, and the Commission's regulations applicable to the activities to be conducted under the LWA, have been met, the applicant is technically qualified to engage in the activities authorized, and that issuance of the LWA will provide reasonable assurance of adequate protection to public health and safety and will not be inimical to the common defense and security; and

Commented [A302]: In 50.30, there is a typographic error ending the sentence at the word "met" rather than continuing the list. Staff should correct this error in the next administrative rulemaking.

(iv) The presiding officer finds that there are no unresolved safety issues relating to the activities to be conducted under the LWA that would constitute good cause for withholding the authorization.

(2) Each LWA will specify the activities that the holder is authorized to perform.

(c) *Effect of limited work authorization*. Any activities undertaken under an LWA are entirely at the risk of the applicant and, except as to the matters determined under paragraph (~~d~~b)(1) of this section, the issuance of the LWA has no bearing on the issuance of a CP or COL with respect to the requirements of the Act~~E~~A and rules, regulations, or orders issued under the Act~~E~~A. The environmental impact statement for a CP or COL application for which an LWA was previously issued will not address, and the presiding officer will not consider, the sunk costs of the holder of the LWA in determining whether the ~~proposed action (i.e., issuance of the~~ CP or COL~~)~~ should be issued, denied, or appropriately conditioned.

Commented [A303]: Edited to cite the findings of paragraph (b)(1) rather than the redress plan implementation, similar to the provisions of 50.10(f).

(d) *Implementation of redress plan*. If construction is terminated by the holder, the underlying application is withdrawn by the applicant or denied by the NRC, or the LWA is revoked by the NRC, then the holder must begin implementation of the redress plan in a reasonable time. The holder must also complete the redress of the site no later than 18 months after termination of construction, revocation of the LWA, or upon effectiveness of the Commission's final decision denying the associated CP application or the ~~associated~~ underlying COL application, as applicable.

Commented [A304]: Edited to follow the existing wording in 50.10(g).

§ 53.1140 Early site permits.

Sections 53.1140 through 53.1188 set out the requirements and procedures applicable to Commission issuance of an early site permit under this part for approval of a site for a commercial nuclear plant separate from the filing of an application for a ~~CP~~construction permit or combined license~~COL~~ for the facility.

§ 53.1143 Filing of applications.

Any person who may apply for a construction permit (CP) or for a combined license (COL) under ~~Framework A of~~ this part, may file an application for an early site

permit with the Director, Office of Nuclear Reactor Regulation. An application for an early site permit may be filed notwithstanding the fact that an application for a CP or a COL has not been filed in connection with the site for which a permit is sought.

§ 53.1144 Contents of applications for early site permits; general information.

The application must contain all of the information required by § 53.1109(a) through (d) and (j).

§ 53.1146 Contents of applications for early site permits; technical information.

(a) The application must contain—

(1) A Site Safety Analysis Report that must include the following:

(i) The specific number, type, and thermal power level of the facilities, or range of possible facilities, for which the site may be used;

(ii) The anticipated maximum levels of radiological and thermal effluents each facility will produce;

(iii) The type of cooling systems, including intakes and outflows, where appropriate, that may be associated with each facility;

(iv) The boundaries of the site;

(v) The proposed general location of each facility on the site;

(vi) The external hazards and site characteristics required by ~~Framework A of~~ this part;

(vii) ~~The location and description of any nearby industrial, military, or transportation facilities and routes~~[Reserved];

Commented [A305]: Deleted because the man-related hazards described in this paragraph are encompassed by the external hazards and site characteristics of the prior paragraph.

(viii) The existing and projected future population profile of the area surrounding the site;

(ix) A description and assessment of the site on which a facility is to be located. The assessment must address the requirements of subpart D of this part;

(x) Information demonstrating that site characteristics are such that adequate security plans and measures can be developed; and

(xi) A description of the quality assurance plan (QAP) ~~required by subpart K of this part~~ applied to site-related activities for the future design, fabrication, construction, and testing of the SSCs of a facility or facilities that may be constructed on the site. Appendix B to part 50 of this chapter sets forth the requirements for QAPs for nuclear power plants. The description of the QAP for a commercial nuclear power plant site must include a discussion of how the applicable requirements of appendix B to part 50 of this chapter will be satisfied.

(2) A complete environmental report as required by § 51.50(b) of this chapter.

(b)(1) The Site Safety Analysis Report must identify physical characteristics of the proposed site, such as egress limitations from the area surrounding the site, that could pose a significant impediment to the development of emergency plans. If physical characteristics are identified that could pose a significant impediment to the development of emergency plans, the application must identify measures that would, when implemented, mitigate or eliminate the significant impediment.

(2) The Site Safety Analysis Report may also—

(i) Propose major features of the emergency plans, ~~in accordance with~~under the pertinent standards of § 53.855, such as the exact size and configuration of the emergency planning zones~~EPZs~~, for review and approval by the NRC, in consultation with the Federal Emergency Management Agency (FEMA), as applicable, in the absence of complete and integrated emergency plans; or

(ii) Propose complete and integrated emergency plans for review and approval by the NRC, in consultation with FEMA, as applicable, in accordance with the applicable standards of § 53.855. To the extent approval of emergency plans is sought, the

application must contain the information required by § 53.1109(g).

(3) Emergency plans submitted under paragraph (b)(2)(ii) of this section must include the proposed inspections, tests, and analyses that the holder of a combined license~~COL~~ referencing the early site permit must perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will be operated in conformity with the emergency plans, the provisions of the Act~~EA~~, and the Commission's rules and regulations. Major features of an emergency plan submitted under paragraph (b)(2)(i) of this section may include proposed ~~ITAAC~~inspections, tests, analyses, and acceptance criteria.

(4) Under paragraphs (b)(1) and (b)(2)(i) of this section, the Site Safety Analysis Report must include, where appropriate, a description of contacts and arrangements made with Federal, State, participating Tribal, and local governmental agencies with emergency planning responsibilities. The Site Safety Analysis Report must contain any certifications that have been obtained. If these certifications, where appropriate, cannot be obtained, the Site Safety Analysis Report must contain information, including a utility plan, sufficient to show that the proposed plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site. Under the option set forth in paragraph (b)(2)(ii) of this section, the applicant must make good faith efforts, where appropriate, to obtain from the same governmental agencies certifications that—

(i) The proposed emergency plans are practicable;

(ii) These agencies are committed to participating in any further development of the plans, including any required field demonstrations; and

(iii) That these agencies are committed to executing their responsibilities under

the plans in the event of an emergency.

(c) An applicant may request that an LWA under § 53.1130 be issued in conjunction with the early site permit. The application must include the information otherwise required by § 53.1130.

~~(d) Each applicant for an early site permit under Framework A of this part must protect safeguards information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.~~

Commented [A306]: Deleted as unnecessary. The draft proposed rule includes this only for ESP and COL applicants, which is a different treatment than for all other applicants and could be interpreted as indicating that the information protection requirements do not apply to those other applicants in the absence of such a requirement in part 53.

§ 53.1149 Review of applications.

(a) *Standards for review of applications.* Applications filed under ~~Framework A of~~ this part will be reviewed according to the applicable standards set out in ~~Framework A of~~ this part. In addition, the Commission must prepare an environmental impact statement during review of the application, ~~in accordance with~~under the applicable provisions of 10 CFR part 51. The Commission must determine, after consultation with Federal Emergency Management Agency~~FEMA~~, as applicable, whether the information required of the applicant by § 53.1146(b)(1) shows that there is no significant impediment to the development of emergency plans that cannot be mitigated or eliminated by measures proposed by the applicant, whether any major features of emergency plans submitted by the applicant under § 53.1146(b)(2)(i) are acceptable ~~in accordance with~~under the applicable standards of § 53.855, and whether any emergency plans submitted by the applicant under § 53.1146(b)(2)(ii) provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

(b) *Administrative review of applications; hearings*. An early site permit application is subject to all procedural requirements in 10 CFR part 2, including the requirements for docketing in § 2.101(a)(1) through (4) of this chapter, and the

requirements for issuance of a notice of hearing in § 2.104(a) and (d) of this chapter, provided that the designated sections may not be construed to require that the environmental report, or draft or final environmental impact statement includes an assessment of the benefits of construction and operation of the reactor or reactors, or an analysis of alternative energy sources. The presiding officer in an early site permit hearing must not admit contentions proffered by any party concerning an assessment of the benefits of construction and operation of the reactor or reactors, or an analysis of alternative energy sources if those issues were not addressed by the applicant in the early site permit application. All hearings conducted on applications for early site permits filed under ~~Framework A of~~ this part are governed by the procedures contained in subparts C, G, L, and N of 10 CFR part 2, as applicable.

§ 53.1155 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application for an early site permit to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS must report on those portions of the application which concern safety.

§ 53.1158 Issuance of early site permit.

(a) After conducting a hearing under § 53.1149(b) and receiving the report to be submitted by the ACRS under § 53.1155, the Commission may issue an early site permit, in the form the Commission deems appropriate, if the Commission finds that—

(1) An application for an early site permit demonstrates compliance with the applicable standards and requirements of the A<u>ct</u>~~EA~~ and the Commission's regulations;

(2) Notifications, if any, to other agencies or bodies have been duly made;

(3) There is reasonable assurance that the site is in conformity with the provisions of the A<u>ct</u>~~EA~~ and the Commission's regulations;

(4) The applicant is technically qualified to engage in any activities authorized;

(5) The proposed inspections, tests, analyses, and acceptance criteria~~ITAAC~~, including any on emergency planning, are necessary and sufficient, within the scope of the early site permit, to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act~~EA~~, and the Commission's regulations;

(6) Issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public;

(7) Any significant adverse environmental impact resulting from activities requested under § 53.1146(c) can be redressed; and

(8) The findings required by subpart A of 10 CFR part 51 have been made.

(b) The early site permit must specify the site characteristics, design parameters, and terms and conditions of the early site permit the Commission deems appropriate. Before issuance of either a construction permit (CP) or combined license (COL) referencing an early site permit, the Commission must find that any relevant terms and conditions of the early site permit have been met. Any terms or conditions of the early site permit that could not be met by the time of issuance of the CP or COL, must be set forth as terms or conditions of the CP or COL.

(c) The early site permit must specify those § 53.1130(b) activities requested under § 53.1146(c) that the permit holder is authorized to perform.

§ 53.1161 Extent of activities permitted.

If the activities authorized by § 53.1158(c) are performed and the site is not referenced in an application for a construction permit~~CP~~ or a combined license~~COL~~ issued under ~~Framework A of~~ this part while the permit remains valid, then the early site permit remains in effect solely for the purpose of site redress, and the holder of the permit must redress the site under the terms of the site redress plan required by

§ 53.1146(c). If, before redress is complete, a use not envisaged in the redress plan is found for the site or parts thereof, the holder of the permit must carry out the redress plan to the greatest extent possible consistent with the alternate use.

§ 53.1164 Duration of permit.

(a) Except as provided in paragraph (b) of this section, an early site permit issued under this subpart may be valid for not less than 10, nor more than 20 years from the date of issuance.

(b) An early site permit continues to be valid beyond the date of expiration in any proceeding on a construction permit (CP) application or a combined license (COL) application that references the early site permit and is docketed either before the date of expiration of the early site permit, or, if a timely application for renewal of the early site permit has been docketed, before the Commission has determined whether to renew the permit.

Commented [A307]: Inserted to clarify the meaning of this sentence.

Commented [A308]: Inserted to specify that the term "permit" refers back to the early site permit and not to the construction permit for which an application was submitted. Staff should clarify 52.26 as accomplished here in an administrative rulemaking.

(c) An applicant for a CP or COL may, at its own risk, reference in its application a site for which an early site permit application has been docketed but not granted.

(d) Upon issuance of a CP or COL, a referenced early site permit is subsumed, to the extent referenced, into the CP or COL.

§ 53.1167 Limited work authorization after issuance of early site permit.

A holder of an early site permit may request an LWA under § 53.113046(c).

Commented [A309]: Edited to correct the citation of the regulation allowing the application for an LWA by the holder of an early site permit. The original citation here, 53.1146(c), is specific to the request for an LWA by an applicant for an early site permit.

§ 53.1170 Transfer of early site permit.

An application to transfer an early site permit will be processed under § 53.1570.

§ 53.1173 Application for renewal.

(a) Not less than 12, nor more than 36 months before the expiration date stated in the early site permit, or any later renewal period, the permit holder may apply for a renewal of the permit. An application for renewal must contain all information necessary

to bring up to date the information and data contained in the previous application.

(b) Any person whose interests may be affected by renewal of the permit may request a hearing on the application for renewal. The request for a hearing must comply with § 2.309 of this chapter. If a hearing is granted, notice of the hearing will be published ~~in accordance with~~under § 2.309 of this chapter.

(c) An early site permit, either original or renewed, for which a timely application for renewal has been filed, remains in effect until the Commission has determined whether to renew the permit. If the permit is not renewed, it continues to be valid in certain proceedings in accordance with the provisions of § 53.1164(b).

(d) The Commission must refer a copy of the application for renewal to the ACRS. The ACRS must report on those portions of the application which concern safety and must apply the criteria set forth in § 53.1176.

§ 53.1176 Criteria for renewal.

(a) The Commission must grant the renewal only if it determines that—

(1) The site complies with the Act~~EA~~, the Commission's regulations, and orders applicable and in effect at the time the site permit was originally issued; and

(2) Any new requirements the Commission may wish to impose—

(i) Are necessary for adequate protection to public health and safety or common defense and security;

(ii) Are necessary for compliance with the Commission's regulations, and orders applicable and in effect at the time the site permit was originally issued; or

(iii) Would~~ill~~ provide a substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementation of those requirements are justified in view of this increased protection.

Commented [A310]: As drafted, this paragraph mandates the renewal by the Commission if the subparagraphs are met but does not prohibit the renewal if they are not met. Section 52.31(a) similarly does not provide criteria that must be met for renewal. The word "only" is inserted after the word "renewal" in order to make this a criterion for renewal. Staff should address this issue in 52.31(a) in an administrative rulemaking.

(b) A denial of renewal ~~for failure to comply with~~under the provisions of § 53.1176(a) does not bar the permit holder or another applicant from filing a new application for the site which proposes changes to the site or the way that it is used to correct the deficiencies cited in the denial of the renewal.

Commented [A311]: The provisions of 53.1176(a) are applicable only to the Commission and not to the applicant for renewal of an early site permit. The same holds true for the provisions of 52.31(a). As a result, the failure to comply with those provisions would only result when the Commission does not grant renewal despite the provisions of the subparagraphs having been met. (N.B., if the Commission were to renew an early site permit despite the failure to meet the provisions of the subparagraphs, it would not be a failure to comply with 53.1176(a) is drafted by the staff.)

Staff should address this issue in 52.31(a) in an administrative rulemaking.

§ 53.1179 Duration of renewal.

Each renewal of an early site permit may be for not less than 10, nor more than 20 years, plus any remaining years on the early site permit then in effect before renewal.

§ 53.1182 Use of site for other purposes.

A site for which an early site permit has been issued under this ~~sub~~part may be used for purposes other than those described in the permit, including the location of other types of energy facilities. The permit holder must inform the Director, Office of Nuclear Reactor Regulation (Director), of any significant uses for the site which have not been approved in the early site permit. The information about the activities must be given to the Director at least 30 days in advance of any actual construction or site modification for the activities. The information provided could be the basis for imposing new requirements on the permit, under the provisions of § 53.1188. If the permit holder informs the Director that the holder no longer intends to use the site for a commercial nuclear plant, the Director may terminate the permit.

§ 53.1188 Finality of early site permit determinations.

(a) *Commission finality*.

(1) While an early site permit is in effect under § 53.1164 or § 53.1179, the Commission may not change or impose new site characteristics, design parameters, or terms and conditions, including emergency planning requirements, on the early site permit unless the Commission—

(i) Determines that a modification is necessary to bring the permit or the site into

compliance with the Commission's regulations and orders applicable and in effect at the time the permit was issued;

(ii) Determines the modification is necessary to assure adequate protection of the public health and safety or the common defense and security;

(iii) Determines that a modification is necessary based on an update under paragraph (b) of this section; or

(iv) Issues a variance requested under paragraph (d) of this section.

(2) In making the findings required for issuance of a construction permit (CP), combined license (COL), or operating license (OL), or the findings required by § 53.1452(g), or in any enforcement hearing other than one initiated by the Commission under paragraph (a)(1) of this section, if the application for the CP, COL, or OL references an early site permit, the Commission must treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the early site permit, except as provided for in paragraphs (b), (c), and (d) of this section.

(i) If the Commission grants a CP application that references an early site permit and an application for an OL or a COL references the CP, the Commission must treat as resolved those matters resolved in the proceeding for the issuance or renewal of the early site permit, except as provided for in paragraphs (b), (c), and (d) of this section.

(ii) If the early site permit approved an emergency plan (or major features thereof) that is in use by a licensee of a commercial nuclear plant, the Commission must treat as resolved changes to the early site permit emergency plan (or major features thereof) that are identical to changes made to the licensee's emergency plans ~~in compliance with~~under § 53.1565 occurring after issuance of the early site permit.

(iii) If the early site permit approved an emergency plan (or major features thereof) that is not in use by a licensee of a commercial nuclear plant, the Commission

must treat as resolved changes that are equivalent to those that could be made under § 53.1565 without prior NRC approval had the emergency plan been in use by a licensee.

(b) *Updating of early site permit-emergency preparedness*. An applicant for a CP, OL, or COL who has filed an application referencing an early site permit issued under this subpart must update the emergency preparedness information that was provided under § 53.1146(b) and discuss whether the updated information materially changes the bases for compliance with applicable NRC requirements.

(c) *Hearings and petitions*. (1) In any proceeding for the issuance of a CP, OL, or COL referencing an early site permit, contentions on the following matters may be litigated in the same manner as other issues material to the proceeding:

(i) The nuclear reactor proposed to be built does not fit within one or more of the site characteristics or design parameters included in the early site permit;

(ii) One or more of the terms and conditions of the early site permit have not been met;

(iii) A variance requested under paragraph (d) of this section is unwarranted or should be modified;

(iv) New or additional information is provided in the application that substantially alters the bases for a previous NRC conclusion or constitutes a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness; or

(v) Any significant environmental issue that was not resolved in the early site permit proceeding, or any issue involving the impacts of construction and operation of the facility that was resolved in the early site permit proceeding for which significant new information has been identified.

(2) Any person may file a petition requesting that the site characteristics, design parameters, or terms and conditions of the early site permit ~~should~~ be modified, or that the permit ~~should~~ be suspended or revoked. The petition will be considered ~~in accordance with~~under § 2.206 of this chapter. Before construction commences, the Commission must consider the petition and determine whether any immediate action is required. If the petition is granted, an appropriate order will be issued. Construction under the CP or COL will not be affected by the granting of the petition unless the order is made immediately effective. Any change required by the Commission in response to the petition must demonstrate compliance with the requirements of paragraph (a)(1) of this section.

Commented [A312]: Edited for clarity. Staff should address this in 52.39 in an administrative rulemaking.

(d) *Variances*. An applicant for a CP, OL, or COL referencing an early site permit may include in its application a request for a variance from one or more site characteristics, design parameters, or terms and conditions of the early site permit, or from the Site Safety Analysis Report. In determining whether to grant the variance, the Commission must apply the same technically relevant criteria applicable to the application for the original or renewed early site permit. Once a CP or COL referencing an early site permit is issued, variances from the early site permit will not be granted for that CP or COL.

(e) *Early site permit amendment*. The holder of an early site permit may not make changes to the early site permit~~, including~~ or the Site Safety Analysis Report~~,~~ without prior Commission approval. The request for a change to the early site permit must be in the form of an application for a license amendment and must demonstrate compliance with the requirements of §§ 53.1510 and 53.1520.

Commented [A313]: As drafted, this implies that the Site Safety Analysis Report is part of the early site permit rather than part of the application for the early site permit, similar to the manner in which technical specifications become part of an operating license or combined license. The edits here are intended to clarify that the Site Safety Analysis Report is a separate document. This same issue exists in 52.39. Staff should address this issue in 52.39 in an administrative rulemaking.

§ 53.1200 Standard design approvals.

Sections 53.1200 through 53.1221 set out procedures for the filing, NRC staff

review, and referral to the ACRS of standard designs, or major portions thereof, for a commercial nuclear plant under ~~Framework A of~~ this part.

§ 53.1203 Filing of applications.

Any person may submit a proposed standard design for a commercial nuclear plant to the NRC staff for its review. The submittal may consist of either the final design for the entire facility or the final design for major portions thereof.

§ 53.1206 Contents of applications for standard design approvals; general information.

The application must contain all of the information required by § 53.1109(a) through (c) and (j).

§ 53.1209 Contents of applications for standard design approvals; technical information.

(a) *Major portion*s *of a standard design*. If the applicant seeks review of ~~a~~ major portions of a standard design, the application need only contain the information required by this section to the extent the requirements are applicable to the major portions of the standard design for which NRC staff approval is sought. If an applicant seeks approval of ~~a~~ major portions of the design, the scope of the application for which approval is sought must include all functional design criteria necessary to demonstrate compliance with the safety criteria in §§ 53.210, 53.220 and 53.450(e), as applicable, for the major portions of the standard design for which NRC staff approval is sought. Such applicants must identify conditions related to interfaces with systems outside the scope of the major portions of the standard design for which NRC staff approval is sought, and functional or physical boundary conditions between the major portions of the standard design for which NRC staff approval is sought and the remainder of the standard design. These conditions must be demonstrated when the standard design approval is incorporated

into a subsequent construction permit (CP), design certification, manufacturing license (ML), operating license (OL), or combined license (COL) application.

Commented [A314]: Inserted to reflect the possibility for an operating license to incorporate a standard design approval as contemplated in the staff's draft proposed 53.1124(g).

(b) *Final Safety Analysis Report.* The application must contain a~~n~~ final safety analysis report (FSAR) that describes the facility and the limits on its operation, and presents a safety analysis of the structures, systems, and components~~SSCs~~ and of the facility, or major portions thereof, for which the applicant seeks design approval, and must include the following information:

(1) *Site Parameters*. The site parameters postulated for the design ~~in accordance with~~under ~~Framework A of~~ this part, including the design-basis external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters.

(2) *Design information.* Except as specified in this paragraph, an application for a standard design approval for a commercial nuclear plant must include the design information equivalent to that required for a standard design certification ~~as provided in~~under § 53.1239(a)(2) through (27) for those portions of a commercial nuclear plant included in the standard design approval.

§ 53.1210 Contents of applications for standard design approvals; other application content

(a) ~~In addition to the FSAR, the application must also include the following:~~

~~(1)~~ *Availability Controls (if not included in the FSAR)*. In addition to the final safety analysis report (FSAR), the application must also include the following ~~A~~a description of the controls on plant operations, including availability controls, to provide reasonable confidence that the configurations and special treatments for NSRSS SSCs provide the capabilities and reliabilities sufficient~~required~~ to demonstrate compliance with the safety criteria of § 53.220.

~~(2) *Safeguards Information*. A description of the program to protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.~~

(b) If there are structures, systems, and components (SSCs) of the plant which required research and development to confirm the adequacy of their design, provide a report in the application which documents the resolution of any safety questions associated with such SSCs.

(c) A description of how the performance of each design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof, in accordance with § 53.440(a).

§ 53.1212 Standards for review of applications.

Applications filed under ~~Framework A of~~ this part will be reviewed ~~for compliance with~~under the standards set out in 10 CFR parts 20, 53, and 73.

§ 53.1215 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application which concern safety.

§ 53.1218 Staff approval of design.

(a) Upon completion of its review of a submittal under §§ 53.1200 through 53.1221 and receipt of a report by the ACRS under § 53.1215, the NRC staff must publish a determination in the *Federal Register* as to whether or not the design is acceptable, subject to appropriate terms and conditions, and make an analysis of the design in the form of a report available at the NRC Web site, https://www.nrc.gov.

(b) A standard design approval issued under this section is valid for 15 years from the date of issuance and may not be renewed. A design approval continues to be

Commented [A315]: Under part 52, applicants for standard design approvals and certifications are not required to submit this information. The need for control of safeguards information by applicants for standard design approvals and certifications is addressed in 53.1109(j) rather than here and by 73.21 and 73.22 directly.

valid beyond the date of expiration in any proceeding on an application for a construction permit (CP), operating license (OL), combined license (COL), or manufacturing license (ML) under ~~Framework A of~~ this part that references the design approval and is docketed before the date of expiration of the design approval.

§ 53.1221 Finality of standard design approvals; information requests.

(a) An approved design must be used by and relied upon by the NRC staff and the ACRS in their reviews of any standard design certification or individual facility license application under ~~Framework A of~~ this part that incorporates by reference a standard design approved under ~~Framework A of~~ this part unless there exists significant new information that substantially affects the earlier determination or other good cause.

(b) The determination and report by the NRC staff do not constitute a commitment to issue a permit or license, or in any way affect the authority of the Commission, Atomic Safety and Licensing Board Panel, or presiding officers in any proceeding under ~~10 CFR~~ part 2 of this chapter.

(c) Except for information requests seeking to verify compliance with the current licensing basis of the standard design approval, information requests to the holder of a standard design approval must be evaluated before issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each evaluation performed by the NRC staff must be in accordance with § 53.1580 and must be approved by the Executive Director for Operations or authorized designee before issuance of the request.

~~(d) The Commission will require, before granting a CP, COL, OL, or ML that references a standard design approval, that engineering documents, such as analyses, drawings, procurement specifications, or construction and installation specifications, be completed and available for audit if the more detailed information is necessary for the~~

~~Commission to verify the information in the application and make its safety determination, including the determination that the application is consistent with the design approval information. This information may be acquired by appropriate arrangements with the design approval applicant.~~

§ 53.1230 Standard design certifications.

Sections 53.1230 through 53.1263 set forth the requirements and procedures applicable to the Commission's issuance of rules granting standard design certifications for commercial nuclear plants under ~~Framework A of~~ this part separate from the filing of an application for a construction permit~~CP~~ or combined license~~COL~~ for such a facility.

§ 53.1233 Filing of applications.

(a) An application for design certification may be filed notwithstanding the fact that an application for a construction permit~~CP~~, combined license~~COL~~, or manufacturing license~~ML~~ for such a facility has not been filed.

(b) The application must comply with the applicable filing requirements of § 53.040 and §§ 2.811 through 2.819 of this chapter.

§ 53.1236 Contents of applications for standard design certifications; general information.

The application must contain all of the information required by § 53.1109(a) through (c) and (j).

§ 53.1239 Contents of applications for standard design certifications; technical information.

The application must contain a level of design information sufficient to enable the Commission to judge the applicant's proposed means of assuring that construction conforms to the design and to reach a final conclusion on all safety questions associated with the design before the certification is granted. The information submitted for a design

Commented [A316]: There is no parallel requirement to this in part 52 for standard design approvals; it only exists for applications that reference standard design certifications. There does not appear to be a need for this due to the provisions of paragraph (b) of this section that limit the affects on the authority of the Commission with respect to such applications.

certification must include performance requirements and design information sufficiently detailed to permit the preparation of acceptance and inspection requirements by the NRC, and procurement specifications and construction and installation specifications by an applicant. The Commission will require, before design certification, that information normally contained in certain ~~engineering documents, such as analyses, drawings,~~ procurement specifications~~, or~~ and construction and installation specifications~~,~~ be completed and available for audit if the ~~more detailed~~ information is necessary for the Commission to ~~verify the information in the application and~~ make its safety determination.

(a) *Final Safety Analysis Report.* The application must contain a~~n~~ final safety analysis report (FSAR) that describes the facility and the limits on its operation, and presents a safety analysis of the structures, systems, and components (SSCs) and of the facility as a whole, and must include the following information:

(1) *Site Parameters*. The site parameters postulated for the design ~~in accordance with~~under ~~Framework A of~~ this part, including the design-basis external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters.

(2)(i) *General Plant Description*. A general description of the commercial nuclear plant including reactor type, the intended use of the reactor, nuclear design (e.g., neutron spectrum, reactor control, multi-unit reactor control), overall layout of the plant including significant plant features and SSCs, maximum power level and the nature and inventory of radioactive materials.

(ii) *Safety functions*. A description of the primary and additional safety functions ~~required~~ under § 53.230 and a summary of how each safety function is satisfied.

(3) *Design Features and functional design criteria – licensing-basis events*. (i) A

Commented [A317]: As drafted, this provision would require the preparation of procurement specifications and other such documents by the design certification applicant prior to submittal of an application. This is a more stringent standard than in part 52, which only requires the provision of the information that would be contained in such documents, which would be expected to be prepared by the COL applicant rather than the DC applicant. These edits return the text to match that of the existing requirements in the prefatory paragraph 52.47.

description of the design features required by § 53.400 and the functional design criteria required by §§ 53.410 and 53.420 that, when combined with corresponding human actions and programmatic controls, demonstrate that the plant will demonstrate compliance with the safety criteria defined in §§ 53.210 and 53.220~~, or more restrictive alternative criteria adopted under § 53.470,~~ during LBEs.

(ii) A description of how design features demonstrate compliance with the requirements of § 53.440(a) through (i) and (k) through (m).

(4) *Design Features and Functional Design Criteria – Normal Operations*. A description of the design features and functional design criteria required by § 53.425 to demonstrate compliance with § 53.260 during normal operations.

(5) *Design Features and Functional Design Criteria – aircraft impact*. A description of the design features and functional design criteria required to demonstrate compliance with the requirements of § 53.440(j) for addressing the impact of a large, commercial aircraft.

(6) *Earthquake engineering*. The information necessary to demonstrate that the commercial nuclear plant complies with the earthquake engineering criteria in § 53.480.

(7) *Programmatic Controls and Interfaces*. (i) A description of the corresponding programmatic controls and interfaces necessary to achieve and maintain the reliability and capability of SSCs relied upon to demonstrate compliance with the functional design criteria required by §§ 53.410 and 53.420 and the safety criteria in §§ 53.210 and 53.220~~, or more restrictive alternative criteria adopted under § 53.470,~~ and necessary to maintain consistency with analyses required by § 53.450.

(ii) For an application for a multi-unit commercial nuclear plant, the programmatic controls and interfaces must also be described for different modular configurations, as required by § 53.440(i), including any restrictions that will be necessary during the

construction and startup of any given unit to ensure the safe operation of the overall commercial nuclear plant to be licensed under this part.

(8) *Programmatic Controls for Normal Operations*. A description of the corresponding programmatic controls, including monitoring programs, necessary to demonstrate that that the criteria defined in § 53.260 are satisfied during normal operations.

(9) *Design Features and Functional Design Criteria for the Protection of Plant Workers*. A description of the design features and functional design criteria required by § 53.430 to demonstrate compliance with § 53.270.

(10) ~~*Programmatic Controls for Protection of Plant Workers.* A description of the corresponding programmatic controls, including monitoring programs, necessary to demonstrate that the worker protection criteria in § 53.270 are satisfied~~[Reserved].

(11) *Codes and Standards*. A description of generally accepted consensus codes and standards used to design the design features~~, as required by § 53.440(b)~~.

(12) *Materials*. A description of the materials used for safety-related (SR) and non-safety-related but safety-significant (NSRSS) SSCs and a description of the qualification of these materials for their service conditions over the plant lifetime, as required by ~~with~~ § 53.440(c) and evaluated under § 53.440(d).

(13) ~~*Integrity Assessment Program.* A description of a design integrity assessment program that addresses the elements described in § 53.440(d)~~.

(14) *Safety and Security*. Confirmation that safety and security were considered together in the design process, as required by § 53.440(f).

(15) *Criticality*. Information demonstrating how the applicant will comply with requirements for criticality accidents in § 53.440(m).

(16) For an application for standard design certification of a multi-unit commercial

nuclear plant, the possible operating configurations of the reactor units, including common systems, interface requirements, and system interactions, as required by § 53.440(i).

(17)(i) The classification of SSCs according to their safety significance ~~in accordance with~~under § 53.460(a).

(ii) For SR and NSRSS SSCs, the conditions under which they must perform the safety functions required by § 53.230, including environmental conditions.

(18) ~~*Probabilistic* *Risk*~~ *Evaluation*~~*Assessment*~~. A description of the ~~PRA~~ risk evaluation required by § 53.450(a)~~,~~ and its results.

(19) *Analyses*. A description of the analyses performed ~~to demonstrate compliance with the requirements in~~under § 53.450(b) through (g)~~,~~ that includes the following information:

(i) A description of the analysis of licensing-basis events (LBEs) and its results, as described in § 53.240. This analysis description must—

(A) Address the elements in § 53.450(e) and (f); and

(B) ~~In accordance with~~under § 53.460(c) —

(*1*) Describe any human actions that are necessary to prevent or mitigate LBEs;

(*2*) Describe how those human actions are capable of being reliably performed under the postulated environmental conditions present; and

(*3*) Describe how those human actions would be addressed by programs established ~~in accordance with~~under subpart F of this part.

(ii)(A) A description of how SSCs ~~needed to ensure~~relied on to meet the safety criteria defined in § 53.210 are protected against or designed to withstand the effects of external hazards ~~as required by~~under § 53.41510.

Commented [A318]: Inserted to align this information requirement with the actual requirements of 53.415.

Commented [A319]: Edited to correct the citation to the section requiring protection or withstanding external hazards.

(B) The information necessary to demonstrate that the commercial nuclear plant

complies with the earthquake engineering criteria in § 53.480.

(iii) A description of the defense-in-depth measures required by § 53.250.

(iv) A description of all plant operating states where there is the potential for the uncontrolled release of radioactive material to the environment, as required by § 53.450(b)(4).

(v) A description of the events that challenge plant control and safety systems whose failure could lead to an undesirable end state and/or radioactive material release, as required by § 53.450(b)(5).

(vi) A description of the analytical codes used in modeling plant behavior in analyses of LBEs and how these codes are qualified for the range of conditions for which they were used, as required by § 53.450(d).

(vii) If not described in addressing paragraph (a)(5) of this section, the results of other analyses required by § 53.450(g).

(20) *Special Treatments*. A description of special treatments established as required by § 53.460.

(21) ~~*Analytical Margins*. A description of any alternative criteria adopted to demonstrate analytical margins supporting operational flexibilities, if applicable, as required by § 53.470~~[Reserved].

(22) *Quality Assurance*. A description of the quality assurance program (QAP) applied to the design of the SSCs of the commercial nuclear plant, as required by § 53.460(b). The description of the QAP for a commercial nuclear plant must include a discussion of how the applicable requirements of ~~subpart K of this~~appendix B to part 50 of this chapter were satisfied.

(23) *Design Features and Controls to Address the Minimization of Contamination*. The information required by § 20.1406 of this chapter.

(24) *Interface Requirements*. (i) A description, analysis, and evaluation of the interfaces between the standard design and the balance of the commercial nuclear plant that may impact the ability of the plant to demonstrate compliance with the functional design criteria~~, performance objectives~~ or the safety criteria of subparts B and C of this part~~required in § 53.210 or § 53.220, or more restrictive alternative criteria adopted under § 53.470~~.

Commented [A320]: Deleted because there is no actual identification of "performance objectives" in 53.210, 53.220 or subpart C.

(ii) Confirmation that interface requirements are verifiable through inspections, testing, or analysis. These requirements must be sufficiently detailed to allow for completion of the final safety analysis by license applicants that reference the certified design under this subpart. The method to be used for verification of interface requirements must be included as part of the proposed inspections, tests, analyses, and acceptance criteria~~ITAAC~~ required by § 53.1241(a)(3).

(iii) A representative conceptual design for those portions of the plant for which the application does not seek certification to aid the NRC in its review of the FSAR and to permit assessment of the adequacy of the interface requirements ~~in~~under paragraph (a)(24)(i) of this section.

(25) *Technical Qualifications*. A description of the technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter.

(26) *Technical Specifications*. Proposed technical specifications prepared ~~in accordance with the requirements of~~under § 53.710(a) for those areas addressed by the design certification.

(27) *Role of personnel.* Information to address the following for the role of personnel in ensuring safe operations:

(i) A description of how the human factors engineering design requirements of

§ 53.440(n)(1) are addressed;

(ii) A description of how the human system interface design requirements of § 53.440(n)(2) are addressed;

(iii) A concept of operations that is of sufficient scope and detail to address the requirements of § 53.440(n)(3);

(iv) A functional requirements analysis and function allocation that is of sufficient scope and detail to address the requirements of § 53.440(n)(4).

(28) *Load following*. For commercial nuclear plants that will operate in a load following mode, information to address the requirements of § 53.440(o).

(b) [Reserved]

§ 53.1241 Contents of applications for standard design certifications; other application content.

(a) In addition to the final safety analysis report (FSAR), the application must also include the following:

(1) *Environmental report*. An environmental report as required by § 51.55 of this chapter.

(2) *Availability Controls* (if not included in the FSAR). A description of the controls on plant operations, including availability controls, to provide reasonable confidence that the configurations and special treatments for non-safety related but safety-significant (NSRSS) structures, systems, and components (SSCs) provide the capabilities and reliabilities required to demonstrate compliance with the safety criteria of § 53.220, or more restrictive alternative criteria adopted under § 53.470.

(3) *Inspections, tests, analyses, and acceptance criteria.* The proposed inspections, tests, analyses, and acceptance criteria~~ITAAC~~ that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses

are performed and the acceptance criteria met, a facility that incorporates the design certification has been constructed and will be operated in conformity with the design certification, the provisions of the ActEA, and the Commission's rules and regulations.

~~(4) *Safeguards information.* A description of the program to protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.~~

(b) If there are SSCs of the plant which required research and development to confirm the adequacy of their design, provide a report in the application which documents the resolution of any safety questions associated with such SSCs.

(c) A description of how the performance of each design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof, ~~in accordance with~~to meet the standard for review of § 53.090(d) ~~53.440(a)~~.

§ 53.1242 Review of applications.

(a*) Standards for review of applications.* Applications filed under ~~Framework A of~~ this part will be reviewed for compliance with the standards set out in 10 CFR parts 20, 51, 53, and 73.

(b) *Administrative review of applications; hearings.* (1) A standard design certification is a rule that will be issued ~~in accordance with~~under the provisions of subpart H of 10 CFR part 2, as supplemented by the provisions of this section. The Commission must initiate the rulemaking after an application has been filed under § 53.1233 and must specify the procedures to be used for the rulemaking. The notice of proposed rulemaking published in the *Federal Register* must provide an opportunity for the submission of comments on the proposed design certification rule. If, at the time a

proposed design certification rule is published in the *Federal Register* under this paragraph, the Commission decides that a legislative hearing should be held, the information required by § 2.1502(c) of this chapter must be included in the *Federal Register* document for the proposed design certification.

(2) Following the submission of comments on the proposed design certification rule, the Commission may, at its discretion, hold a legislative hearing under the procedures in subpart O of ~~10 CFR~~ part 2 of this chapter. The Commission must publish a document in the *Federal Register* of its decision to hold a legislative hearing. The document must contain the information specified in § 2.1502(c) of this chapter and specify whether the Commission or a presiding officer will conduct the legislative hearing.

(3) Notwithstanding anything in § 2.390 of this chapter to the contrary, proprietary information will be protected in the same manner and to the same extent as proprietary information submitted in connection with applications for licenses, provided that the design certification will~~must~~ be published in chapter I of this title.

(c) *Reference to an issued operating license or combined license*. In those cases where a design certification application is preceded by the issuance of an operating license~~OL~~ or custom combined license~~COL~~ for a commercial nuclear plant that is essentially the same as the standard design for which certification is being requested, the NRC review will follow the processes for referencing a standard design approval in § 53.1221, to the extent practicable.

§ 53.1245 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application which concern safety.

§ 53.1248 Issuance of standard design certification.

(a) After conducting a rulemaking proceeding under § 53.1242 on an application for a standard design certification and receiving the report to be submitted by the ACRS under § 53.1245, the Commission may issue a standard design certification in the form of a rule for the design~~,~~ that~~which~~ is the subject of the application, if the Commission determines that—

(1) The application demonstrates compliance with the applicable standards and requirements of the Act~~EA~~ and the Commission's regulations;

(2) Notifications, if any, to other agencies or bodies have been duly made;

(3) There is reasonable assurance that the standard design conforms with the provisions of the Act~~EA~~ and the Commission's regulations;

(4) The applicant is technically qualified;

(5) The proposed inspections, tests, analyses, and acceptance criteria ~~ITAAC~~ are necessary and sufficient, within the scope of the standard design, to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will be operated in accordance with the design certification, the provisions of the Act~~EA~~, and the Commission's regulations;

(6) Issuance of the standard design certification will not be inimical to the common defense and security or to the health and safety of the public;

(7) The findings required by subpart A of part 51 of this chapter have been made; and

(8) The applicant has implemented the quality assurance program~~QAP~~ described or referenced in the Safety Analysis Report.

(b) The design certification rule must specify the site parameters, design characteristics, and any additional requirements and restrictions of the design certification rule.

(c) After the Commission has adopted a final design certification rule, the applicant must not permit any individual to have access to or any facility or to possess restricted data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95, as applicable.

Commented [A321]: Edited to match the requirement in 52.54(c).

§ 53.1251 ~~Duration of~~Reference to certification prior to granting.

~~(a) Except as provided in paragraph (b) of this section, a standard design certification issued under this subpart is valid for 15 years from the effective date of the rule.~~

~~(b) A standard design certification continues to be valid beyond the date of expiration in any proceeding on an application for a COL or an OL under Framework A of this part that references the standard design certification and is docketed either before the date of expiration of the certification, or, if a timely application for renewal of the certification has been filed, before the Commission has determined whether to renew the certification. A design certification also continues to be valid beyond the date of expiration in any hearing held under § 53.1452 before operation begins under a COL that references the design certification.~~

~~(c)~~ An applicant for a construction permit~~CP~~, operating license~~OL~~, combined license~~COL~~, or manufacturing license~~ML~~ under ~~Framework A of~~ this part may, at its own risk, reference in its application a design for which a design certification application has been docketed but not granted.

~~**§ 53.1254 Application for renewal.**~~

~~(a) Not less than 12 nor more than 36 months before the expiration of the initial 15-year period, or any later renewal period, any person may apply for renewal of the certification. An application for renewal must contain all information necessary to bring~~

~~up to date the information and data contained in the previous application. The Commission will require, before renewal of certification, that engineering documents, such as analyses, drawings, procurement specifications, or construction and installation specifications, be completed and available for audit if the more detailed information is necessary for the Commission to verify the information in the application and make its safety determination. Notice and comment procedures must be used for a rulemaking proceeding on the application for renewal. The Commission, in its discretion, may require the use of additional procedures in individual renewal proceedings.~~

~~(b) A design certification, either original or renewed, for which a timely application for renewal has been filed remains in effect until the Commission has determined whether to renew the certification. If the certification is not renewed, it continues to be valid in certain proceedings under § 53.1251.~~

~~(c) The Commission must refer a copy of the application for renewal to the ACRS. The ACRS must report on those portions of the application which concern safety and must apply the criteria set forth in § 53.1257.~~

~~§ 53.1257 Criteria for renewal.~~

~~(a) The Commission must issue a rule granting the renewal if the design, either as originally certified or as modified during the rulemaking on the renewal, complies with the Act~~EA and the Commission's regulations applicable and in effect at the time the certification was issued.

~~(b) The Commission may impose other requirements if it determines that—~~

~~(1) They are necessary for adequate protection to public health and safety or common defense and security;~~

~~(2) They are necessary for compliance with the Commission's regulations and orders applicable and in effect at the time the design certification was issued; or~~

~~(3) There is a substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementing those requirements are justified in view of this increased protection.~~

~~(c) In addition, the applicant for renewal may request an amendment to the design certification. The Commission must grant the amendment request if it determines that the amendment will comply with the Act~~EA and the Commission's regulations in effect at the time of renewal. ~~If the amendment request entails such an extensive change to the design certification that an essentially new standard design is being proposed, an application for a design certification must be filed in accordance with this subpart.~~

~~(d) Denial of renewal does not bar the applicant, or another applicant, from filing a new application for certification of the design, which proposes design changes that correct the deficiencies cited in the denial of the renewal.~~

~~§ 53.1260 Duration of renewal.~~

~~Each renewal of certification for a standard design will be for not less than 10, nor more than 15 years.~~

§ 53.1263 Finality of standard design certifications.

(a)(1) ~~While a standard design certification rule is in effect under § 53.1251 or § 53.1260, t~~The Commission may not modify, rescind, or impose new requirements on the certification information, whether on its own motion, or in response to a petition from any person, unless the Commission determines in a rulemaking that the change—

(i) Is necessary either to bring the certification information or the referencing plants into compliance with the Commission's regulations applicable and in effect at the time the certification was issued;

(ii) Is necessary to provide adequate protection of the public health and safety or

the common defense and security;

(iii) Reduces unnecessary regulatory burden and maintains protection to public health and safety and the common defense and security;

(iv) Provides the detailed design information to be verified under those inspections, tests, analyses, and acceptance criteria~~ITAAC~~ that~~which~~ are directed at certification information (i.e., design acceptance criteria);

(v) Is necessary to correct material errors in the certification information;

(vi) Substantially increases overall safety, reliability, or security of facility design, construction, or operation, and the direct and indirect costs of implementation of the rule change are justified in view of this increased safety, reliability, or security; or

(vii) Contributes to increased standardization of the certification information.

(2)(i) In a rulemaking under § 53.1263(a)(1), except for § 53.1263(a)(1)(ii), the Commission will give consideration to whether the benefits justify the costs for plants that are already licensed or for which an application for a permit or license is under consideration.

(ii) The rulemaking procedures for changes under § 53.1263(a)(1) must provide for notice and opportunity for public comment.

(3) Any modification the NRC imposes on a design certification rule under paragraph (a)(1) of this section will be applied to all plants referencing the certified design, except those to which the modification has been rendered technically irrelevant by action taken under paragraphs (a)(4) or (b) of this section.

(4) The Commission may not impose new requirements by plant-specific order on any part of the design of a specific plant referencing the design certification rule if that part was approved in the design certification ~~while a design certification rule is in effect under § 53.1248,~~ unless—

(i) A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time the certification was issued, or to assure adequate protection of the public health and safety or the common defense and security; and

(ii) Special circumstances as defined in § 53.080 are present. In addition to the factors listed in § 53.080, the Commission must consider whether the special circumstances which § 53.080 requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the plant-specific order.

(5) Except as provided in § 2.335 of this chapter, in making the findings required for issuance of a combined license (COL), construction permit (CP), operating license (OL), or manufacturing license (ML), or for any hearing under § 53.1452, the Commission must treat as resolved those matters resolved in connection with the issuance or renewal of a design certification rule.

(b) An applicant who references a design certification rule may request an exemption from one or more elements of the certification information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 53.080. In addition to the factors listed in § 53.080, the Commission must consider whether the special circumstances that § 53.080 requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. The granting of an exemption on request of an applicant is subject to litigation in the same manner as other issues in the OL or COL hearing.

(c) The Commission will require, before granting a CP, COL, OL, or ML that references a design certification rule, that information normally contained in certain~~engineering documents, such as analyses, drawings,~~ procurement specifications~~,~~ ~~or~~ and construction and installation specifications~~,~~ be completed and available for audit if

the ~~more detailed~~ information is necessary for the Commission to ~~verify the information in the application and~~ make its safety determination, including the determination that the application is consistent with the certification information. This information may be acquired by appropriate arrangements with the design certification applicant.

§ 53.1270 Manufacturing licenses.

Sections 53.1270 through 53.1295 set out the requirements and procedures applicable to Commission issuance of a license under ~~Framework A of~~ this part authorizing manufacture of manufactured reactors to be installed at sites not identified in the manufacturing license~~ML~~ application.

§ 53.1273 Filing of applications.

Any person, except one excluded by § 53.1118, may file an application for a~~n~~ manufacturing license~~ML~~ under this part~~section~~ with the Director, Office of Nuclear Reactor Regulation.

~~Reserved~~

§ 53.1276 Contents of applications for manufacturing licenses; general information.

Each application for a~~n~~ manufacturing license~~ML~~ must include the information contained in § 53.1109(a) through (e), and (j).

§ 53.1279 Contents of applications for manufacturing licenses; technical information.

(a) *Final Safety Analysis Report-siting and design.* The application must include a~~n~~ final safety analysis report (FSAR) containing the information set forth below, with a level of design information sufficient to enable the Commission to judge the applicant's proposed means of ensuring that the manufacturing conforms to the design and to reach a final conclusion on all safety questions associated with the design, permit the

Commented [A322]: Edited to follow the language used in 52.63.

Commented [A323]: Deleted as unnecessary in light of the removal of the paragraph numbering. Staff should address the need for licensing to receive, possess, and handle SNM by a manufacturer fueling manufactured reactors at the factory in guidance as those requirements are self-executing.

preparation of ~~manufacturing~~ construction and installation specifications by an applicant who seeks to use the manufactured reactor, and permit the preparation of acceptance and inspection requirements by the NRC. The application must include the following information:

(1) *Site Parameters.* The site parameters postulated for the design ~~in accordance with~~under ~~Framework A of~~ this part, including the design-basis external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters.

(2) *Design information.* Except as specified in this paragraph, the design information equivalent to that required for a standard design certification as defined in § 53.1239(a)(2) through (27) for those portions of a commercial nuclear plant included in the manufactured reactor.

(3) *Quality assurance program.* A description of the quality assurance program~~QAP, as required by § 53.620(a)(6),~~ applied to the design~~,~~ and to be applied to the fabrication~~,~~ and testing of the structures, systems, and components (SSCs) of the manufactured reactor under § 53.620(a)(6), including a discussion of how the applicable requirements of appendix B to part 50 of this chapter have been and will be satisfied;

(4) *Conceptual designs*. Representative conceptual designs for one or more commercial nuclear plants using the manufactured reactor;

(5) *Operating configurations*. If multiple manufactured reactors may be installed at a commercial nuclear plant, a description of the possible operating configurations, including common systems, interface requirements, and system interactions. The final safety analysis must also account for differences among the possible configurations, including any restrictions that will be necessary during the construction and startup of a given manufactured reactor to ensure the safe operation of any ~~commercial nuclear~~

Commented [A324]: Edited to reflect that the specifications described here are to be prepared by an applicant that desires to use the manufactured reactor under a COL through the act of constructing a commercial nuclear plant and installing the manufactured reactor. This is not the ML applicant that will be manufacturing the reactor.

reactor already operating;

(6) *Interface requirements.* (i) The interface requirements between the manufactured reactor and the remaining portions of the commercial nuclear plant or connections to other facilities outside of the commercial nuclear plant.

(ii) Confirmation that interface requirements are verifiable through inspections, testing, or analysis. These requirements must be sufficiently detailed to allow for completion of the final safety analysis by license applicants that reference the manufactured reactor manufactured under this subpart. Applicants for a combined license (COL) under this part~~§ 53.1410~~ will need to verify the interface requirements at the installation site. The method to be used for verification of interface requirements must be included as part of the proposed inspections, tests, analyses, and acceptance criteria (ITAAC) required by § 53.1282(a).

Commented [A325]: 53.1410 merely describes the location of requirements and procedures for processing COLAs. It provides none of them.

(iii) ~~The FSAR must identify~~Information to support development of radiation monitoring programs required under subpart F of this part by an applicant for a COL, including potential pathways for radionuclides produced within the manufactured reactor to enter interfacing systems ~~to support development of radiation monitoring programs required under subpart F of this part~~.

(b) *Final Safety Analysis Report - Manufacturing information*. The FSAR must include the following information related to the manufacturing processes, organization, controls, and inspections:

(1) A description, including references to generally accepted consensus codes and standards, of the processes that will be used to procure, fabricate, and assemble components that make up the manufactured reactor. The description should clearly define which activities are proposed to be within the scope of the ML and those, such as the making of a component to be procured from a separate company for installation in

the manufactured reactor, that are not considered to be within the scope of the ML;

(2) A description of the organizational and management structure singularly responsible for direction of design and manufacture of the manufactured reactor. The information should include a description of the management plans, technical qualifications, and controls in place to demonstrate compliance with the requirements of § 53.620~~, including those~~ for all~~ny~~ facilities~~y~~ performing an activity within the scope of the ML;

(3) A description of the inspections and tests to be performed as part of the manufacturing process, including the inspection of procured components, inspection and testing of fabrication processes such as the molding, welding, or coating of components, and inspections and testing of the assembled manufactured reactor or portions of the manufactured reactor;

(4) A description of the fitness for duty~~FFD~~ program required by ~~10 CFR~~ part 26 of this chapter and its implementation.

(c) *Deployment of the completed manufactured reactor*. The application must include the following information related to the deployment of a manufactured reactor:

(1) Procedures governing the preparation of the manufactured reactor or portions of the manufactured reactor for shipping to the site where it is to be operated; the conduct of shipping; and verifying the condition of the shipped items upon receipt at the site;

(2) A description of how the portions of the applicant's organization responsible for ~~Details of the interaction of~~ the design, manufacture, and installation of a manufactured reactor ~~within the applicant's organization~~interact and how ~~the manner by which~~ the applicant will ~~ensure close integration~~facilitate interaction between them~~designer, contractors,~~ and any facility in which the manufactured reactor is to be

installed;

(3) A description of the measures to be used for the control of interfaces, including the consideration of ~~key~~ site parameters, between the holder of the ML and the holder of the COL for the commercial nuclear plant at which the manufactured reactor is to be installed.

Commented [A326]: Deleted to avoid introducing an undefined term.

(d) *Special considerations for factory fueling.* An application for a manufacturing license that authorizes fueling of the manufactured reactors at the factory must also include the following information related to the fueling operations and the required independent mechanisms to prevent inadvertent criticality and to otherwise ensure the safety of workers and the public during the manufacture, storage, and transport of each manufactured reactor module:

(1) A description of the safety program and integrated safety analysis required by subpart H of 10 CFR part 70. The description must include the procedures to be used for receipt, storage and loading of the fuel into the manufactured reactor. The description must either be in the form of a reference to the applicable part 70 application and license, if issued, or provided in the Safety Analysis Report supporting the manufacturing license if one application is used for both the manufacturing license and part 70 license.

(i) The application must specifically address the measures taken for fuel loading, in-factory inspections and non-nuclear testing, including at least two independent mechanisms each of which is sufficient to prevent inadvertent criticality, and an analysis of the safety and security of the fueled manufactured reactor within the factory, during possible periods of storage, and during transportation to the licensed site. The storage and transport of a fueled manufactured reactor must comply § 53.620(d) and 10 CFR parts 70, 71, and 73.

(ii) The application must specifically address the functional design criteria and

design features included in the manufactured reactor, or physical or programmatic controls implemented during manufacturing, storage, or transport to prevent inadvertent criticality during various conditions, including when subject to potential hazards and human errors.

(2) A description of the procedures governing the transfer of authorities and responsibilities for the fueled manufactured reactor from the holder of the ML to the holder of the COL for the installation site.

(3) A description of the controls under § 53.620 to address the receipt, storage, and loading of special nuclear material into a manufactured reactor, including:

(i) The fitness-for-duty program, under 10 CFR part 26.

(ii) A Radiation Protection Program under 10 CFR part 20.

(iii) An information security program under 10 CFR part 73.

(iv) A physical security program under 10 CFR part 73.

(v) A fire protection program under § 53.620(c)(2).

(vi) An emergency plan under § 53.620(c)(3).

(vii) A description of the plant staff training program under § 53.620(d).

§ 53.1282 Contents of applications for manufacturing licenses; other application content.

(a) *Inspections, tests, analyses, and acceptance criteria*. (1) The application must contain proposed inspections, tests, and analyses that the combined license~~COL~~ holder must perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met:

(i) The reactor has been manufactured in conformity with the manufacturing

license (ML), the provisions of the ActEA, and the Commission's rules and regulations; and

Commented [A327]: There is a parallel usage of a semicolon in this list in 52.158(a)(1)(i) between "manufacturing license" and "the provisions of the Act". Staff should correct that typographic error in an administrative rulemaking.

(ii) The manufactured reactor will be operated in conformity with the approved design and any license authorizing operation of the manufactured reactor.

(2) If the application references a standard design certification, the inspections, tests, analyses, and acceptance criteria (ITAAC) contained in the certified design must apply to those portions of the facility design thatwhich are covered by the design certification.

(3) If the application references a standard design certification, the application may include a notification that a required inspection, test, or analysis in the design certification ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The *Federal Register* notification required by § 53.1285 must indicate that the application includes this notification.

(b) *Environmental report*. (1) The application must contain an environmental report as required by § 51.54 of this chapter.

(2) If the ML application references a standard design certification, the environmental report need not contain a discussion of severe accident mitigation design alternatives for the manufactured reactor as used in a commercial nuclear plant. Nonetheless, an application for an ML that references a standard design certification but includes the loading of fuel into the manufactured reactor at the factory must discuss severe accident mitigation design alternatives for the manufactured reactor while at the factory and must also discuss severe accident mitigation alternatives for the factory itself

(c) *Safeguards information*. The An application for an ML authorizing loading of fuel into the manufactured reactor at the factory must contain a description of the program to protect safeguards information against unauthorized disclosure in

accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

(d) *Performance demonstration.* A description of how the performance of each design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof, in accordance with § 53.090(d)~~440(a)~~.

§ 53.1285 Review of applications.

(a) *Standards for review of applications.* Applications for manufacturing license~~MLs~~ under ~~Framework A of~~ this part will be reviewed ~~according to the applicable standards set out in this subpart as well as applicable~~for compliance with the standards in 10 CFR parts 20, ~~25,~~ 26, 51, 53, and~~70, 71,~~ 73~~, and 75~~.

(b) *Administrative review of applications, hearings.* A proceeding on a~~n~~ manufacturing license (ML) is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing in § 2.101(a)(1) through (4) of this chapter, and the requirements for issuance of a notice of proposed action in § 2.105 of this chapter, *provided, howeve*r, that the designated sections may not be construed to require that the environmental report or draft or final environmental impact statement include an assessment of the benefits of constructing and/or operating the manufactured reactor or an evaluation of alternative energy sources. All hearings on MLs are governed by the hearing procedures contained in 10 CFR part 2, subparts C, E, G, L, and N.

§ 53.1286 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application which concern safety.

§ 53.1287 Issuance of manufacturing license.

(a) After completing any hearing under § 53.1285(b), and receiving the report submitted by the ACRS, the Commission may issue a~~n~~ manufacturing license (ML) if the Commission finds that—

(1) Applicable standards and requirements of the Act~~EA~~ and the Commission's regulations have been met;

(2) There is reasonable assurance that the manufactured reactor will be manufactured, and can be transported, incorporated into a commercial nuclear plant, and operated in conformity with the ML, the provision of the Act~~EA~~, and the Commission's regulations;

(3) The proposed manufactured reactor can be incorporated into a commercial nuclear plant and operated at sites having characteristics that fall within the site parameters postulated for the design of the manufactured reactors without undue risk to the health and safety of the public;

(4) The applicant is technically qualified to design and manufacture the proposed manufactured reactor;

(5) The proposed inspections, tests, analyses, and acceptance criteria~~ITAAC~~ are necessary and sufficient, within the scope of the ML, to provide reasonable assurance that the manufactured reactor has been manufactured and will be operated in conformity with the license, the provisions of the Act~~EA~~, and the Commission's regulations;

(6) The issuance of a license to the applicant will not be inimical to the common defense and security or to the health and safety of the public; and

(7) The findings required by subpart A of 10 CFR part 51 have been made.

(b) Each ML issued under this subpart must specify—

(1) Terms and conditions as the Commission deems necessary and appropriate;

(2) Technical specifications for operation of the manufactured reactor, as the

Commission deems necessary and appropriate;

(3) Site parameters and design characteristics for the manufactured reactor; ~~and~~

(4) The interface requirements to be met by the site-specific elements of the facility, such as the energy conversions systems and ultimate heat sink, not within the scope of the manufactured reactor~~.~~; and

(5) The entity with design authority for the manufactured reactor covered by the license.

§ 53.1288 Finality of manufacturing licenses.

(a)(1) Notwithstanding any provision in § 53.1590, during the term of a~~n~~ manufacturing license (ML) issued under ~~Framework A of~~ this part the Commission may not modify, rescind, or impose new requirements on the design of the manufactured reactor, or the requirements for the manufacture of the manufactured reactor, unless the Commission determines that a modification is necessary to bring the design of the reactor or its manufacture into compliance with the Commission's requirements applicable and in effect at the time the ML was issued, or to provide reasonable assurance of adequate protection to public health and safety or common defense and security.

(2) Any modification to the design of a manufactured reactor that is imposed by the Commission under paragraph (a)(1) of this section will be applied to all manufactured reactors manufactured under the license, including those that have already been transported and sited, except those manufactured reactors to which the modification has been rendered technically irrelevant by action taken under § 53.1530 or paragraph (b) of this section.

(3) In making the findings required under ~~Framework A of~~ this part for issuance of a combined license (COL), in any hearing under § 53.1452, or in any enforcement

hearing other than one initiated by the Commission under paragraph (a)(1) of this section, for which a manufactured reactor manufactured under this subpart is referenced or used, the Commission must treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the ML, including the adequacy of design of the manufactured reactor, the costs and benefits of severe accident mitigation design alternatives, and the bases for not incorporating severe accident mitigation design alternatives into the design of the manufactured reactor to be manufactured.

(b) An applicant who references or uses a manufactured reactor manufactured under an ML under ~~Framework A of~~ this part may include in the application a request for a departure from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The Commission may grant a request only if it determines that the departure will comply with the requirements of § 53.080, and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure. The granting of a departure on request of an applicant is subject to litigation in the same manner as other issues in the COL hearing.

§ 53.1291 Duration of manufacturing licenses.

A~~n~~ manufacturing license (ML) issued under ~~Framework A of~~ this part is valid for not less than 5, nor more than 15 years from the date of issuance. Upon expiration of the ML, the manufacture of any uncompleted manufactured reactors must cease unless a timely application for renewal has been docketed with the NRC.

§ 53.1293 Transfer of manufacturing licenses.

A~~n~~ manufacturing license~~ML~~ may be transferred under § 53.1570.

§ 53.1295 Renewal of manufacturing licenses.

(a)(1) Not less than 12 months, nor more than 5~~five~~ years before the expiration of the manufacturing license (ML), or any later renewal period, the holder of the ML issued under ~~Framework A of~~ this part may apply for a renewal of the license. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application.

(2) The filing of an application for a renewed license must be in accordance with subpart A of 10 CFR part 2 and § 53.1100.

(3) An ML issued under ~~Framework A of~~ this part, either original or renewed, for which a timely application for renewal has been filed, remains in effect until the Commission has made a final determination on the renewal application~~, *provided, however,* that the holder of an ML may not begin manufacture of a manufactured reactor less than 6 months before the expiration of the license~~. Upon a final determination by the Commission to deny a renewal application for an ML, the manufacture of any uncompleted reactors must cease.

(4) Any person whose interest may be affected by renewal of the license may request a hearing on the application for renewal. The request for a hearing must comply with § 2.309 of this chapter. If a hearing is granted, notice of the hearing will be published in accordance with § 2.104 of this chapter.

(5) The Commission must refer a copy of the application for renewal to the ACRS. The ACRS must report on those portions of the application which concern safety ~~and must apply the criteria set forth in § 53.1285~~.

(b) The Commission may grant the renewal if the Commission determines—

(1) The ML complies with the Act~~EA~~ and the Commission's regulations and orders applicable and in effect at the time the ML was originally issued; and

(2) Any new requirements the Commission may wish to impose are—

Commented [A328]: Edited to conform to NUREG-1379, Revision 4, Section 5.4.

Commented [A329]: Deleted as unnecessary in light of the requirement to cease manufacture of uncompleted reactors upon expiration of the ML.

Commented [A330]: There is a typographic error in 52.177 for the requirement that this draft proposed paragraph parallels, using the word "permit" rather than "license" in this sentence. Staff should correct that error in an administrative rulemaking.

Commented [A331]: Deleted to parallel the referral to the ACRS provisions for other applications and avoid the potential inconsistencies with the criteria of paragraph (b)(1) of this section regarding the Commission's regulations and orders applicable and in effect at the time the ML was originally issued rather than those that are current and would be used by the ACRS under 53.1285.

Staff should consider whether the parallel requirement for the use by the ACRS of the criteria in 52.159 under 52.177(e) is appropriate in light of the similar conflict with the Commission's criteria for renewal in 52.179(a) and take appropriate action to harmonize them.

(i) Necessary for adequate protection to public health and safety or common defense and security;

(ii) Necessary for compliance with the Commission's regulations and orders applicable and in effect at the time the ML was originally issued; or

(iii) A substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementation of those requirements are justified in view of this increased protection.

(c) A renewed ML may be issued for a term of not less than 5, nor more than 15 years, plus any remaining years on the ML then in effect before renewal. The renewed license must be subject to the requirements of §§ 53.1288 and 53.1293.

§ 53.1300 Construction permits.

Sections 53.1300 through 53.1348 set out the requirements and procedures applicable to Commission issuance of aconstruction permits (CPs) for commercial nuclear plants. A CP for the construction of a commercial nuclear plant under Framework A of this part will be issued before the issuance of an operating license (OL) if the application is otherwise acceptable and will be converted upon completion of the facility and Commission action, into an OL as provided underin §§ 53.13876060 through 53.1405.

§ 53.1306 Contents of applications for construction permits; general information.

An application for a construction permit (CP) must include the information required by § 53.1109 and the following information:

(a) Information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, under the regulations in this chapter, the activities for which the permit is sought. As applicable, the following should be provided:

(1) The applicant must submit~~The~~ information that demonstrates that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs, including estimates of the total construction costs and related fuel cycle costs of the facility and must indicate the source(s) of funds to cover these costs.~~;~~

(2) Each application for a CP submitted by a newly-formed entity organized for the primary purpose of constructing and operating a facility must also include information showing:

(i) The legal and financial relationships the entity has or proposes to have with its stockholders or owners;

(ii) The stockholders' or owners' financial ability to ~~demonstrate compliance with~~ meet any contractual obligation to the entity that~~which~~ they have incurred or proposed to incur.~~; and~~

~~(iii) Any other information considered necessary by the Commission to enable it to determine the applicant's financial qualification; and~~

(3) The Commission may request an established entity or newly-formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding an applicant's ability to continue the conduct of the activities authorized by the CP and to decommission the facility.

(b) If the applicant proposes to construct or alter a facility, the application must state the earliest and latest dates for completion of the construction or alteration.

§ 53.1309 Contents of applications for construction permits; technical information.

The application must contain a Preliminary Safety Analysis Report (PSAR) that describes the facility and the limits on its operation and presents a preliminary safety

Commented [A332]: Edited to conform to the guidance of NUREG-1379, Revision 4, Section 6.38.

Commented [A333]: Deleted as redundant to paragraph (a)(3) of this section.

analysis of the structures, systems, and components (SSCs) of the facility as a whole. The PSAR must include the following information, at a level of detail sufficient to enable the Commission to reach a conclusion on safety matters that must be resolved by the Commission before issuance of a construction permit (CP):

(a)(1) *Site information.* An application for a CP for a commercial nuclear reactor must include the site information equivalent to that required for an early site permit in § 53.1146(a)(1)(iv) through (x).

(2) *Design information*. Except as specified in this paragraph, an application for a CP for a commercial nuclear plant must include the design information equivalent to that required for a standard design certification as defined in § 53.1239(a)(2) through (27).

(i) *Quality assurance program.* A description of the ~~QAP~~quality assurance program~~, as required by § 53.610(a)(6),~~ to be applied to the design, fabrication, construction, and testing of the SSCs of the facility under § 53.610(a)(6), including a discussion of how the requirements of appendix B to part 50 of this chapter will be satisfied.

(ii) *Preliminary design information.* The information provided in the application may include some aspects of the design that are not fully developed, and the information is therefore preliminary. The completed design, including any changes during construction, must be described in the final safety analysis report (FSAR) required in § 53.1369 that supports an application for an operating license (OL).

(iii) *Planned research or testing*. Descriptions of how design features and related functional design criteria will fulfill the safety criteria in subpart B~~, or more restrictive alternative criteria adopted under § 53.470,~~ and how that has been or will be demonstrated through either analysis, appropriate test programs, experience, or a combination thereof. Where any design feature has not been fully developed or

demonstrated to fulfill the functional design criteria at the time of an application for a CP, the applicant must provide a plan for future analysis, research and development, test programs, gathering of experience, or a combination thereof to provide reasonable confidence that the required demonstration will be available for an application for an OL

(iv) *Programmatic controls*. Descriptions of the programmatic controls may include those to be provided in the FSAR or other licensing basis documents because they are necessary to achieve and maintain the reliability and capability of SSCs relied upon to demonstrate compliance with the established safety criteria and functional design criteria required in subpart B, and to maintain consistency with analyses required by § 53.450.

(3) *Technical qualifications*. A description of the technical qualifications of the applicant to engage in the proposed activities ~~in accordance with~~under the regulations in this chapter.

(4) *Emergency preparedness*. A discussion of the applicant's preliminary plans for coping with emergencies. Appendix E to part 50 of this chapter sets forth items which shall be included in these plans.~~A preliminary description of the plans for coping with emergencies with sufficient information to ensure the compatibility of proposed emergency plans for both onsite areas and the EPZs, with facility design features, site layout, and site location with respect to such considerations as access routes, surrounding population distributions, land use, and local jurisdictional boundaries for the EPZs as well as the means by which the standards of § 53.855 will be met. As a minimum, the following items must be described:~~

~~(i) Onsite and offsite organizations for coping with emergencies and the means for notification, in the event of an emergency, of persons assigned to the emergency organizations.~~

(ii) Contacts and arrangements made and documented with local, State, participating Tribal and Federal governmental agencies with responsibility for coping with emergencies, including identification of the principal agencies.

(iii) Measures to protect health and safety in the event of an accident; procedures by which these measures are to be carried out (e.g., in the case of an evacuation, who authorizes the evacuation, how the public is to be notified and instructed, how the evacuation is to be carried out); and the expected response of offsite agencies in the event of an emergency.

(iv) Features of the facility to be provided for onsite emergency first aid and decontamination and for emergency transportation of onsite individuals to offsite treatment facilities.

(v) Provisions to be made for emergency treatment at offsite facilities of individuals injured as a result of licensed activities.

(vi) Provisions for a training program for employees of the licensee, including those who are assigned specific authority and responsibility in the event of an emergency, and for other persons who are not employees of the licensee but whose assistance may be needed in the event of a radiological emergency.

(vii) A preliminary analysis that projects the time and means to be employed in the notification of State, participating Tribal and local governments and the public in the event of an emergency. A commercial nuclear plant applicant with an EPZ extending beyond the site boundary must perform a preliminary analysis of the time required to evacuate various sectors and distances within the plume exposure pathway EPZ for transient and permanent populations, noting major impediments to the evacuation or taking of protective actions.

(viii) A preliminary analysis reflecting the need to include facilities, systems, and

~~methods for identifying the degree of seriousness and potential scope of radiological consequences of emergency situations within and outside the site boundary, including capabilities for dose projection using real-time meteorological information and for dispatch of radiological monitoring teams within the EPZs, and a preliminary analysis reflecting the role of the emergency response facilities in assessing information, recommending protective action, and disseminating information to the public.~~

Commented [A334]: Revised to align with the requirements of 50.34(a)(10) in light of the reliance on appendix E to part 50 and 50.47 in 53.855.

(5) *Physical security*. A report that provides a preliminary description of how the site characteristics support the development of adequate security plans and measures consistent with the requirements in § 53.540.

(6) *Fitness-for-duty program*. A description of the fitness-for-duty~~FFD~~ program required by 10 CFR part 26 and its implementation.

Commented [A335]: Deleted to align with the submittal requirements for part 50 CP applications.

(b) ~~*Safeguards information*. A description of the program to protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable~~[Reserved].

§ 53.1312 Contents of applications for construction permits; other application content.

(a) In addition to the preliminary safety analysis report (PSAR), the application must include the following:

(1) An environmental report either under § 51.50(a) of this chapter if a~~n~~ limited work authorization (LWA) under § 53.1130 is not requested in conjunction with the construction permit (CP) application, or under §§ 51.49 and 51.50(a) of this chapter if an LWA is requested in conjunction with the CP application; or

(2) If the applicant wishes to request that an LWA under § 53.1130 be issued before issuance of the CP, the information otherwise required by § 53.1130, in accordance with either § 2.101(a)(1) through (a)(5), or § 2.101(a)(9) of this chapter.

(b) If the CP application references an early site permit, standard design approval, or standard design certification issued under ~~Framework A of~~ this part, then the following requirements apply:

(1) The PSAR need not contain information or analyses submitted to the Commission in connection with the referenced NRC approval, permit, or certification, provided, however, that the PSAR incorporates the material by reference and confirms that the site and design of the facility falls within parameter values postulated in the referenced NRC approval, permit, or certification.

(2) The PSAR must provide a means to demonstrate that all terms and conditions that have been included in the referenced NRC approval, permit, or certification will be satisfied by the date of issuance of the operating license (OL), as appropriate. If the PSAR does not demonstrate that each site characteristic falls within the corresponding postulated site parameter and each design characteristic of the facility falls within the corresponding postulated design parameter, the application must justify a departure, variance, or exemption from the referenced NRC approval, license, or certification in regard to that particular site or design characteristic in compliance with the requirements of ~~Framework A of~~ this part.

(3) If a referenced early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the PSAR must include any new or additional information that updates and corrects the information that was provided under § 53.1146(b)(2) and discuss whether the new or additional information materially changes the bases for compliance with the applicable requirements.

§ 53.1315 Review of applications.

(a) *Standards for review of applications.* Applications filed under ~~Framework A of~~ this part will be reviewed according to the standards set out in 10 CFR parts 20, 51, 53,

73, and 140.

(b) *Administrative review of applications; hearings*. A proceeding on a construction permit (CP) application is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). All hearings on CP applications are governed by the procedures contained in 10 CFR part 2.

§ 53.1318 Finality of referenced NRC approvals, permits, and certifications.

If the application for a construction permit~~CP~~ under this part references an early site permit, standard design approval, or standard design certification, the scope and nature of matters resolved for the application are governed by the relevant provisions addressing finality, including §§ 53.1188, 53.1221, and 53.1263.

§ 53.1324 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application that concern safety and must apply the standards referenced in § 53.1315, in accordance with the finality provisions in § 53.1318.

§ 53.1327 Authorization to conduct limited work authorization activities.

(a) If the application does not reference an early site permit which authorizes the holder to perform the activities under § 53.1130, the applicant may not perform those activities without obtaining the separate authorization required by § 53.1130. Authorization may be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by § 53.1130(b)(1)(ii) and (iv), and the Director, Office of Nuclear Reactor Regulation makes the determination required by § 53.1130(b)(1)(iii).

(b) If, after an applicant has performed the activities permitted by paragraph (a)

of this section, the application for the construction permit~~CP~~ is withdrawn or denied, then the applicant must implement an approved site redress plan.

§ 53.1330 Exemptions, departures, and variances.

(a) Applicants for a construction permit (CP) under this ~~sub~~part, or any amendment to a CP, may include in the application a request for an exemption from one or more of the Commission's regulations. The Commission may grant a request if it determines that the exemption complies with § 53.080.

(b) An applicant for a CP who has filed an application referencing an NRC approval, permit, or certification issued under ~~Framework A of~~ this part may include in the application a request for exemptions, departures, or variances related to the subject referenced NRC approval, permit, or certification. In determining whether to grant the departure, variance, or exemption, the Commission must apply the same technically relevant criteria as were applicable to the application for the original or renewed approval, license, or certification.

§ 53.1333 Issuance of construction permits.

(a) After conducting a hearing in accordance with § 53.1315 and receiving the report submitted by the ACRS, the Commission may issue a construction permit (CP) only if the Commission finds that—

(1) The applicant has described the proposed design of the facility and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report~~FSAR~~;

(3) Safety features or components, if any, ~~which~~ that require research and

development have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components; and

(4) On the basis of the foregoing, there is reasonable assurance of the following—

(i) Such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility; and

(ii) Taking into consideration the site criteria contained subpart D, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

(b) A CP must contain the terms and conditions for the permit, as the Commission deems necessary and appropriate. The Commission may, in its discretion, incorporate in any CP provisions requiring the applicant to furnish periodic reports of the progress and results of research and development programs designed to resolve safety questions.

§ 53.1336 Finality of construction permits.

Notwithstanding any provision in § 53.1590, a construction permit (CP) constitutes an authorization to proceed with construction but does not constitute Commission approval of the safety of any design feature or specification unless the applicant specifically requests such approval and such approval is incorporated in the permit. The applicant, at its option, may request such approvals in the CP or by amendment to the CP. If approved by the NRC and included in the permit, the NRC will consider modifications to the approved design features or specifications in accordance with § 53.1590.

§ 53.1342 Duration of construction permit.

Commented [A336]: Space between "following" and the em dash has been deleted to keep these on the same line.

(a) A construction permit (CP) will state the earliest and latest dates for completion of construction or alteration of the facility, not to exceed 40 years from date of issuance.

(b) If the proposed construction or alteration of the facility is not completed by the latest completion date, the CP shall expire, and all rights are forfeited. However, upon good cause shown, the Commission will extend the completion date for a reasonable period of time. The Commission will recognize, among other things, developmental problems attributed to the experimental nature of the facility or fire, flood, explosion, strike, sabotage, domestic violence, enemy action, an act of the elements, and other acts beyond the control of the permit holder, as a basis for extending the completion date.

§ 53.1345 Transfer of construction permits.

A construction permit (CP) may be transferred under § 53.1570.

§ 53.1348 Termination of construction permits.

When a permit holder has determined to permanently cease construction, the holder must, within 30 days, submit a written certification to the NRC.

§ 53.1360 Operating licenses.

Sections 53.1360 through 53.1405 set out the requirements and procedures applicable to Commission issuance of an operating license~~OL~~ for a nuclear power facility.

§ 53.1366 Contents of applications for operating licenses; general information.

An application for an operating license (OL) must include the information required by § 53.1109 and the following information:

(a) Except for an electric utility applicant, information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, in accordance

with the regulations in this chapter, the activities for which the license is sought. As applicable, the following should be provided:

(1) The applicant must submit information that demonstrates the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license. The applicant must submit estimates for total annual operating costs for each of the first 5 years of operation of the facility. The applicant must also indicate the source(s) of funds to cover these costs.

(2) Each application for an OL submitted by a newly-formed entity organized for the primary purpose of operating the facility must also include information showing—

(i) The legal and financial relationships the entity has or proposes to have with its stockholders or owners;

(ii) The stockholders' or owners' financial ability to meet~~demonstrate compliance with~~ any contractual obligation to the entity which they have incurred or proposed to incur.~~; and~~

~~(iii) Any other information considered necessary by the Commission to enable it to determine the applicant's financial qualification.~~

Commented [A337]: Deleted as redundant to paragraph (a)(3) of this section.

(3) The Commission may request an established entity or newly-formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding a licensee's ability to continue the conduct of the activities authorized by the license and to decommission the facility.

(b) The application must include information in the form of a report, as described in subpart G, indicating how reasonable assurance will be provided that funds will be available to decommission the facility, including a copy of the financial instrument obtained to satisfy the requirements of § 53.1040.

§ 53.1369 Contents of applications for operating licenses; technical information.

Commented [A338]: Structure of this section has been modified to follow that of the other content of applications; technical information sections.

(a) *Final Safety Analysis Report*. The application must contain a~~n~~ final safety analysis report (FSAR) that describes the facility and the limits on its operation and presents a safety analysis of the structures, systems, and components (SSCs) of the facility as a whole. The FSAR must include the following information, at a level of detail sufficient to enable the Commission to reach a final conclusion on all safety matters that must be resolved by the Commission before issuance of an operating license (OL). The ~~application~~ FSAR must include the following information:

(~~a~~1) *Site information*. An application for an OL for a commercial nuclear reactor must include the site information equivalent to that required for an early site permit in § 53.1146(a)(1)(iv) through (x), including all current information, such as the results of environmental and meteorological monitoring programs, which has been developed since issuance of the construction permit (CP), relating to site evaluation factors identified in ~~Framework A of~~ this part.

(2~~b~~) *Design information*. Except as specified in this paragraph, an ~~application~~ FSAR for an OL for a commercial nuclear plant must include the final design information equivalent to that required for a standard design certification as defined in § 53.1239(a)(2) through (27).

(~~1~~i) The completed design, including any changes during construction, must be described.

(~~2~~ii) Where any design feature had not been fully developed or demonstrated at the time of application for the CP, the applicant must provide the analysis, research and development, test programs, gathering of experience, or a combination thereof to provide the required demonstration to fulfill the functional design criteria.

(~~c~~3) *Technical qualifications*. A description of the technical qualifications of the

applicant to engage in the proposed activities in accordance with the regulations in this chapter.

~~(d) *Integrity assessment program.* A description of an Integrity Assessment Program that addresses the elements described in § 53.870.~~

(4~~e~~) *Safeguards information.* A description of the program to protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

~~(f) *Emergency response facility or facilities.* A Ddescription of the locations and capabilities to be established for command and control, support, and coordination of onsite and offsite, as applicable, functions during reactor accident conditions.~~

(~~g~~5) *Role of personnel.* (i~~1~~) A description of the completed assessments related to the role of personnel in ensuring safe operations considering the analyses required by § 53.730. These assessments must include the following:

(i*1*) Human factors engineering design requirements of § 53.~~730~~440(n~~a~~)(1);

(i~~i~~2) Human system interface design requirements of § 53.~~730~~440(~~b~~n)(2);

(iii*3*) Concept of operations of § 53.730(c);

(iv*4*) Functional requirements analysis and function allocation of § 53.730(d);

(2ii) A description of the program to be used for evaluating and applying operating experience as required by § 53.730(e);

(iii3) A staffing plan and supporting analyses as required by § 53.730(f).

(~~h~~6) *Training, examination, and proficiency programs.* (i~~1~~) A description of ~~T~~the training, examination, and proficiency programs required by § 53.730(g);

(2ii) A description of the training programs required by § 53.830.

(i7) *Emergency plan*. Emergency plans complying with the requirements of § 53.855.

(~~4~~i) The emergency plan must ~~i~~include all emergency plan certifications, as applicable, that have been obtained from the State, local, and participating Tribal governmental agencies with emergency planning responsibilities that are wholly or partially within the emergency planning zone~~EPZ~~ plume exposure pathway. These certifications must state that—

(~~i~~1) The proposed emergency plans are practicable;

(~~ii~~2) These agencies are committed to participating in any further development of the plans, including any required field demonstrations; and

(~~iii~~3) These agencies are committed to executing their responsibilities under the plans in the event of an emergency.

(ii2) If certifications cannot be obtained after sustained, good faith efforts by the applicant, then the application must contain information, including a utility plan, sufficient to show that the proposed plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site.

(~~3~~iii) If complete and integrated emergency plans were ~~approved as part of an early site permit, or~~ submitted, reviewed, and approved as part of the CP application, new certifications that demonstrate compliance with the requirements of paragraph (i)(1) of this section are not required.

(~~8~~j) *Organization.* A description of the applicant's organizational structure, allocations o~~f~~ responsibilities and authorities, and personnel qualifications requirements for operation.

(~~9~~k) *Maintenance program*. A description of a maintenance program ~~that demonstrates compliance with the requirements in~~under § 53.715.

(~~10~~l) *Quality assurance*. A description of the quality assurance program~~QAP~~ ~~that demonstrates compliance with the requirements of~~under § 53.865.

Commented [A339]: Deleted as unnecessary with the insertion of paragraph (b)(5) of this section, which covers this possibility.

Commented [A340]: This is faithful to 50.34(b)(6(i), which also has the typographic error using the word "or" instead of the word "of" in the phrase "allocation or responsibilities" (sic). Staff should correct the typographic error in 50.34(b)(6)(i) in an administrative rulemaking.

(11~~m~~) *Radiation protection program*. A radiation protection program description ~~that demonstrates compliance with the requirements of~~under § 53.850.

(12~~n~~) *Security program*. A physical security plan that describes how the applicant will ~~demonstrate~~ compl~~y~~iance with ~~the requirements of~~ § 53.860 (and 10 CFR part 11, if applicable, including the identification and description of jobs as required by § 11.11(a) of this chapter, at the proposed facility). The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with the requirements of 10 CFR parts 11 and 73, if applicable.

(13~~o~~) *Safeguards contingency plan*. A safeguards contingency plan in accordance with the criteria set forth in appendix C to 10 CFR part 73. The safeguards contingency plan must include plans for dealing with threats, thefts, and radiological sabotage, as defined in 10 CFR part 73, relating to the special nuclear material~~SNM~~ and nuclear facilities licensed under this chapter and in the applicant's possession and control. Each application for this type of license must include the information contained in the applicant's safeguards contingency plan. (Implementing procedures required for this plan need not be submitted for approval.)~~7~~[1]

(14~~p~~) *Security training and qualification*. A training and qualification plan that describes how the applicant will demonstrate compliance with the criteria set forth in § 73.100 of this chapter or appendix B to 10 CFR part 73.

(15~~q~~) *Cyber security plan*. A cyber security plan in accordance with the criteria set forth in § 73.54 or § 73.110 of this chapter.

(16~~r~~) *Security, safeguards and cyber security plan implementation*. A description of the implementation of the physical security plan, safeguards contingency plan, training and qualification plan, and cyber security plan. Each applicant who prepares a physical security plan, a safeguards contingency plan, a training and qualification plan, or a cyber

security plan must protect the plans and other related Safeguards Information against unauthorized disclosure in accordance with the requirements of §§ 73.21 and 73.22 of this chapter.

(17s) *Fire protection program*. A description of the fire protection program description that demonstrates compliance with the requirements ofunder § 53.875.

(18t) *Inservice inspection/inservice testing program*. An description of the ISIinservice inspection/IST inservice testing program description that demonstrates compliance with the requirements ofunder § 53.880.

(u) [Reserved]

(v) *Facility safety program*. An FSP plan that demonstrates compliance with the requirements of § 53.890.

(w) *General employee training*. A description of the training program required to demonstrate compliance with § 53.830 and its implementation.

Commented [A341]: Deleted as redundant to paragraph (a)(7)(ii) of this section (formerly paragraph (h)(2)).

(19x) *Fitness-for-duty program*. A description of the fitness-for-dutyFFD program required by 10 CFR part 26 and its implementation.

(20y) *Other programs*. A description and evaluation of the results of the applicant's programs, including research and development, if any, to demonstrate that any safety questions identified at the CP stage have been resolved.

(21z) *Safety design feature performance*. A description of how the performance of each safety design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof, in accordance with § 53.440090(da).

(aa) *Technical specifications*. Proposed technical specifications prepared in accordance with the requirements of § 53.710(a).

(b) If the OL application references an early site permit, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the early site permit provided that the FSAR must either include or incorporate by reference the early site permit Site Safety Analysis Report and contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit.

(2) If the FSAR does not demonstrate that design of the facility falls within the site characteristics and design parameters, the application must include a request for a variance that complies with the requirements of §§ 53.1188(d) and 53.1384.

(3) The FSAR must demonstrate that all terms and conditions that have been included in the early site permit will be satisfied by the date of issuance of the OL. Any terms or conditions of the early site permit that could not be met by the time of issuance of the OL must be set forth as terms or conditions of the OL.

(4) If the early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the FSAR must include any new or additional information that updates and corrects the information that was provided under § 53.1146(b)(2) and discuss whether the new or additional information materially changes the bases for compliance with the applicable requirements. The application must identify changes to the emergency plans or major features of emergency plans that have been incorporated into the proposed facility emergency plans and that constitute or would constitute a change in an emergency plan that results in reducing the licensee's capability to perform an emergency planning function in the event of a radiological emergency.

(5) If complete and integrated emergency plans are approved as part of the early site permit, new certifications meeting the requirements of paragraph (a)(8)(i) of this section are not required.

(c) If the OL application references a standard design approval, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the design approval, provided, however, that the FSAR must either include or incorporate by reference the standard design approval FSAR and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the characteristics of the site fall within the site parameters specified in the design approval. In addition, the plant-specific risk evaluation must use the risk evaluation for the design approval and must be updated to account for site specific design information and any design changes or departures.

(2) The FSAR must demonstrate that all terms and conditions that have been included in the design approval will be satisfied by the date of issuance of the OL.

(d) If the OL application references a standard design certification, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the standard design certification, provided, however, that the FSAR must either include or incorporate by reference the standard design certification FSAR and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the standard design certification. In addition, the plant-specific risk evaluation must use the risk evaluation for the standard design certification and must be updated to account for site-specific design information and any

design changes or departures.

(2) The FSAR must demonstrate that the interface requirements established for the design under § 53.1239(a)(24) have been met.

(3) The FSAR must demonstrate that all requirements and restrictions set forth in the referenced standard design certification rule must be satisfied by the date of issuance of the OL. Any requirements and restrictions set forth in the referenced standard design certification rule that could not be satisfied by the time of issuance of the OL, must be set forth as terms or conditions of the OL.

[61] A physical security plan that contains all the information required in both § 73.55 or § 73.100 of this chapter and appendix C to 10 CFR part 73 satisfies the requirement for a contingency plan.

§ 53.1372 Contents of applications for operating licenses; other application content.

In addition to the final safety analysis report (FSAR), the application must also include the following:

(a) *Environmental report*. An environmental report in accordance with § 51.53(b) of this chapter.

(b) *Availability controls (if not included in the FSAR*). A description of the controls on plant operations, including availability controls, to provide reasonable confidence of safe operation and that the configurations and special treatments for non-safety-related but safety significant~~NSRSS~~ structures, systems, and components~~SSCs~~ provide the capabilities and reliabilities required to satisfy the safety criteria of § 53.220~~, or more restrictive alternative criteria adopted under § 53.470,~~ if not addressed by Technical Specifications under § 53.~~1369~~710(a~~a~~).

§ 53.1375 Review of applications.

(a) *Standards for review of applications.* Applications filed under ~~Framework A of~~ this part will be reviewed according to the standards set out in 10 CFR parts 20, 26, 51,

53, 73, and 140. ~~Upon receipt of an application, the NRC will —~~

~~(1) Give notice in writing to the regulatory agency or State as may have jurisdiction over the rates and services incident to the proposed activity;~~

~~(2) Publish notice of the application in trade or news publications as appropriate to give reasonable notice to municipalities, private utilities, public bodies and cooperatives which might have a potential interest in the facility; and~~

~~(3) Publish notice of the application once each week for four consecutive weeks in the *Federal Register*.~~

Commented [A342]: Deleted as redundant to 53.090(c)(1).

(b) *Administrative review of applications; hearings*. A proceeding on an OL is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). All hearings on OLs are governed by the procedures contained in 10 CFR part 2.

§ 53.1381 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application that concern safety ~~and must apply the standards referenced in § 53.1375~~.

§ 53.1384 Exemptions, departures, and variances.

(a) Applicants for an operating license (OL) under this ~~sub~~part, or any amendment to an OL, may include in the application a request for an exemption from one or more of the Commission's regulations. The Commission may grant an exemption request if it determines that the exemption complies with § 53.080.

(b) An applicant for an OL who has filed an application referencing an NRC approval, permit, license, or certification issued under ~~Framework A of~~ this part may include in the application a request for departures, variances, or exemptions related to

the subject referenced NRC approval, permit, license, or certification. In determining whether to grant the departure, variance, or exemption, the Commission must apply the same technically relevant criteria as were applicable to the application for the original or renewed approval, license, or certification.

§ 53.1387 Issuance of operating licenses.

Upon completion of the construction or alteration of a facility, in compliance with the terms and conditions of the construction permit and subject to any necessary testing of the facility for health or safety purposes, the Commission will, in the absence of good cause shown to the contrary, issue an operating license (OL) or an appropriate amendment of the license, as the case may be.

(a)(1) After receiving the report submitted by the ACRS, the Commission may issue an OL if the Commission finds that—

(i) Construction of the facility has been substantially completed in conformity with the CP and the application as amended, the provisions of the Act~~E~~A, and the rules and regulations of the Commission;

(ii) Any required notifications to other agencies or bodies have been duly made;

(iii) The facility will operate in conformity with the application as amended, the provisions of the Act~~E~~A, and the rules and regulations of the Commission;

(iv) There is reasonable assurance that—

(A) the activities authorized by the OL can be conducted without endangering the health and safety of the public; and

(B) such activities will be conducted in compliance with the regulations in this chapter.

(v) The applicant is technically and financially qualified to engage in the activities authorized, however, no finding of financial qualification is necessary for an electric utility

applicant for an OL;

(vi) Issuance of the license will not be inimical to the common defense and security or to the health and safety of the public;

(vii) The applicable provisions of 10 CFR part 140 have been satisfied; and

(viii) The findings required by subpart A of 10 CFR part 51 have been made.

(2) [Reserved]

(b) [Reserved]

(c) The OL ~~may~~will include appropriate provisions with respect to any uncompleted items of construction and such limitations or conditions as are required to assure that operation during the period of the completion of such items will not endanger public health and safety.

(d) The Commission will issue an OL in such form and containing such conditions and limitations, including technical specifications, as it deems necessary and appropriate.

§ 53.1390 ~~Backfitting~~ Finality of operating licenses.

(a) After issuance of an operating license (OL), the Commission may not modify, add, or delete any term or condition of the OL that are not derived from a referenced standard design certification, except in accordance with the provisions of § 53.1590.

(b) If the OL references a certified design, then changes to or departures from information within the scope of the referenced standard design certification rule are subject to the applicable change processes in that rule.

§ 53.1396 Duration of operating license.

The Commission will issue an operating license~~OL~~ under ~~Framework A of~~ this part for the term requested by the applicant, not to exceed 40 years from the date of issuance, or for the estimated useful life of the facility if the Commission determines that

Commented [A343]: Edited to reflect the purpose of 52.98, which formed the basis for this section. That purpose is to aid in determining how NRC-imposed changes are controlled based upon either the Backfit Rule, implemented as 53.1590, or by the controls on certification information. Staff should determine whether any other portions of 52.98 are appropriate to adapt in this section in the course of this rulemaking (e.g., the potential for referencing a manufactured reactor if that capability is added to the CP-OL process).

the estimated useful life is less than the term requested.

§ 53.1399 Transfer of an operating license.

An operating license~~OL~~ may be transferred ~~in accordance with~~under § 53.1570.

§ 53.1402 Application for renewal.

The filing of an application for a renewed license must be in accordance with § 53.1595.

§ 53.1405 Continuation of an operating license.

Each operating license (OL) for a facility that has permanently ceased operations continues in effect beyond the expiration date to authorize ownership and possession of the facility until the Commission notifies the licensee in writing that the license is terminated. During this period of continued effectiveness, the licensee must—

(a) Take actions necessary to decommission and decontaminate the facility and continue to maintain the facility, including, where applicable, the storage, control, and maintenance of the spent fuel in a safe condition; and

(b) Conduct activities in accordance with all other restrictions applicable to the facility in accordance with the NRC's regulations and the provisions of the OL for the facility.

Commented [A344]: N.B., the source material for this section should be 50.51(b) rather than 52.109.

§ 53.1410 Combined licenses.

Sections 53.1410 through 53.1461 set out the requirements and procedures applicable to Commission issuance of combined licenses~~COLs~~ for commercial nuclear plants under ~~Framework A of~~ this part.

§ 53.1413 Contents of applications for combined licenses; general information.

An application for a combined license~~COL~~ must include the information required by § 53.1109 and the following information:

(a) Except for an electric utility applicant in regard to financial assurance required

after a Commission finding under § 53.1452, the application must include information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, in accordance with the regulations in this chapter, the activities for which the permit or license is sought. As applicable, the following should be provided:

(1) The applicant must submit information that demonstrates that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs. The applicant must submit estimates of the total construction costs of the facility and related fuel cycle costs and must indicate the source(s) of funds to cover these costs.

(2) The applicant must submit information that demonstrates the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license. The applicant must submit estimates for total annual operating costs for each of the first 5 years of operation of the facility. The applicant must also indicate the source(s) of funds to cover these costs.

(3) Each application for a COL submitted by a newly-formed entity organized for the primary purpose of constructing and operating a facility must also include information showing—

(i) The legal and financial relationships the entity has or proposes to have with its stockholders or owners; and

(ii) The stockholders' or owners' financial ability to meet~~demonstrate compliance with~~ any contractual obligation to the entity which they have incurred or proposed to incur.~~; and~~

~~(iii) Any other information considered necessary by the Commission to enable it to determine the applicant's financial qualification.~~

Commented [A345]: Deleted as redundant to paragraph (4).

(4) The Commission may request an established entity or newly-formed entity to

submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding a licensee's ability to continue the conduct of the activities authorized by the license and to decommission the facility.

(b) The application must include information in the form of a report, as described in subpart G of this part, indicating how reasonable assurance will be provided that funds will be available to decommission the facility.

§ 53.1416 Contents of applications for combined licenses; technical information.

(a) *Final Safety Analysis Report*. The application must contain a~~n~~ final safety analysis report (FSAR) that describes the facility and the limits on its operation and presents a safety analysis of the structures, systems, and components (SSCs) of the facility as a whole. The Commission will require, before issuance of a combined license (COL), that engineering documents, such as analyses, drawings, procurement specifications, or construction and installation specifications, be completed and available for audit if the more detailed information is necessary for the Commission to verify the information in the application and make its safety determination. The FSAR must include the following information, at a level of detail sufficient to enable the Commission to reach a final conclusion on all safety matters that must be resolved by the Commission before issuance of a COL:

Commented [A346]: Font for the words "Safety Analysis" within "Final Safety Analysis Report" modified to be in italics with the rest of the phrase.

(1) *Site information*. An application for a COL for a commercial nuclear reactor must include the site information required for an early site permit in § 53.1146(a)(1)(iv) through (x).

(2) *Design information*. An application for a COL for a commercial nuclear plant must include the design information equivalent to that required for a standard design certification as defined in § 53.1239(a)(2) through (27).

(3) *Technical qualifications*. A description of the technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter.

(4) ~~*Integrity assessment program.* A description of an Integrity Assessment Program that addresses the elements described in § 53.870.~~

~~(5)~~ *Safeguards information*. A description of the program to protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

~~(6) *Emergency response facility or facilities.* Description of the locations and capabilities to be established for command and control, support, and coordination of onsite and offsite, as applicable, functions during reactor accident conditions.~~

(~~7~~5) *Role of personnel*. (i) A description of the completed assessments related to the role of personnel in ensuring safe operations considering the analyses required by § 53.730. These assessments must include the following:

(A) Human factors engineering design requirements of § 53.440~~730~~(~~a~~n)(1);

(B) Human system interface design requirements of § 53.440~~730~~(~~b~~n)(2);

(C) Concept of operations of § 53.730(c); and

(D) Functional requirements analysis and function allocation of § 53.730(d);

(ii) A description of the program to be used for evaluating and applying operating experience as required by § 53.730(e);

(iii) A staffing plan and supporting analyses as required by § 53.730(f).

(6~~8~~) *Training, examination, and proficiency programs.* (i) A description of ~~T~~the training, examination, and proficiency programs required by § 53.730(g); and

(ii) A description of the training programs required by § 53.830.

(7~~9~~) *Emergency plan*. Emergency plans complying with the requirements of

§ 53.855.

(i) The emergency plans must ~~i~~include, as applicable, all emergency plan certifications that have been obtained from the State, local and participating Tribal governmental agencies with emergency planning responsibilities. These certifications must state that—

(A) The proposed emergency plans are practicable;

(B) These agencies are committed to participating in any further development of the plans, including any required field demonstrations; and

(C) These agencies are committed to executing their responsibilities under the plans in the event of an emergency.

(ii) If certifications cannot be obtained after sustained, good faith efforts by the applicant, then the application must contain information, including a utility plan, sufficient to show that the proposed plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site.

(8~~10~~) *Organization.* A description of the applicant's organizational structure, allocations of responsibilities and authorities, and personnel qualifications requirements for operation.

(9~~11~~) *Maintenance program*. A description of a maintenance program ~~that demonstrates compliance with the requirements in~~under § 53.715.

(10~~2~~) *Quality assurance*. A description of the quality assurance program~~QAP that demonstrates compliance with the requirements of~~under § 53.865.

(11~~3~~) *Radiation protection program*. A radiation protection program description ~~that demonstrates compliance with the requirements of~~under § 53.850.

(12~~4~~) *Security program*. A physical security plan that describes how the applicant will ~~demonstrate~~ compl~~y~~i~~ance~~ with ~~the requirements of~~ § 53.860 (and 10 CFR part 11, if

applicable, including the identification and description of jobs as required by § 11.11(a) of this chapter, at the proposed facility). The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with the requirements of 10 CFR parts 11 and 73, if applicable.

(135) *Safeguards contingency plan*. A safeguards contingency plan in accordance with the criteria set forth in appendix C to 10 CFR part 73. The safeguards contingency plan must include plans for dealing with threats, thefts, and radiological sabotage, as defined in 10 CFR part 73, relating to the special nuclear materialSNM and nuclear facilities licensed under this chapter and in the applicant's possession and control. Each application for this type of license must include the information contained in the applicant's safeguards contingency plan.[71] (Implementing procedures required for this plan need not be submitted for approval.)

(146) *Security training and qualification*. A training and qualification plan that describes how the applicant will demonstrate compliance with the criteria set forth in § 73.100 of this chapter or appendix B to 10 CFR part 73.

(157) *Cyber security plan*. A cyber security plan in accordance with the criteria set forth in § 73.54 or § 73.110 of this chapter.

(168) *Security, safeguards and cyber security plan implementation*. A description of the implementation of the physical security plan, safeguards contingency plan, training and qualification plan, and cyber security plan. Each applicant who prepares a physical security plan, a safeguards contingency plan, a training and qualification plan, or a cyber security plan must protect the plans and other related Safeguards Information against unauthorized disclosure in accordance with the requirements of §§ 73.21 and 73.22 of this chapter.

(179) *Fire protection program*. A description of the fire protection program

~~description that demonstrates compliance with the requirements of~~under § 53.875.

(~~18~~20) *Inservice inspection/inservice testing program*. A~~n~~ description of the ~~IS~~Iinservice inspection/~~IST~~ inservice testing program ~~description that demonstrates compliance with the requirements of~~under § 53.880.

~~(21) [Reserved]~~

~~(22) *Facility safety program.* An FSP plan that demonstrates compliance with the requirements of § 53.890.~~

~~(23) *General employee training.* A description of the training program required to demonstrate compliance with § 53.830 and its implementation.~~

(~~19~~24) *Fitness-for-duty program*. A description of the ~~FFD~~ fitness-for-duty program ~~required by 10 CFR~~under part 26 of this chapter and its implementation.

~~(25) *Technical specifications.* Proposed technical specifications prepared in accordance with the requirements of § 53.710(a).~~

(b) If there are SSCs of the plant for which research and development is necessary to confirm the adequacy of their design, a report which documents the resolution of any safety questions associated with such SSCs.

(c) A description of how the performance of each safety design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof, in accordance with § 53.~~44~~090(~~a~~d).

(d) If the COL application references an early site permit, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the early site permit provided that the FSAR must either include or incorporate by reference the early site permit Site Safety Analysis Report and

Commented [A347]: Paragraph (a)(2) of this section would require the information equivalent to that required for a standard design certification in 53.1239(a)(2) through (27). Paragraph 53.1239(a)(26) would require submittal of TS for those areas addressed by the design certification. The equivalent to that would be TS for the complete design, rendering this paragraph redundant.

contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit.

(2) If the FSAR does not demonstrate that design of the facility falls within the site characteristics and design parameters, the application must include a request for a variance that complies with the requirements of §§ 53.1188(d) and 53.1437.

(3) The FSAR must demonstrate that all terms and conditions that have been included in the early site permit will be satisfied by the date of issuance of the COL. Any terms or conditions of the early site permit that could not be met by the time of issuance of the COL must be set forth as terms or conditions of the COL.

(4) If the early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the FSAR must include any new or additional information that updates and corrects the information that was provided under § 53.1146(b)(2) and discuss whether the new or additional information materially changes the bases for compliance with the applicable requirements. The application must identify changes to the emergency plans or major features of emergency plans that have been incorporated into the proposed facility emergency plans and that constitute or would constitute a change in an emergency plan that results in reducing the licensee's capability to perform an emergency planning function in the event of a radiological emergency.

(5) If complete and integrated emergency plans are approved as part of the early site permit, new certifications meeting the requirements of paragraph (a)(9)(i) of this section are not required.

(e) If the COL application references a standard design approval, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the design approval, provided, however, that the FSAR must either include or incorporate by reference the standard design approval FSAR and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the characteristics of the site fall within the site parameters specified in the design approval. In addition, the plant-specific ~~PRA information~~ risk evaluation must use the ~~PRA information~~ risk evaluation for the design approval and must be updated to account for site specific design information and any design changes or departures.

(2) The FSAR must demonstrate that all terms and conditions that have been included in the design approval will be satisfied by the date of issuance of the COL.

(f) If the COL application references a standard design certification, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the standard design certification, provided, however, that the FSAR must either include or incorporate by reference the standard design certification FSAR and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the standard design certification. In addition, the plant-specific ~~PRA information~~risk evaluation must use the ~~PRA information~~ risk evaluation for the standard design certification and must be updated to account for site-specific design information and any design changes or departures.

(2) The FSAR must demonstrate that the interface requirements established for the design under § 53.1239(a)(24) have been met.

(3) The FSAR must demonstrate that all requirements and restrictions set forth in

the referenced standard design certification rule must be satisfied by the date of issuance of the COL. Any requirements and restrictions set forth in the referenced standard design certification rule that could not be satisfied by the time of issuance of the COL, must be set forth as terms or conditions of the COL.

(g) If the COL application references the use of one or more manufactured reactors licensed under § 53.1270, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the manufacturing license (ML), provided, however, that the FSAR must either include or incorporate by reference the ML FSAR and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the ML. In addition, the plant-specific ~~PRA information~~ risk evaluation must use the risk evaluation~~PRA information~~ for the manufactured reactor and must be updated to account for site-specific design information and any design changes or departures.

(2) The FSAR must demonstrate that the interface requirements established for the design have been met.

(3) The FSAR must demonstrate that all terms and conditions that have been included in the ML will be satisfied by the date of issuance of the COL. Any terms or conditions of the ML that could not be met by the time of issuance of the COL, must be set forth as terms or conditions of the COL.

~~(h) Each applicant for a COL under this part must protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.~~

~~71~~ A physical security plan that contains all the information required in both § 73.55 or § 73.100 of this chapter and appendix C to 10 CFR part 73 demonstrates compliance with the requirement for a

contingency plan.

§ 53.1419 Contents of applications for combined licenses; other application content.

(a) In addition to the final safety analysis report (FSAR), the application must also include the following:

(1) *Environmental report.*

(i) An environmental report either in accordance with § 51.50(c) of this chapter if a~~n~~ limited work authorization (LWA) under § 53.1130 is not requested in conjunction with the combined license (COL) application, or in accordance with §§ 51.49 and 51.50(c) of this chapter if an LWA is requested in conjunction with the COL application; or

(ii) If the applicant wishes to request that an LWA under § 53.1130 be issued before issuance of the COL, the information otherwise required by § 53.1130, in accordance with either § 2.101(a)(1) through (a)(4), or § 2.101(a)(9) of this chapter;

(2) *Availability controls (if not included in the FSAR).* A description of the controls on plant operations, including availability controls, to provide reasonable confidence of safe operation and that the configurations and special treatments for non-safety-related but safety-significant~~NSRSS~~ structures, systems, and components~~SSCs~~ provide the capabilities and reliabilities required to satisfy the safety criteria of § 53.220~~, or more restrictive alternative criteria adopted under § 53.470,~~ if not addressed by Technical Specifications under § 53.710~~1416~~(a)~~(25)~~; and

(3) *Inspections, tests, analyses, and acceptance criteria~~ITAAC~~.* The proposed inspections, tests, and analyses, including those applicable to emergency planning, that the licensee must perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will be

operated in conformity with the COL, the provisions of the Act~~EA~~, and the Commission's rules and regulations.

(i) If the application references an early site permit with inspections, tests, analyses, and acceptance criteria (ITAAC), the early site permit ITAAC must apply to those aspects of the COL which are approved in the early site permit.

(ii) If the application references a standard design certification, the ITAAC contained in the certified design must apply to those portions of the facility design which are approved in the standard design certification.

(iii) If the application references a~~n~~ manufacturing license (ML), the ITAAC contained in the ML must apply to those portions of the facility design which are approved in the ML.

(iv) If the application references an early site permit with ITAAC, a standard design certification, an ML, or combination thereof, the application may include a notification that a required inspection, test, or analysis in the ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The *Federal Register* notification required by § 53.1422 of this chapter must indicate that the application includes this notification.

(b) [Reserved]

§ 53.1422 Review of applications.

(a) *Standards for review of applications.* Applications filed under ~~Framework A of~~ this part will be reviewed according to the standards set out in 10 CFR parts 20, 51, 53, 73, and 140.

(b) *Administrative review of applications; hearings*. A proceeding on a combined license (COL) is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and

issuance of a notice of hearing (§ 2.104 of this chapter). If an applicant requests a Commission finding on certain inspections, tests, analyses, and acceptance criteria (ITAAC) with the issuance of the COL, then those ITAAC will be identified in the notice of hearing. All hearings on COLs are governed by the procedures contained in 10 CFR part 2.

§ 53.1425 Finality of referenced NRC approvals.

If the application for a combined license (COL) under ~~Framework A of~~ this part references an early site permit, standard design certification rule, standard design approval, or manufacturing license~~ML~~, issued under this part, the scope and nature of matters resolved for the application and any COL issued are governed by the relevant provisions addressing finality, including §§ 53.1188, 53.1221, 53.1263, and 53.1288.

§ 53.1431 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application that concern safety and must apply the standards referenced in § 53.1422, in accordance with the finality provisions in § 53.1425.

§ 53.1434 Authorization to conduct limited work authorization activities.

(a) If the application for a combined license (COL) under ~~Framework A of~~ this part does not reference an early site permit which authorizes the holder to perform the activities under § 53.1130(b), the applicant may not perform those activities without obtaining the separate authorization required by § 53.1130(a). Authorization may be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by § 53.1130(b)(1)(ii) and (b)(1)(iv), and the Director, Office of Nuclear Reactor Regulation makes the determination required by § 53.1130(b)(1)(iii).

(b) If, after an applicant has performed the activities permitted by ~~paragraph (a) of this section~~ a limited work authorization issued under § 53.1130, the application for the COL is withdrawn or denied, then the applicant must implement the approved site redress plan.

Commented [A348]: Edited to reflect the fact that the sole activities of the applicant permitted under paragraph (a) of this section are the submittal of an application for a limited work authorization under 53.1130. A similar issue exists in 52.91, where the reference to activities permitted under paragraph (a) of that section should be to activities permitted under a limited work authorization issued under 50.10. Staff should correct the error in 52.91 in an administrative rulemaking.

§ 53.1437 Exemptions, departures, and variances.

(a) An applicant~~s~~ for a combined license (COL), or any amendment to a COL, may include in the application a request for an exemption from one or more of the Commission's regulations.

(1) If the request is for an exemption from any part of a referenced standard design certification rule, the Commission may grant the request if it determines that the exemption complies with any exemption provisions of the referenced standard design certification rule, or with § 53.1263 if there are no applicable exemption provisions in the referenced standard design certification rule.

(2) For all other requests for exemptions, the Commission may grant a request if it determines that the exemption complies with § 53.080.

(b) An applicant for a COL who has filed an application referencing an early site permit issued under § 53.1158 may include in the application a request for a variance from one or more site characteristics, design parameters, or terms and conditions of the permit, or from the Site Safety Analysis Report. In determining whether to grant the variance, the Commission must apply the same technically relevant criteria as were applicable to the application for the original or renewed site permit. Once a COL referencing an early site permit is issued, variances from the early site permit will not be granted for that CP or COL.

(c) An applicant for a COL who has filed an application referencing a ~~nuclear power~~ manufactured reactor ~~manufactured under an ML issued under § 53.1270~~ may

include in the application a request for a departure from one or more design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor under the manufacturing license issued under § 53.1287. The Commission may grant such a request only if it determines that the departure will comply with the requirements of § 53.080, and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure.

(d) Issuance of a variance under paragraph (b) of this section or a departure under paragraph (c) of this section is subject to litigation during the COL proceeding in the same manner as other issues material to that proceeding.

§ 53.1440 Issuance of combined licenses.

(a)(1) After conducting a hearing ~~in accordance with~~under § 53.1422(b) and receiving the report submitted by the ACRS, the Commission may issue a combined license (COL) if the Commission finds that—

(i) The applicable standards and requirements of the Act~~EA~~ and the Commission's regulations have been met;

(ii) Any required notifications to other agencies or bodies have been duly made;

(iii) There is reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of the Act~~EA~~, and the Commission's regulations;

(iv) The applicant is technically and financially qualified to engage in the activities authorized; however, no finding of financial qualification is necessary for an electric utility applicant for a COL;

(v) Issuance of the license will not be inimical to the common defense and security or to the health and safety of the public; and

(vi) The findings required by subpart A of 10 CFR part 51 have been made.

(2) The Commission may also find, at the time it issues the COL, that certain acceptance criteria in one or more of the inspections, tests, analyses, and acceptance criteria~~ITAAC~~ in a referenced early site permit, standard design certification, or manufacturing license~~ML~~ have been met. This finding will finally resolve that those acceptance criteria have been met, those acceptance criteria will be deemed to be excluded from the COL, and findings under § 53.1452(g) with respect to those acceptance criteria are unnecessary.

(b) The Commission must identify within the COL the inspections, tests, and analyses, including those applicable to emergency planning, that the licensee must perform, and the acceptance criteria that, if met, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act~~EA~~, and the Commission's rules and regulations.

(c) A COL must contain the terms and conditions, including technical specifications, as the Commission deems necessary and appropriate.

§ 53.1443 Finality of combined licenses.

(a) After issuance of a combined license (COL), the Commission may not modify, add, or delete any term or condition of the COL, the design of the facility, the inspections, tests, analyses, and acceptance criteria~~ITAAC~~ contained in the license that are not derived from a referenced standard design certification or manufacturing license (ML), except ~~in accordance with~~under the provisions of § 53.1452 or § 53.1590.

(b) If the COL does not reference a standard design certification or a manufactured reactor ~~manufactured~~ under a manufacturing license (ML) issued under § 53.1287~~0~~, then a licensee may make changes ~~in the facility as described in the FSAR~~

~~(as updated) and make changes in the procedures as described in the FSAR (as updated) under~~subject to the applicable change processes in ~~§ 53.1550~~subpart I of this part.

(c) If the COL references a certified design, then—

(1) Changes to or departures from information within the scope of the referenced standard design certification rule are subject to the applicable change processes in that rule; and

(2) Changes that are not within the scope of the referenced standard design certification rule are subject to the applicable change processes in subpart I of this part~~,~~ unless they also involve changes to or noncompliance with information within the scope of the referenced standard design certification rule. In these cases, the applicable provisions of this section and the standard design certification rule apply.

(d) If the COL references a manufactured reactor ~~manufactured~~ under an ML issued under § 53.1287~~Framework A of this part~~, then—

(1) Changes to or departures from information within the scope of the manufactured reactor's design are subject to the change processes in § 53.1288; and

(2) Changes that are not within the scope of the manufactured reactor's design are subject to the applicable change processes in subpart I.

(e) The Commission may issue and make immediately effective any amendment to a COL upon a determination by the Commission that the amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person. The amendment may be issued and made immediately effective in advance of the holding and completion of any required hearing. The amendment will be processed ~~in accordance with~~under the procedures specified in § 53.1515.

(f) Any modification to, addition to, or deletion from the terms and conditions of a COL, including any modification to, addition to, or deletion from the inspections, tests, and analyses, or related acceptance criteria contained in the license is a proposed amendment to the license. There must be an opportunity for a hearing on the amendment.

§ 53.1449 Inspection during construction.

(a) *Licensee schedule for inspections, tests, or analyses*. The licensee must submit to the NRC, no later than 1 year after issuance of the combined license (COL) or at the start of construction as defined at § 53.020, whichever is later, its schedule for completing the inspections, tests, or analyses in the inspections, tests, analyses and acceptance criteria (ITAAC). The licensee must submit updates to the ITAAC schedules every 6 months thereafter and, within 1 year of its scheduled date for initial loading of fuel, the licensee must submit updates to the ITAAC schedule every 30 days until the final notification is provided to the NRC under paragraph (c)(1) of this section.

(b) *Licensee and applicant conduct of activities subject to ITAAC*. With respect to activities subject to an ITAAC, an applicant for a COL may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any one of the prescribed acceptance criteria are met.

(c) *Licensee notifications*. (1) *ITAAC closure notification*. The licensee must notify the NRC that prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria are met. The notification must contain sufficient information to demonstrate that the prescribed inspections, test, and analyses have been performed and that the prescribed acceptance criteria are met.

(2) *ITAAC post-closure notifications*. Following the licensee's ITAAC closure

notifications under paragraph (c)(1) of this section until the Commission makes the finding under § 53.1452(g), the licensee must notify the NRC, in a timely manner, of new information that materially alters the basis for determining that either inspections, tests, ~~and~~or analyses were performed as required, or that acceptance criteria are met. The notification must contain sufficient information to demonstrate that, notwithstanding the new information, the prescribed inspections, tests, and analyses have been performed as required, and the prescribed acceptance criteria are met.

(3) *Uncompleted ITAAC notification*. If the licensee has not provided, by the date 225 days before the scheduled date for initial loading of fuel, the notification required by paragraph (c)(1) of this section for all ITAAC, then the licensee must notify the NRC that the prescribed inspections, tests, ~~and~~or analyses for all uncompleted ITAAC will be performed and that the prescribed acceptance criteria will be met prior to operation. The notification must be provided no later than the date 225 days before the scheduled date for initial loading of fuel, and must provide sufficient information to demonstrate that the prescribed inspections, tests, ~~and~~or analyses will be performed and the prescribed acceptance criteria for the uncompleted ITAAC will be met, including, but not limited to, a description of the specific procedures and analytical methods to be used for performing the prescribed inspections, tests, and analyses and determining that the prescribed acceptance criteria are met.

(4) *All ITAAC complete notification*. The licensee must notify the NRC that all ITAAC are complete.

(d) *Licensee determination of noncompliance with ITAAC*. (1) In the event that an activity is subject to an ITAAC derived from a referenced standard design certification and the licensee has not demonstrated that the prescribed acceptance criteria are met, the licensee may take corrective actions to successfully complete that ITAAC or request

an exemption from the standard design certification ITAAC, as applicable. A request for an exemption must also be accompanied by a request for a license amendment under § 53.1443(f)~~subpart I~~.

(2) In the event that an activity is subject to an ITAAC not derived from a referenced standard design certification and the licensee has not demonstrated that the prescribed acceptance criteria are met, the licensee may take corrective actions to successfully complete that ITAAC or request a license amendment under § 53.1443(f)~~subpart I~~.

(e) *NRC inspection, publication of notices, and availability of licensee notifications*. The NRC must ensure that the prescribed inspections, tests, and analyses in the ITAAC are performed.

(1) At appropriate intervals until the last date for submission of requests for hearing under § 53.1452(a), the NRC must publish notices in the *Federal Register* of the NRC staff's determination of the successful completion of inspections, tests, and analyses.

(2) The NRC must make publicly available the licensee notifications under paragraph (c) of this section. The NRC must, no later than the date of publication of the notice of intended operation required by § 53.1452(a), make publicly available those licensee notifications under paragraph (c) of this section that have been submitted to the NRC at least 7 days before that notice.

§ 53.1452 Operation under a combined license.

(a) The licensee must notify the NRC of its scheduled date for initial loading of fuel no later than 270 days before the scheduled date and must notify the NRC of updates to its schedule every 30 days thereafter. For licensees installing fueled manufactured reactors under a combined license (COL), the scheduled date for the

Commented [A349]: Edited to parallel the provisions of 52.99(d)(1), which cites the paragraph in 52.98 that requires the use of the license amendment process to modify the ITAAC. If the staff examines this and determines that the citation should instead be to the provisions of the regulations providing the procedures for accomplishing a license amendment, the staff should modify 52.99(d)(1) to cite the appropriate requirements rather than 52.98(f).

initial loading of fuel is the scheduled date for completion of installation of the fueled manufactured reactor. Not less than 180 days before the date scheduled for initial loading of fuel into a plant by a licensee that has been issued a COL under ~~Framework A of~~ this part, the Commission must publish notice of intended operation in the *Federal Register*. The notice must provide that any person whose interest may be affected by operation of the plant may, within 60 days, request that the Commission hold a hearing on whether the facility as constructed complies, or on completion will comply, with the acceptance criteria in the COL, except that a hearing must not be granted for those inspections, tests, analyses, and acceptance criteria (ITAAC) that~~which~~ the Commission found were met under § 53.1440(a)(2).

(b) A request for hearing under paragraph (a) of this section must show, *prima facie* that—

(1) ~~That o~~One or more of the acceptance criteria of the ITAAC in the COL have not been, or will not be, met; and

(2) The specific operational consequences of nonconformance ~~that~~ would be contrary to providing reasonable assurance of adequate protection of the public health and safety.

(c) The Commission, acting as the presiding officer, must determine whether to grant or deny the request for hearing ~~in accordance with~~under the applicable requirements of § 2.309 of this chapter. If the Commission grants the request, the Commission, acting as the presiding officer, must determine whether during a period of interim operation there will be reasonable assurance of adequate protection to the public health and safety. The Commission's determination must consider the petitioner's *prima facie* showing and any answers thereto. If the Commission determines there is such reasonable assurance, it must allow operation during an interim period under the COL.

Commented [A350]: Edited to match the criteria provided in 2.309(f)(1)(vii).

In 52.103(b)(2), there is a typographic error including the word "that" after the word "nonconformance" similar to the wording provided in the draft proposed version of 53.1452(b)(2) despite the proper positioning of the word "that" before the em dash on the introductory portion of the sentence in 52.103(b). Staff should amend 52.103(b)(2) to remove the word "that" after the word "nonconformance" in an administrative rulemaking.

(d) The Commission, in its discretion, must determine appropriate hearing procedures, whether informal or formal adjudicatory, for any hearing under paragraph (a) of this section, and must state its reasons therefore.

(e) The Commission must, to the maximum possible extent, render a decision on issues raised by the hearing request within 180 days of the publication of the notice provided by paragraph (a) of this section or by the anticipated date for initial loading of fuel into the reactor, whichever is later.

(f) A petition to modify the terms and conditions of the COL will be processed as a request for action ~~in accordance with~~under § 2.206 of this chapter. The petitioner must file the petition with the Secretary of the Commission. Before the licensed activity allegedly affected by the petition (fuel loading, low power testing, etc.) commences, the Commission must determine whether any immediate action is required. If the petition is granted, then an appropriate order will be issued. Fuel loading and operation under the COL will not be affected by the granting of the petition unless the order is made immediately effective.

(g) The licensee must not operate the facility until the Commission makes a finding that the acceptance criteria in the COL are met, except for those acceptance criteria that the Commission found were met under § 53.1440(a)(2). If the COL is for a modular design, each reactor unit may require a separate finding as construction proceeds.

(h) After the Commission has made the finding in paragraph (g) of this section, the ITAAC do not, by virtue of their inclusion in the COL, constitute regulatory requirements either for licensees or for renewal of the license; except for the specific ITAAC for which the Commission has granted a hearing under paragraph (a) of this section, all ITAAC expire upon final Commission action in the proceeding. However,

subsequent changes to the facility or procedures described in the FSAR (as updated) must comply with the requirements in § 53.1443(e) or (f), as applicable.

§ 53.1455 Duration of combined license.

(a) A combined license~~COL~~ is issued for a specified period not to exceed 40 years from the date on which the Commission makes a finding that acceptance criteria are met under § 53.1452(g) or allowing operation during an interim period under the COL under § 53.1452(c).

(b) If the proposed construction or alteration of the facility is not completed by the latest completion date, the COL shall expire, and all rights are forfeited. However, upon good cause shown, the Commission will extend the completion date for a reasonable period of time. The Commission will recognize, among other things, developmental problems attributed to the experimental nature of the facility or fire, flood, explosion, strike, sabotage, domestic violence, enemy action, an act of the elements, and other acts beyond the control of the permit holder, as a basis for extending the completion date.

Commented [A351]: Inserted to provide the 50.55(b) condition for construction delays under a COL that is recognized under 50.100.

§ 53.1456 Transfer of a combined license.

A combined license~~COL~~ may be transferred under § 53.1570.

§ 53.1458 Application for renewal.

The filing of an application for a renewed license must be in accordance with § 53.1595.

§ 53.1461 Continuation of combined license.

Each combined license (COL) for a facility that has permanently ceased operations continues in effect beyond the expiration date to authorize ownership and possession of the facility until the Commission notifies the licensee in writing that the license is terminated. During this period of continued effectiveness, the licensee must—

(a) Take actions necessary to decommission and decontaminate the facility and continue to maintain the facility, including, where applicable, the storage, control and maintenance of the spent fuel, in a safe condition; and

(b) Conduct activities in accordance with all other restrictions applicable to the facility in accordance with the NRC's regulations and the provisions of the COL for the facility.

§ 53.1470 Standardization of commercial nuclear plant designs: licenses to construct and operate nuclear power reactors of identical design at multiple sites.

(a) Except as otherwise specified in this section, the provisions of this section apply to construction permit (CP), operating license (OL), and combined license (COL) applications for commercial nuclear plants of identical design (the "common design") under ~~Framework A of~~ this part.

(b) Each application for a CP, OL, or COL submitted pursuant to this section must be submitted as specified in ~~§ 53.1300, § 53.1360, or § 53.1410, respectively,~~ subpart H of this part and § 2.101 of this chapter. Each application must state that the applicant wishes to construct a facility identical to a facility proposed for one or more sites other than the applicant's ~~(the "common design"),~~ and the applicant wishes to have the application considered under this section. Each application must list each of the other applications to be treated together under this section.

Commented [A352]: Moved to paragraph (a) of this section because there is no discussion of a particular design in this sentence.

(c) Each application must include the information required by the applicable sections of this subpart, *provided however*, that the application must identify the common design, and, if applicable, reference a standard design certification or standard design approval under ~~Framework A of~~ this part, or the use of a reactor manufactured under ~~Framework A of~~ this part. The final safety analysis report (FSAR) for each application must either incorporate by reference or include the final safety analysis of the

common design, including, if applicable, the FSAR for the referenced standard design certification, standard design approval, or the manufactured reactor.

(d) Each application submitted pursuant to this section must contain an environmental report ~~as required by~~under § 53.1312(a)(1), § 53.1372(a), or § 53.1419(a)(1), as applicable, ~~and which~~that complies with the applicable provisions of 10 CFR part 51, *provided, however*, that the application may incorporate by reference a single environmental report on the environmental impacts of the common design that are applicable to each site.

(e) Upon a determination that each application is acceptable for docketing under § 2.101 of this chapter, each application will be docketed and a notice of docketing for each application will be published in the *Federal Register*, ~~in accordance with~~under § 2.104 of this chapter, *provided, however*, that the notice must state that the application will be processed under the provisions of this section and subpart D of 10 CFR part 2. At the discretion of the Commission, a single notice of docketing for multiple applications may be published in the *Federal Register.*

(f) The NRC must prepare an environmental assessment or draft and final environmental impact statements for each of the applications under 10 CFR part 51. Scoping under §§ 51.28 and 51.29 of this chapter for each of the license applications may be conducted simultaneously and joint scoping may be conducted with respect to the environmental issues relevant to the common design. If the applications reference a standard design certification, then the environmental assessment or environmental impact statement for each of the applications must incorporate by reference the standard design certification environmental assessment. If the applications do not reference a standard design certification, then the NRC must prepare environmental assessments or draft and final supplemental environmental impact statements which address severe

accident mitigation design alternatives for the common design, which must be incorporated by reference into the environmental assessment or environmental impact statement prepared for each application. Scoping under §§ 51.28 and 51.29 of this chapter for the supplemental environmental impact statement may be conducted simultaneously and may be part of the scoping for each of the applications.

(g) The ACRS must report on each of the applications as required by the applicable sections of this subpart. Each report must be limited to those safety matters for each application ~~which~~that are not relevant to the common design. In addition, the ACRS must separately report on the safety of the common design, *provided, however*, that the report need not address the safety of a referenced standard design certification or reactor manufactured under ~~Framework A of~~ this part.

(h) The Commission must designate a presiding officer to conduct the proceeding with respect to the health and safety, common defense and security, and environmental matters relating to the common design and affecting at least two applications. The hearing will be governed by the applicable provisions of subparts A, C, G, L, N, and O of 10 CFR part 2 relating to applications for CPs, OLs, and COLs. The presiding officer must issue a partial initial decision on the common design.

(i) If the design for the power reactor(s) proposed in a particular application is not identical to the others, that application may not be processed under this section and subpart D of 10 CFR part 2.

(j) As used in this section, the design of a nuclear power reactor included in a single referenced Safety Analysis Report means the design of those structures, systems, and components~~SSCs~~ important to radiological health and safety and the common defense and security.

Subpart I — Maintaining and Revising Licensing Basis Information

§ 53.1500 Licensing basis information.

This subpart provides the requirements for each holder of a license for a commercial nuclear plant licensed under ~~Framework A of~~ this part to maintain licensing basis information as defined in § 53.020; evaluate changes to site characteristics, plant design features, and programmatic controls to determine needed approvals and revisions; and submit appropriate updates to the NRC.

§ 53.1502 Specific terms and conditions of licenses.

(a) Each license issued under ~~Framework A of~~ this part is subject to the provisions of the Act~~EA~~ and to all rules, regulations, and orders of the Commission. The terms and conditions of the license will be subject to amendment, revision, or modification, by reason of amendments of the Act~~EA~~ or by reason of rules, regulations, and orders issued in accordance with the terms of the Act~~EA~~.

(b) Each license issued under ~~Framework A of~~ this part must be subject to all conditions imposed as a matter of law by sections 401(a)(2) and 401(d) of the Federal Water Pollution Control Act, as amended (33 U.S.C.A. 1341(a)(2) and (d)).

(c) A holder of an operating license~~OL~~ or combined license~~COL~~ under ~~Framework A of~~ this part may take reasonable action that departs from a license condition or a technical specification ~~(~~included in a license issued under ~~Framework A of~~ this part~~)~~ in a national security emergency established by a law enacted by the Congress or by an order or directive issued by the President pursuant to statutes or the Constitution of the United States. The authority under this paragraph must be exercised in accordance with law, including section 57e. of the Act, and is in addition to the authority granted under § 53.740(h), which remains in effect unless otherwise directed by the Commission during a national security emergency. The authority under this paragraph may be exercised~~—~~:

(1) When this action is immediately needed to implement national security objectives as designated by the national command authority through the Commission, and

(2) No action consistent with license conditions and technical specifications that can satisfy national security objectives is immediately apparent.

~~(3) A national security emergency is established by a law enacted by the Congress or by an order or directive issued by the President pursuant to statutes or the Constitution of the United States. The authority under this paragraph must be exercised in accordance with law, including section 57e. of the Act, and is in addition to the authority granted under § 53.740(h), which remains in effect unless otherwise directed by the Commission during a national security emergency.~~

Commented [A353]: Moved up to paragraph (c) to reflect that this is not a condition on when the authority may be used but instead a definition.

(d)(1) If the NRC finds that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency (including findings based on requirements of 10 CFR part 50, appendix E, section IV.D.3) and if the deficiencies (including deficiencies based on requirements of 10 CFR part 50, appendix E, section IV.D.3) are not corrected within 4 months of that finding, the Commission will determine whether the facility must be shut down or cease operations until such deficiencies are remedied or whether other enforcement action is appropriate. In determining whether a shutdown, cessation of operations, or other enforcement action is appropriate, the Commission will take into account, among other factors, whether the licensee can demonstrate to the Commission's satisfaction that the deficiencies in the plan are not significant for the plant in question, or that adequate interim compensating actions have been or will be taken promptly, or that that there are other compelling reasons for continued operation.

(2) If the planning standards for radiological emergency preparedness apply to offsite emergency response plans, then the NRC will base its finding on a review of the Federal Emergency Management Agency~~FEMA~~ findings and determinations as to whether State, participating Tribal and local emergency plans are adequate and capable of being implemented, and on the NRC assessment as to whether the licensee's emergency plans are adequate and capable of being implemented. Nothing in this paragraph must be construed as limiting the authority of the Commission to take action under any other regulation or authority of the Commission or at any time other than that specified in this paragraph.

§ 53.1505 Changes to licensing basis information requiring prior NRC approval.

(a) Sections 53.1510 through 53.1520 provide the process for a licensee to request and the NRC to issue amendments to licenses, including any conditions contained therein, technical specifications or other attachments to a license, and any orders issued by the NRC modifying a license. Sections 53.1525 and 53.1530 govern proposed changes to a commercial nuclear plant referencing a certified design or manufacturing license~~ML~~.

(b) A licensee may propose changing licensing basis information established by NRC regulations by requesting an exemption in accordance with § 53.080.

§ 53.1510 Application for amendment of license.

Whenever a holder of a license under ~~Framework A of~~ this part desires to amend the license, an application for an amendment must be filed with the Commission, as specified in § 53.040, that fully describes the changes desired and, following as far as applicable, the form prescribed for original applications. Applications for amendments involving changes to plant structures, systems, and components~~SSCs~~, programmatic controls, or the role of plant personnel must include an assessment of the changes in

relation to the safety requirements in subpart B of this part and the analyses requirements of § 53.450, as applicable, an analysis of whether the amendment involves no significant hazards consideration using the standards in § 53.1520, and a consideration of environmental factors.

§ 53.1515 Public notices; State consultation.

The Commission will use the following procedures for an application requesting an amendment to an operating license~~OL~~ or combined license~~COL~~ issued under ~~Framework A of~~ this part.

(a) *Public notices.*

(1)(i) The Commission may publish in the *Federal Register* under § 2.105 an individual notice of proposed action for an amendment for which it makes a proposed determination that no significant hazards consideration is involved, or, at least once every 30 days, publish a periodic *Federal Register* notice of proposed actions, which identifies each amendment issued and each amendment proposed to be issued since the last such periodic notice, or it may publish both such notices.

(ii) For each amendment proposed to be issued, the notice will—

(A) Contain the staff's proposed determination under the standards in § 53.1520;

(B) Provide a brief description of the amendment and of the facility involved; (C) Solicit public comments on the proposed determination; and

(D) Provide for a 30-day comment period.

(iii) The comment period will begin on the day after the date of the publication of the first notice, and, normally, the amendment will not be granted until after this comment period expires.

(2) The Commission may inform the public about the final disposition of an amendment request for which it has made a proposed determination of no significant hazards consideration either by issuing an individual notice of issuance under § 2.106 of this chapter or by publishing such a notice in its periodic system of *Federal Register* notices. In either event, it will not make and will not publish a final determination of no significant hazards consideration unless it receives a request for a hearing on that amendment request.

(3) Where the Commission makes a final determination that no significant hazards consideration is involved and that the amendment should be issued, the amendment will be effective on issuance, even if adverse public comments have been received and even if an interested person meeting the provisions for intervention called for in § 2.309 of this chapter has filed a request for a hearing. The Commission need hold any required hearing only after it issues an amendment, unless it determines that a significant hazards consideration is involved, in which case the Commission will provide an opportunity for a prior hearing.

(4) Where the Commission finds that an emergency situation exists, in that failure to act in a timely way would result in derating or shutdown of a ~~commercial~~ nuclear reactor, or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, it may issue a license amendment involving no significant hazards consideration without prior notice and opportunity for a hearing or for public comment. In such a situation, the Commission will not publish a notice of proposed determination on no significant hazards consideration but will publish a notice of issuance under § 2.106 of this chapter providing for opportunity for a hearing and for public comment after issuance. The Commission expects its licensees to apply for license amendments in timely fashion. It will decline to dispense with notice and

comment on the determination of no significant hazards consideration if it determines that the licensee has abused the emergency provision by failing to make timely application for the amendment and thus itself creating the emergency. Whenever an emergency situation exists, a licensee requesting an amendment must explain why this emergency situation occurred and why it could not avoid this situation, and the Commission will assess the licensee's reasons for failing to file an application sufficiently in advance of that event.

(5) Where the Commission finds that exigent circumstances exist, in that a licensee and the Commission must act quickly and that time does not permit the Commission to publish a *Federal Register* notice allowing 30 days for prior public comment, and it also determines that the amendment involves no significant hazards considerations, it—

(i)(A) Will either issue a *Federal Register* notice providing notice of an opportunity for hearing and allowing at least 2 weeks from the date of the notice for prior public comment; or

(B) Will use local media to provide reasonable notice to the public in the area surrounding a licensee's facility of the licensee's amendment and of its proposed determination as described in paragraph (a)(1) of this section, consulting with the licensee on the proposed media release and on the geographical area of its coverage;

(ii) Will provide for a reasonable opportunity for the public to comment, using its best efforts to make available to the public whatever means of communication it can for the public to respond quickly, and, in the case of telephone comments, have these comments recorded or transcribed, as necessary and appropriate;

(iii) When it has issued a local media release, may inform the licensee of the public's comments, as necessary and appropriate;

(iv) Will publish a notice of issuance under § 2.106 of this chapter;

(v) Will provide a hearing after issuance, if one has been requested by a person who satisfies the provisions for intervention specified in § 2.309 of this chapter; and

(vi) Will require the licensee to explain the exigency and why the licensee cannot avoid it and use its normal public notice and comment procedures in paragraph (a)(1) of this section if it determines that the licensee has failed to use its best efforts to make a timely application for the amendment in order to create the exigency and to take advantage of this procedure.

(6) Where the Commission finds that significant hazards considerations are involved, it will issue a *Federal Register* notice providing an opportunity for a prior hearing even in an emergency situation, unless it finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

(b) *State consultation*.

(1) At the time a licensee requests an amendment, it must notify the State in which its facility is located of its request by providing that State with a copy of its application and its reasoned analysis about no significant hazards considerations and indicate on the application that it has done so.

(2) The Commission will advise the State of its proposed determination about no significant hazards consideration normally by sending it a copy of the *Federal Register* notice.

(3) The Commission will make the names of the Project Manager or other NRC personnel it designated to consult with the State available to the State official designated to consult about its proposed determination. The Commission will consider any comments of that State official. If it does not hear from the State in a timely manner, it

will consider that the State has no interest in its determination; nonetheless, to ensure that the State is aware of the application, before it issues the amendment, it will make a good faith effort to communicate directly with that official. (Inability to consult with a responsible State official following good faith attempts will not prevent the Commission from making effective a license amendment involving no significant hazards consideration.)

(4) The Commission will make a good faith attempt to consult with the State before it issues a license amendment involving no significant hazards consideration. If, however, it does not have time to use its normal consultation procedures because of an emergency situation, it will attempt to communicate directly with the appropriate State official. (Inability to consult with a responsible State official following good faith attempts will not prevent the Commission from making effective a license amendment involving no significant hazards consideration, if the Commission deems it necessary in an emergency situation.)

(5) After the Commission issues the requested amendment, it will send a copy of its determination to the State.

(c) *Caveats about State consultation.*

(1) The State consultation procedures in paragraph (b) of this section do not give the State a right—

(i) To veto the Commission's proposed or final determination;

(ii) To a hearing on the determination before the amendment becomes effective; or

(iii) To insist upon a postponement of the determination or upon issuance of the amendment.

(2) These procedures do not alter present provisions of law that reserve to the Commission exclusive responsibility for setting and enforcing radiological health and safety requirements for commercial nuclear plants.

§ 53.1520 Issuance of amendment.

(a) In determining whether an amendment to a license will be issued to the applicant, the Commission will be guided by the considerations which govern the issuance of initial licenses to the extent applicable and appropriate. If the application is for amendment of an operating license (OL) or combined license (COL) and involves the material alteration of a ~~licensed facility~~commercial nuclear plant, a construction permit (CP) will be issued before the issuance of the amendment to the license, provided however, that if the application involves ~~a material alteration to a manufactured reactor under Framework A of this part before its installation at a site, or~~ a COL before the date that the Commission makes the finding under § 53.1452(g), no application for or issuance of a CP is required. If the amendment involves a significant hazards consideration, the Commission will give notice of its proposed action—

(1) Under § 2.105 of this chapter before acting thereon; and

(2) As soon as practicable after the application has been docketed.

(b) The Commission will be particularly sensitive to a license amendment request that involves irreversible consequences (such as one that permits a significant increase in the amount of effluents or radiation emitted by a commercial nuclear plant).

(c) The Commission may make a final determination, under the procedures in § 53.1515, that a proposed amendment to an OL or a COL for a commercial nuclear plant under ~~Framework A of~~ this part involves no significant hazards consideration, if operation of the plant in accordance with the proposed amendment would not—

Commented [A354]: This parallels the usage in 50.92, which is somewhat problematic because there is no definition of the term "licensed facility." It is edited to eliminate coverage of facilities being constructed under a CP, which are governed by 50.35(b).

Commented [A355]: This exception would have no effect given the limitation to installation of manufactured reactors using COLs and the inability to complete the ITAAC until the installation of the manufactured reactor at the site.

Commented [A356]: Edited to clarify that no CP will be issued. This parallels the treatment of CP amendments under 50.35(b), which appears to be the intent of this provision.

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of an accident from any accident previously evaluated; or

(3) Involve a significant reduction in a margin of safety.

§ 53.1525 Revising certification information within a design certification rule.

(a) A holder of an operating license~~OL~~ or combined license~~COL~~ who references a design certification rule issued under ~~Framework A of~~ this part must request an exemption if proposing to change one or more elements of the certification information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 53.080 and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure.

(b) The request for an exemption must be included with any associated license amendment request, which must be requested and processed in accordance with §§ 53.1510, 53.1515, and 53.1520.

(c) Licensees must evaluate changes to the design as described in the final safety analysis report~~FSAR~~ not involving changes to the certification information using the criteria in § 53.1550.

§ 53.1530 Revising design information within a manufacturing license.

(a) The holder of a~~n~~ manufacturing license (ML) may not make changes to the design of the manufactured reactor authorized to be manufactured without obtaining an amendment pursuant to § 53.1510 and, as applicable, § 53.1520.

(b) The holder of a combined license (COL) under ~~Framework A of~~ this part who references or uses a manufactured reactor under ~~Framework A of~~ this part must request

approval for any proposed departure from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The Commission may grant such a request only if it determines that the departure will comply with the requirements of § 53.080, and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure. The granting of a departure on request of an applicant is subject to litigation in the same manner as other issues in the combined license hearing. The application for such departures must be submitted and processed in accordance with §§ 53.080, 53.1510, 53.1515, and 53.1520. In those cases where an ML references a design certification rule, the amendment application from the holder of the COL must also request an exemption from the design certification rule ~~in accordance with~~under § 53.1525 if one or more elements of the certification information are adversely affected by the proposed change. The holder of the COL must evaluate changes to the commercial nuclear plant as described in the final safety analysis report~~FSAR~~ but outside of the scope of the referenced ML using the criteria in § 53.1550.

Commented [A357]: Edited to conform to the 52.171(b)(2) treatment of departures from the design characteristics, site parameters, terms and conditions, or approved design of a manufactured reactor as discussed in the preamble on page 124 of the draft proposed notice.

§ 53.1535 Amendments during construction.

(a) The holder of a construction permit (CP) or limited work authorization (LWA) under ~~Framework A of~~ this part may request an amendment to the CP or LWA in order to gain Commission approval of the safety of selected design features or specifications, including proposed departures from a design certification rule or manufacturing license~~ML~~. Amendments to CPs or LWAs under ~~Framework A of~~ this part must be requested and processed ~~in accordance with~~under §§ 53.1510 and 53.1520.

(b) The holder of a combined license~~COL~~ under ~~Framework A of~~ this part for which the NRC has not yet made a finding in accordance with § 53.1452(g) must request amendments required by § 53.1525 or § 53.1550 no later than 45 days from the date the

licensee begins the construction of the structures, systems, and components~~SSCs~~ to implement the change or departure requiring NRC approval. The licensee proceeds with such changes at its own risk recognizing that there is a possibility that the amendment will not be granted.

§ 53.1540 Updating licensing basis information and determining the need for NRC approval.

(a) Sections 53.1545 through 53.1565 provide the process for a holder of an operating license (OL), ~~or~~combined license (COL), or ML to modify licensing basis information and to evaluate potential changes to its facilities, procedures, programs, and organizations to determine if NRC approval is required. These sections ~~also~~ apply ~~to the holder of a license authorizing operation of a nuclear power reactor that has submitted the certification of permanent cessation of operations required under § 53.1070(a) or a reactor licensee whose license has been amended to allow possession of nuclear fuel but not operation of the facility~~through termination of the operating license or combined license or expiration of the manufacturing license.

(b) Definitions for the purposes of §§ 53.1545 through 53.15605—

Change means a modification or addition to, or removal from, the commercial nuclear plant or procedures that affects a safety function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions, including functions that are necessary under § 53.440, will be accomplished.

Departure from a method of evaluation described in the ~~U~~FSAR (as updated) used in establishing the functional design criteria for safety-related~~SR~~ structures, systems, or components~~SSCs~~ or in the safety analyses means—

(1) Changing any of the elements of the method described in the ~~U~~FSAR (as updated) unless the results of the analysis are conservative or essentially the same; or

Commented [A358]: This phrasing seems odd because the submittal of this certification has no effect on the license. If we must mention the submittal of the certification of permanent cessation of operations do we need to mention the submittal of the certification o f permanent removal of fuel from the reactor vessel? The license is not altered in any way by the submittal of these certifications until they are both docketed - the one actually cited here is generally first submitted by the licensee when it determines that it will at some defined point in the near future cease operations.

Edited to clarify the scope in time of the requirements.

Commented [A359]: This phrase is parallel to the provisions of 50.82(a)(1)(iii) and 52.110(a)(3), which are both limited in applicability to the licensees meeting this description before "the effective date of this rule" and September 27, 2007, respectively. The reason for that inclusion in those sections was the lack of a requirement to submit the certifications; those paragraphs result in deeming the certifications as having been submitted in order to avoid imposing a requirement on such licensees to submit the certifications due to the new requirement without any change resulting in their licenses. The phrase is deleted as being surplusage because there will be no licensees in this position under part 53 if the certification requirement is included in the regulation.

Staff should correct 50.82(a)(1)(iii) to replace the phrase "the effective date of this rule" with the date of the rule that inserted that provision in the regulations in an administrative rulemaking in order to correct the regulation and provide clarity to readers. (N.B., the listed amendments of the section in the CFR do not include 72 FR ~49503; August 28, 2007, so it is likely an earlier date different from September 27, 2007.)

Commented [A360]: The term "safety function" is specifically defined in 53.230(c) as being limited to those that are required to satisfy the safety criteria in 53.210 and 53.220. This seems to eliminate the items required in 53.440 such as the GDC 3 and GDC 27 equivalents in paragraphs (e) and (g) respectively. This can be addressed by the insertion regarding functions necessary under 53.440.

Commented [A361]: The phrase "including the functions that are necessary under 53.440" is inserted to support the element of evaluation in 53.1550(a)(2)(x).

Commented [A362]: Edited for uniformity.

(2) Changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

Facility as described in the ~~U~~FSAR (as updated) means—

(1) The structures, systems and components (SSCs) that are described in the ~~U~~FSAR (as updated),

(2) The design and performance requirements for such SSCs described in the ~~U~~FSAR (as updated), and

(3) The evaluations or methods of evaluation included in the UFSAR (as updated) for such SSCs which demonstrate that their intended function(s) will be accomplished.

Final Safety Analysis Report (as updated) means the FSAR submitted ~~in accordance with~~under § 53.1369 or § 53.1416, as amended and supplemented, and as updated ~~per the requirements in~~under § 53.1545, as applicable.

Procedures as described in the Final Safety Analysis Report (as updated) means those procedures that contain information described in the UFSAR such as how SSCs are operated and controlled (including assumed operator actions and response times).

Commented [A363]: Staff should move these definitions to 53.1550 and limit their effect to that section in order to avoid limiting the meaning of the defined term "change" in 53.1545 and leaving out a requirement to submit modifications to the FSAR that don't meet the change definition. This would also effect 53.1560 and 53.1565. It is not entirely clear that this definition of "change" would encompass emergency plans, security plans, and the QA program.

§ 53.1545 Updating Final Safety Analysis Reports.

(a) Each holder of an operating license (OL) or combined license (COL) under ~~Framework B of~~ this part for which the Commission has made the finding under § 53.1452(g) must update the final safety analysis report (FSAR) originally submitted as part of the application for the license every 24 months or more frequently to assure that the information included in the report contains the latest information developed. The submittal must include the effects on the content of the FSAR of—

(1) Changes made to the facility or procedures as described in the FSAR;

Commented [A364]: This should not be limited to "changes" as the term is defined.

(2) Safety analyses and evaluations performed by the licensee either in support of approved license amendments or in support of conclusions that changes did not require a license amendment ~~in accordance with~~under § 53.1550;

(3) Updates to the ~~PRAs required~~risk evaluations under § 53.450;

(4) The cumulative effects of the changes to the facility or procedures on the margins to the safety criteria in §§ 53.210, 53.220, and 53.450(e)~~, and 53.470~~ since the last FSAR update; and

(5) Analyses of new safety issues performed by or on behalf of the licensee at Commission request.

(b)(1) The licensee must submit revisions containing updated information to the Commission, ~~as specified in~~under § 53.040, identifying the location of revised or new information.

(2) The submittal must include—

(i) A certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittal, necessary to reflect information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made; and

(ii) An identification of changes made under the provisions of § 53.1550 but not previously submitted to the Commission.

(c) Each applicant for or holder of a COL under ~~Framework A of~~ this part for which the Commission has not made the finding under § 53.1452(g) must submit an update to the FSAR annually by providing the information required in (a)(1) through (a)(5) of this section and meeting the requirements of paragraph (b) of this section. COL applicants who have requested the NRC to suspend its review of the COL application and COL holders who have informed the NRC that they do not plan to pursue

construction need not submit an annual update of the FSAR. If a COL applicant requests that the NRC resume its review, or a COL holder notifies the NRC that the COL holder plans to commence or resume construction, then the COL applicant or holder must submit to NRC an update to its FSAR within 90 days of the request or notification, as applicable, and annually thereafter.

(~~c~~d) Each holder of an ML under ~~Framework A of~~ this part must submit an update of the FSAR reflecting any modification to the design that is directed or approved by the Commission under § 53.1288 or § 53.1530, and any new analyses of the design requested by the Commission under § 53.1580.

(~~d~~e) The ~~U~~updated FSAR must be retained by the licensee ~~until the Commission terminates its license~~.

~~(e) Each holder of an ML under Framework A of this part must submit an update of the FSAR reflecting any modification to the design that is directed or approved by the Commission under § 53.1288 or § 53.1530, and any new analyses of the design requested by the Commission under § 53.1580.~~

§ 53.1550 Evaluating changes to facility as described in Final Safety Analysis Reports.

(a) A ~~licensee~~The holder of an operating license or combined license may make changes in the facility as described in the final safety analysis report ~~U~~FSAR (as updated) and make changes in the procedures as described in the ~~U~~FSAR (as updated) without obtaining a license amendment pursuant to § 53.1510 only if—

(1) An amendment ~~change~~ to the technical specifications incorporated in the license is not required and

(2) The change meets all of the following criteria:

Commented [A365]: Time scope addressed in 53.1540.

Commented [A366]: Moved prior to the retention paragraph and renumbered to clarify that retention is also necessary for MLs.

Commented [A367]: Edited to clarify that this section is not available for use with MLs.

Commented [A368]: Edited to avoid using the defined term "change." This usage is faithful to that of 50.59(c)(1)(i). Staff should correct 50.59(c)(1)(i) in an administrative rulemaking.

Commented [A369]: Edited to align with the criteria in 50.59(b)(2). This alignment will avoid imposing tighter regulatory controls on changes for licensees under part 53 than exists for licensees under parts 50 and 52 (i.e., the need for amendments based on comparison to the QHOs). This will also align with the guidance under development for change control screening and evaluation for LMP licensees under parts 50 and 52.

(i) ~~Does~~ The change would not result in a~~n~~ more than minimal increase in~~to~~ the frequency of occurrence ~~or consequences~~ of design-basis accident (DBA) previously evaluated in the FSAR (as updated)~~an event sequence such that an event sequence not previously identified as risk significant becomes risk significant by the analyses performed in accordance with § 53.450(e)~~.

(ii) ~~Does~~ The change would not result in a~~n~~ more than minimal increase in~~to~~ the frequency ~~or consequences~~ of occurrence of a malfunction of a safety-related (SR) or non-safety-related but safety-significant (NSRSS) structure, system, or component (SSC) previously evaluated in the FSAR (as updated)~~an event sequence such that an event sequence identified as risk significant in accordance with § 53.450(e) exceeds the LBE evaluation criteria required to be established in accordance with § 53.450(e)~~.

(iii) The change would~~Does~~ not result in a more than minimal increase in~~to~~ the ~~frequency or~~ consequences of a DBA previously evaluated in the FSAR (as updated)~~one or more event sequences such that the margin between the calculated cumulative risks posed by the commercial nuclear plant and the safety criteria of § 53.220 decreases by 10 percent or more~~.

(iv) The change would not involve a more than minor increase in the consequences of a malfunction of an SR or NSRSS SSC previously evaluated in the FSAR (as updated).

(v) The change would not result in the identification of a new DBA under § 53.450(f) than any previously evaluated in the FSAR (as updated).

(vi) The change would not create a possibility for a malfunction of an SR or NSRSS SSC with a different result than any previously evaluated in the FSAR (as updated).

(vii) The change would not result in a design-basis limit for a fission product barrier as described in the FSAR (as updated) being exceeded or altered.

(viii) The change would ~~Does~~ not ~~involve~~ result in a departure from a method of evaluation described in the UFSAR used in assessing LBEs under~~in accordance with~~ § 53.450 unless the results of the analysis under § 53.450 are conservative or essentially the same, the revised method of evaluation has been previously approved by the NRC for the intended application, or the revised method of evaluation can be used under~~in accordance with~~ an NRC~~-~~endorsed consensus code or standard.

~~(v) Does not result in the escalation in the safety classification of an SSC from non-safety-related (NSR) to NSRSS or from NSRSS to SR.~~

~~(vi) Does not result in more than a minimal decrease in defense-in-depth.~~

~~(vii) For commercial nuclear plants licensed under Framework A of this part for which alternative evaluation criteria are adopted in accordance with § 53.470, does not result in a change to the frequency or consequences of event sequences such that the calculated margins between the results for event sequences evaluated in accordance with § 53.450(e) and the alternative evaluation criteria decreases by 25 percent or more.~~

~~(viii) Does not result in the identification of a new DBA in accordance with § 53.450(f).~~

~~(ix) Does not result in a decrease by 10 percent or more in the margin between the consequence of any DBA and the safety criteria in § 53.210.~~Th

(x) The change would ~~Does~~ not prevent meeting the design requirements in § 53.440(j) to limit the release of radionuclides from reactor systems, waste stores, or other significant inventories of radioactive materials assuming the impact of a large, commercial aircraft.

Commented [A370]: This criterion is addressed in the new paragraphs (iv) and (vi).

Commented [A371]: This criterion is addressed in the new paragraph (vii).

Commented [A372]: This criterion is unnecessary with the elimination of 53.470.

Commented [A373]: This criterion is addressed in the new paragraph (v).

Commented [A374]: Is criterion is addressed in the new paragraph (iii).

(3) In implementing this paragraph, the ~~U~~FSAR (as updated) is considered to include FSAR changes since submittal of the last update of the FSAR ~~pursuant to~~under § 53.1545.

(4) The provisions in this section do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(b)(1) A licensee who references a design certification rule may make departures from the standard design, without prior Commission approval, unless the proposed departure involves a change to the design as described in the rule certifying the design, in which case the requirements of § 53.1525 are applicable.

(2) The licensee must maintain records of all departures from the certified design of the facility and these records must be maintained and available for audit until the ~~date of~~ termination of the license. The licensee must identify the location and nature of departures from licensing basis information within supporting documents for a certified design within the updates to the Safety Analysis Report required by § 53.1545.

(3) Licensees for which the NRC has docketed the certifications required under § 53.1070 ~~are~~ need not ~~required to~~ retain records of departures from the design of the facility associated with SSCs that have been permanently removed from service using an NRC-approved change process.

(c)(1) The licensee must maintain records of changes in the facility and procedures made ~~pursuant to~~under paragraph (a) of this section. These records must include a written evaluation which provides the bases for the determination that the change does not require a license amendment ~~pursuant to~~under paragraph (a)(2) of this section.

(2) The licensee must submit, as specified in § 53.040, a report containing a brief description of any departures and changes, including a summary of the evaluation of each. A report must be submitted at intervals not to exceed 24 months. For COLs, the report must be submitted at intervals not to exceed 6 months during the period from the date of application for a COL to the date the Commission makes its findings under § 53.1452(g).

(3) The records of changes in the facility must be maintained until the termination of an OL or COL issued under ~~Framework A of~~ this part, or the termination of a renewed license issued under § 53.1595—whichever is later. Records of changes in procedures must be maintained for a period of 5 years.

§ 53.1560 Updating program documents included in licensing basis information.

(a) Each holder under ~~Framework A of~~ this part of an operating license (OL) or combined license (COL) for which the Commission has made the finding under § 53.1452(g) must biennially or more frequently update the program documents submitted as part of the~~an~~ application for~~to obtain or maintain~~ the license to assure that the information included in the documents contains the latest information developed. The submittals must include the effects on the content of the program documents of—

Commented [A375]: What is an application to maintain a license?

Commented [A376]: It is not clear at all what submittals are the subject of this portion of this updating requirement.

(1) Changes made in the facility, procedures, licensee's organization, or site environs;

(2) Safety analyses and evaluations performed by the applicant or licensee either in support of approved license amendments or in support of conclusions that changes did not require a license amendment in accordance with § 53.1550;

(3) Analyses of new safety issues performed by or on behalf of the licensee at Commission request; and

(4) Changes to the programs as a result of operating experience, corrective actions, or other reasons deemed appropriate to ensure the programs serve their underlying purpose to ~~support the requirements in subpart B of this part or others~~satisfy applicable NRC regulations.

(b)(1) The licensee must submit revisions containing updated information to the Commission, as specified in § 53.040, identifying the location of revised or new information.

(2) The submittal must include—

(i) A certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittals, necessary to reflect information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made; and

(ii) An identification of changes made under the provisions of § 53.1550 but not previously submitted to the Commission.

Commented [A377]: This would require submittal of updated versions of many program documents that are subject to inspection instead for currently operating reactors. Staff should seek specific response from stakeholders on the appropriate program documents that should be submitted periodically to the NRC.

(c) The updated program documents must be retained by the licensee until the Commission terminates their license.

§ 53.1565 Evaluating changes to programs included in licensing basis information.

(a) A licensee may make changes to the facility, procedures, or organizations or address changes to site environs as described in the program documents included in licensing basis information without obtaining prior NRC approval only if—

(1) An ~~change~~amendment to the technical specifications incorporated in the license is not required;

(2) An exemption from an NRC regulation is not required; and

(3) The change conforms to program-specific requirements included in regulations in ~~Framework A of~~ this part, technical specifications, or the NRC-approved program document included and reviewed as part of a license application under subpart H or an amendment under this subpart.

(b) In implementing this ~~paragraph~~section, the program documents (as updated) include changes since submittal of the last updates of the program documents pursuant to § 53.1560.

(c) [Reserved] ~~The provisions in this section do not apply to changes to the program documents when the applicable regulations establish more specific criteria for accomplishing such changes~~.

(d) To make changes to the facility, procedures, or organizations or to address changes to site environs as described in the program documents included in licensing basis information for individual programs, the following requirements must be satisfied:

(1) *Quality assurance program—operation*. (i) Each holder under ~~Framework A of~~ this part of an operating license~~OL~~ or combined license (COL), after the Commission makes the finding under § 53.1452(g), may make a change to a previously accepted quality assurance program (QAP) description included or referenced in the Safety Analysis Report without prior NRC approval, provided the change does not reduce the commitments in the program description as accepted by the NRC. Changes to the QAP description that do not reduce the commitments must be submitted to the NRC in accordance with the requirements of § 53.1545. In addition to QAP changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered to be reductions in commitment:

Commented [A378]: Given the criteria in paragraph (a) of this section in combination with the incorporation by reference of the applicable regulations in paragraph (a)(3), it seems as though the provisions in this section will always have more specific criteria for accomplishing changes to the programs than the applicable requirements alone.

Commented [A379]: N.B., this paragraph is 53.1565(d)(1)(i) and should be at the same level in the organizational structure of this section as the paragraph that follows that begins with "Changes to the QAP description that do reduce the commitments …."

(A) The use of a QA standard approved by the NRC which is more recent than the QA standard in the licensee's QAP at the time of the change;

(B) The use of a QA alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility;

(C) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

(D) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text;

(E) The elimination of QAP information that duplicates language in QA regulatory guides and QA standards to which the licensee is committed; and

(F)~~(1)~~ Organizational revisions that ensure that persons and organizations performing QA functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(ii2) Changes to the QAP description that do reduce the commitments must be submitted to the NRC and receive NRC approval prior to implementation, as follows:

Commented [A380]: Format changed to non-italicized end edited to place this on the same level as 53.1565(d)(1)(i) in the same manner as 50.54(a)(3), which corresponds to 53.1565(d)(1)(i), is at the same level as 50.54(a)(4), which corresponds to this paragraph.

(~~i~~A) Changes made to the QAP description as presented in the Safety Analysis Report or in a topical report must be submitted as specified in § 53.040.

(~~ii~~B) The submittal of a change to the Safety Analysis Report QAP description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of subpart K of this part and the Safety Analysis Report QAP description

commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(~~iii~~C) A copy of the forwarding letter identifying the change must be maintained as a facility record for 3 years.

(~~iv~~D) Changes to the QAP description included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

~~(ii) [Reserved]~~

(2) *Quality assurance program—siting, construction, and manufacturing*. Each holder of a~~n~~ limited work authorization~~LWA~~, early site permit, construction permit~~CP~~, manufacturing license~~ML~~, or COL, before the Commission makes the finding under § 53.1452(g) of this chapter, under ~~Framework A of~~ this part may make a change to a previously accepted QAP description included or referenced in the Safety Analysis Report without prior NRC approval, provided the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the QAP description that do not reduce the commitments must be submitted to NRC within 90 days. Changes to the QAP description that reduce the commitments must be submitted to NRC and receive NRC approval before implementation, as follows:

(i) Changes to the Safety Analysis Report must be submitted for review as specified in § 53.040. Changes made to NRC-accepted QA topical report descriptions must be submitted as specified in § 53.040.

(ii) The submittal of a change to the Safety Analysis Report QAP description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for

concluding that the revised program incorporating the change continues to satisfy the criteria of subpart K of this part and the Safety Analysis Report QAP description commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(iii) A copy of the forwarding letter identifying the changes must be maintained as a facility record for 3 years.

(iv) Changes to the QAP description included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

(3) *Emergency preparedness program*.

(i) Definitions for the purpose of paragraph (d)(3) of this section:

(*1*) Change means an action that results in modification or addition to, or removal from, the licensee's emergency plan. All such changes are subject to the provisions of this section except where the applicable regulations establish specific criteria for accomplishing a particular change.

(*2*) Emergency plan means the document(s), prepared and maintained by the licensee, that identify and describe the licensee's methods for maintaining emergency preparedness and responding to emergencies. An emergency plan includes the plan as originally approved by the NRC and all subsequent changes made by the licensee with, and without, prior NRC review and approval under paragraph (d)(3) of this section.

(*3*) Emergency planning function means a capability or resource necessary to prepare for and respond to a radiological emergency, as set forth in the elements of section Iv. of appendix E to this part and, for nuclear power reactor licensees, the planning standards of § 50.47(b).

(*4*) Reduction in effectiveness means a change in an emergency plan that results in reducing the licensee's capability to perform an emergency planning function in the event of a radiological emergency.

(ii)(A) The licensee must provide for the development, revision, implementation, and maintenance of its emergency preparedness program. The licensee must ensure that all program elements are reviewed by persons who have no direct responsibility for the implementation of the emergency preparedness program either—

(*1*) At intervals not to exceed 12 months or,

(*2*) As necessary, based on an assessment by the licensee against performance indicators, and as soon as reasonably practicable after a change occurs in personnel, procedures, equipment, or facilities that potentially could adversely affect emergency preparedness, but no longer than 12 months after the change. In any case, all elements of the emergency preparedness program must be reviewed at least once every 24 months.

(B) The review must include an evaluation for adequacy of interfaces with State participating Tribal and local governments and of licensee drills, exercises, capabilities, and procedures. The results of the review, along with recommendations for improvements, must be documented, reported to the licensee's corporate and plant management, and retained for a period of 5 years. The part of the review involving the evaluation for adequacy of interface with State, participating Tribal and local governments must be available to the appropriate State, participating Tribal and local governments.

(iii) The licensee may make changes to its emergency plan without NRC approval only if the licensee performs and retains an analysis demonstrating that the changes do not reduce the effectiveness of the plan and the plan, as changed, continues

to satisfy the requirements in § 53.855. A change reduces the effectiveness of the plan if it results in reducing the licensee's capability to perform an emergency planning function required by § 53.855 in the event of a radiological emergency.

(iv~~ii~~) The licensee must retain a record of each change to the emergency plan made without prior NRC approval for a period of 3 years from the date of the change and must submit, as specified in § 53.040, a report of each such change, including a summary of its analysis, within 30 days after the change is put in effect.

(~~i~~v) The changes to a licensee's emergency plan that reduce the effectiveness of the plan may not be implemented without prior approval by the NRC. A licensee desiring to make such a change must submit an application for an amendment to its license. In addition to the filing requirements of §§ 53.1510, 53.1515, and 53.1520, the request must include all emergency plan pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the licensee's emergency plan, as revised, will continue to satisfy the requirements of § 53.855.

(vi) The nuclear power reactor licensee must retain the emergency plan and each change for which NRC approval was obtained, pursuant to paragraph (d)(3)(iv) of this section, as a record until the Commission terminates the license for the nuclear power reactor.

(4) *Security programs.*

(i) The licensee must prepare and maintain safeguards contingency plan procedures in accordance with appendix C of part 73 of this chapter for affecting the actions and decisions contained in the Responsibility Matrix of the safeguards contingency plan. The licensee may not make a change that~~which~~ would decrease the safeguard effectiveness of a physical security plan, or guard training and qualification

Commented [A381]: Inserted to be consistent with the next paragraph.

plan, or cyber security plan submitted under subpart H or part 73 of this chapter, or of the first four categories of information (Background, Generic Planning Base, Licensee Planning Base, Responsibility Matrix) contained in a licensee safeguards contingency plan submitted under subpart H or part 73 of this chapter, as applicable, without prior approval of the Commission. A licensee desiring to make such a change must submit an application for amendment to the licensee's license under §§ 53.1510, 53.1515, and 53.1520.

(ii) The licensee may make changes to the plans referenced in paragraph (4)(i) of this section without prior Commission approval if the changes do not decrease the safeguards effectiveness of the plan. The licensee must maintain records of changes to the plans made without prior Commission approval for a period of 3 years from the date of the change, and must submit, as specified in § 53.040, a report containing a description of each change within 2 months after the change is made. Prior to the safeguards contingency plan being put into effect, the licensee must have—

(A) All safeguards capabilities specified in the safeguards contingency plan available and functional;

(B) Detailed procedures developed according to appendix C to part 73 of this chapter available at the licensee's site; and

(C) All appropriate personnel trained to respond to safeguards incidents as outlined in the plan and specified in the detailed procedures.

(iii) The licensee must provide for the development, revision, implementation, and maintenance of its safeguards contingency plan. The licensee must ensure that all program elements are reviewed by individuals independent of both security program management and personnel who have direct responsibility for implementation of the security program either—

(A) At intervals not to exceed 12 months; or

(B) As necessary, based on an assessment by the licensee against performance indicators, and as soon as reasonably practicable after a change occurs in personnel, procedures, equipment, or facilities that potentially could adversely affect security, but no longer than 12 months after the change. In any case, all elements of the safeguards contingency plan must be reviewed at least once every 24 months.

(iv) The review must include a review and audit of safeguards contingency procedures and practices, an audit of the security system testing and maintenance program, and a test of the safeguards systems along with commitments established for response by local law enforcement authorities. The results of the review and audit, along with recommendations for improvements, must be documented, reported to the licensee's corporate and plant management, and kept available at the plant for inspection for a period of 3 years.

§ 53.1570 Transfer of licenses.

(a) No commercial nuclear plant license issued under ~~Framework A of~~ this part, or any right thereunder, shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission gives its consent in writing.

(b)(1) An application for transfer of a license must include—

~~(i)~~ As much of the information described in §§ 53.1109, 53.1306, 53.1366, and 53.1413 with respect to the identity and technical and financial qualifications of the proposed transferee as would be required by those sections if the application were for an initial license. The Commission may require additional information such as data respecting proposed safeguards against hazards from radioactive materials and the applicant's qualifications to protect against such hazards.

Commented [A382]: Moved up to paragraph (b)(1).

(~~i~~2) The application must also include ~~A~~a statement of the purposes for which the transfer of the license is requested, the nature of the transaction necessitating or making desirable the transfer of the license, and an agreement to limit access to Restricted Data or Classified National Security Information pursuant to § 53.1115. The Commission may require any person who submits an application for license pursuant to the provisions of this section to file a written consent from the existing licensee or a certified copy of an order or judgment of a court of competent jurisdiction attesting to the person's right (subject to the licensing requirements of the Act~~EA~~ and these regulations) to possession of the facility or site involved.

~~(2) [Reserved]~~

(c) After appropriate notice to interested persons, including the existing licensee, and observance of such procedures as may be required by the Act~~EA~~ or regulations or orders of the Commission, the Commission will approve an application for the transfer of a license, if the Commission determines—

(1) That the proposed transferee is qualified to be the holder of the license; and

(2) That transfer of the license is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.

~~**§ 53.1575 Termination of license.**~~

~~(a) When the holder of an OL or COL under Framework A of this part has determined to permanently cease operations the licensee must, within 30 days, submit a written certification to the NRC, consistent with the requirements of § 53.1070.~~

~~(b) Once fuel has been permanently removed from the reactor system, the licensee must submit a written certification to the NRC that meets the requirements of § 53.1070.~~

Commented [A383]: Redundant to 53.1070(a).

~~(c)(1) Upon docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor system, or when a final legally effective order to permanently cease operations has come into effect, the license no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor system.~~

Commented [A384]: Redundant to 53.1070(b).

~~(2) Activities associated with decommissioning will be carried out in accordance with the requirements and procedures in subpart G of this part.~~

Commented [A385]: Subpart G is self-executing.

~~(3) The Commission shall terminate the license if it determines that—~~

~~(i) The remaining dismantlement has been performed in accordance with the approved license termination plan required in subpart G of this part, and~~

~~(ii) The final radiation survey and associated documentation, including an assessment of dose contributions associated with parts released for use before approval of the license termination plan, demonstrate that the facility and site have met the criteria for decommissioning in subpart E of 10 CFR part 20.~~

~~(d) A holder of a CP or COL under Framework A of this part may request the termination of the license as well as licenses issued by the NRC under parts 30, 40, 70 of this chapter prior to plant operations. Such requests may support an immediate NRC approval of the site for unrestricted use.~~

Commented [A386]: Redundant to 53.1070(k).

§ 53.1580 Information requests.

~~Any~~ Each licensee under ~~Framework A of~~ this part must at any time before termination~~expiration~~ of the license, upon request of the Commission, submit, as specified in § 53.040 written statements, signed under oath or affirmation, to enable the Commission to determine whether or not the license should be modified, suspended, or revoked. Except for information sought to verify licensee compliance with the current licensing basis for that facility, the NRC must prepare the reason or reasons for each

information request prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such justification provided for an evaluation performed by the NRC staff must be approved by the Executive Director for Operations or his or her designee prior to issuance of the request.

§ 53.1585 Revocation, suspension, modification of licenses and approvals for cause.

A license for a facility or standard design approval issued under ~~Framework A of~~ this part may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or in the supplemental or other statement of fact required of the applicant; or because of conditions revealed by the application or statement of fact of any report, record, inspection, or other means which would warrant the Commission to refuse to grant a license or approval on an original application (other than those relating to the duration of the license, those relating to § 53.090(b), and those relating to § 53.090(c)(2)); or for failure to manufacture a reactor, or construct or operate a facility in accordance with the terms of the license, provided, however, that failure to make timely completion of the proposed construction or alteration of a facility under a construction permit~~CP~~ or combined license under ~~Framework A of~~ this part shall be governed by the provisions of § 53.1342(b) and § 53.1455(b), respectively; or for violation of, or failure to observe, any of the terms and provisions of the act, regulations, license, approval, or order of the Commission.

§ 53.1590 Backfitting.

(a)(1) Backfitting means the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license~~ML~~ for a facility; or the procedures or organization required to design, construct or operate a

Commented [A387]: Inserted to avoid inclusion of the general license for reactor operators under subpart F within the scope of this section. 53.810(d) provides the regulations for suspension of those licenses.

Commented [A388]: Inserted to address the limitations with respect to 50.51 in 50.100.

Commented [A389]: Inserted to address the limitations with respect to the former 50.42(a) in 50.100. Those provisions were moved from 50.42(a) to 50.42 by 73 FR 44620, July 31, 2008 without changing the limitation in 50.100, which was last modified by 72 FR 49504, August 28, 2007. Staff should correct the improper citation in 50.100 in an administrative rulemaking.

Commented [A390]: Inserted to reflect the limitations with respect to 50.43(b) in 50.100.

facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after the date of issuance of the license or design approval for a~~the~~ commercial nuclear plant or the manufacturing license issued under ~~Framework A of~~ this part.

Commented [A391]: Inserted to provide the reference date for the design approvals that are subject to these provisions in line 2 of this paragraph.

(2) Except as provided in paragraph (a)(4) of this section, the Commission shall require a systematic and documented analysis pursuant to paragraph (b) of this section for backfits which it seeks to impose.

(3) Except as provided in paragraph (a)(4) of this section, the Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (b) of this section, that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.

(4) The provisions of paragraphs (a)(2) and (a)(3) of this section are inapplicable and, therefore, backfit analysis is not required and the standards in paragraph (a)(3) of this section do not apply where the Commission or staff, as appropriate, finds and declares, with appropriate~~d~~ documented evaluation for its finding, either—

Commented [A392]: This accurately reflects a typographic error in 50.109(a)(4). Staff should correct the error in the next administrative rulemaking.

(i) That a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee; or

(ii) That regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security; or

(iii) That the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate.

(5) The Commission must~~shall~~ always require the backfitting of a facility if it determines that such regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security.

(6) The documented evaluation required by paragraph (a)(4) of this section must include a statement of the objectives of and reasons for the modification and the basis for invoking the exception. If immediately effective regulatory action is required, then the documented evaluation may follow rather than precede the regulatory action.

(7) If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written licensee commitments, or there are two or more ways to reach a level of protection which is adequate, then ordinarily the applicant or licensee is free to choose the way which best suits its purposes. However, should it be necessary or appropriate for the Commission to prescribe a specific way to comply with its requirements or to achieve adequate protection, then cost may be a factor in selecting the way, provided that the objective of compliance or adequate protection is met.

(b) In reaching the determination required by paragraph (a)(3) of this section, the Commission will consider how the backfit should be scheduled in light of other ongoing regulatory activities at the facility and, in addition, will consider information available concerning any of the following factors as may be appropriate and any other information relevant and material to the proposed backfit:

(1) The statement of the specific objectives that the proposed backfit is designed to achieve;

(2) The general description of the activity that would be required by the licensee or applicant in order to complete the backfit;

(3) The potential change in the risk to the public from the accidental off-site release of radioactive material;

(4) The potential impact on radiological exposure of facility employees;

(5) The installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay;

(6) The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements;

(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;

(8) The potential impact of differences in facility type, design or age on the relevancy and practicality of the proposed backfit;

(9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

(c) No licensing action will be withheld during the pendency of backfit analyses required by the Commission's rules.

(d) The Executive Director for Operations shall be responsible for implementation of this section, and all analyses required by this section shall be approved by the Executive Director for Operations or his or her designee.

§ 53.1595 Renewal.

~~Licenses may be renewed by the Commission upon expiration of the period of the license~~[Reserved].

Subpart J — Reporting and Other Administrative Requirements

§ 53.1600 General information.

Each applicant and licensee under ~~Framework A of~~ this part must ~~ensure that NRC inspectors have unfettered~~ provide access to sites and facilities licensed or proposed to be licensed in § 53.1610, must maintain records and make reports to the NRC in accordance with requirements in §§ 53.1620 through 53.1650, must satisfy financial qualification and reporting requirements in §§ 53.1660 through 53.1700, and must obtain and maintain required financial protections in case of an accident in §§ 53.1720 ~~and 53.1730~~.

Commented [A393]: This would exceed the unfettered access provisions of 50.70 and has not been justified or acknowledged in the preamble.

§ 53.1610 ~~Unfettered access for i~~Inspections.

(a) Each applicant for or holder of a~~n~~ manufacturing license (ML), operating license (OL), combined license (COL), construction permit (CP), or early site permit must permit inspection, by duly authorized representatives of the Commission, of its records, premises, activities, and of licensed materials in possession or use, related to the license ~~or CP or early site permit~~ as may be necessary to effectuate the purposes of the Act~~EA~~ and the Energy Reorganization Act of 1974.

Commented [A394]: Edited to reflect that the defined term "license" in 53.020, with respect to facilities, includes construction permits and early site permits.

(b)(1) Each holder of an ML, OL, COL, or CP must, upon request by the Director, Office of Nuclear Reactor Regulation, provide rent-free office space for the exclusive use of the Commission inspection personnel. Heat, air conditioning, light, electrical outlets, and janitorial services must be furnished by each licensee and each holder of a CP. The office must be convenient to and have full access to the facility and must provide the inspectors both visual and acoustic privacy.

(2) For a site or facility with an assigned resident inspector, the space provided must be adequate to accommodate a full-time inspector, a part-time secretary, and transient NRC personnel and must be generally commensurate with other office facilities

at the site. For sites or facilities assigned multiple resident inspectors, additional space may be requested. The office space that is provided must be subject to the approval of the Director, Office of Nuclear Reactor Regulation. All furniture, supplies, and communication equipment will be furnished by the Commission.

~~(3) For a site or facility without an assigned resident inspector, temporary space to accommodate periodic or special inspections must be provided. The office space must be generally commensurate with other office accommodations at the site.~~

(34) The licensee or permit holder must afford any NRC resident inspector assigned to that site, or other NRC inspectors identified by the Regional Administrator as likely to inspect the facility, immediate unfettered access, equivalent to access provided regular plant employees, following proper identification and compliance with applicable access control measures for security, radiological protection, and personal safety.

(45) The licensee or permit holder must ensure that the arrival and presence of an NRC inspector, who has been properly authorized facility access as described in paragraph (b)(34) of this section, is not announced or otherwise communicated by its employees or contractors to other persons at the facility unless specifically requested by the NRC inspector.

§ 53.1620 Maintenance of records, making of reports.

(a) Each holder of a~~n~~ manufacturing license (ML), operating license (OL), combined license (COL), construction permit (CP), or early site permit must maintain all records and make all reports, in connection with the activity, as may be required by the conditions of the license or permit or by the regulations and orders of the Commission in effectuating the purposes of the Act~~EA~~ and the Energy Reorganization Act of 1974. Reports must be submitted in accordance with § 53.040.

(b) [Reserved]

Commented [A395]: Deleted to bring this section in line with the requirements in 50.70 and reflect that paragraph (b)(1) of this section requires these licensees and permit holders to provide office space upon request by the Director of Nuclear Reactor Regulation. Staff should make use of that requirement to request the temporary space assignment rather than this paragraph in order to gain the benefits of visual and acoustic privacy and convenience to and full access to the facility, which would not be necessary for the temporary space requirement here.

(c) Records that are required by the regulations in ~~Framework A of~~ this part, by license condition, or by technical specifications must be retained for the period specified by the appropriate regulation, license condition, or technical specification. If a retention period is not otherwise specified, these records must be retained until the Commission terminates the facility license or, in the case of an early site permit, until the permit expires.

(d)(1) Records which must be retained under ~~Framework A of~~ this part may be the original or a reproduced copy or a microform if the reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations. The record may also be stored in electronic media with the capability of producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with, and loss of records.

(2) If there is a conflict between the Commission's regulations in ~~Framework A of~~ this part, license condition, or technical specification, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in ~~Framework A of~~ this part for such records shall apply unless the Commission, under~~pursuant to~~ § 53.080 of this part, has granted a specific exemption from the record retention requirements in the regulations in ~~Framework A of~~ this part.

(e) Each licensee must notify the Commission as specified in § 53.040 of this ~~chapter~~part, of successfully completing power ascension testing or startup testing as applicable within 30 calendar days of completing the testing.

§ 53.1630 Immediate notification requirements for operating commercial nuclear plants.

(a) *General requirements.*[18]: (1) Each holder of an operating licenseOL under Framework A of this part or a combined licenseCOL under Framework A of this part after the Commission makes the finding under § 53.1452(g), must notify the NRC Operations Center via the Emergency Notification System of—

(i) The declaration of any of the Emergency Classes specified in the licensee's approved Emergency Plan; or

(ii) Those non-emergency events specified in paragraph (b) of this section that occurred within 3 years of the date of discovery.

(2) If the Emergency Notification System is inoperative, the licensee must make the required notifications via commercial telephone service, other dedicated telephone system, or any other method which will ensure that a report is made as soon as practical to the NRC Headquarters Operations Center at the numbers specified in appendix A to part 73 of this chapter.

(3) The licensee must notify the NRC immediately after notification of the appropriate State or local agencies and not later than 1 hour after the time the licensee declares one of the Emergency Classes.

(4) The licensee must activate the data links with the NRC as specified in their emergency plans after declaring an Emergency Class for events of actual or potential substantial degradation of plant safety or security, probable risk to site personnel life, or site equipment damage caused by hostile action. The data links may also be activated by the licensee during emergency drills or exercises if the licensee's computer system has the capability to transmit the exercise data.

(5) When making a report under paragraph (a)(1) of this section, the licensee must identify—

(i) The Emergency Class declared; or

(ii) Paragraph (b)(1), “One-hour reports,” paragraph (b)(2), “Four-hour reports,” or paragraph (b)(3), “Eight-hour reports,” as the paragraph of this section requiring notification of the non-emergency event.

(b) *Non-emergency events* – (1) *One-hour reports*. If not reported as a declaration of an Emergency Class under paragraph (a) of this section, the licensee must notify the NRC as soon as practical and in all cases within one hour of the occurrence of any deviation from the plant’s Technical Specifications authorized underpursuant to § 53.740(h) of this part.

(2) *Four-hour reports*. If not reported under paragraphs (a) or (b)(1) of this section, the licensee must notify the NRC as soon as practical, and in all cases, within 4 hours of the occurrence of any of the following:

(i) The initiation of any commercial nuclear plant shutdown required by the plant’s Technical Specifications.

(ii) Any event or condition that results in actuation of the reactor protection system (RPS) when the reactor is critical except when the actuation results from and is part of a pre-planned sequence during testing or reactor operation.

(iii) Any event or condition that results in an unplanned actuation of an safety-related (SR) standby cooling system or the unplanned sole reliance on an SR standby cooling system for those systems that are in constant operation.

(iv) Any event or condition that results in an unplanned movement of, change of state in, or chemical interaction involving a significant amount of radioactive material within the commercial nuclear plant.

(v) Any event or situation, related to the health and safety of the public or onsite personnel, or protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made. Such an event may include an onsite fatality or inadvertent release of radioactively contaminated materials.

(3) *Eight-hour reports*. If not reported under paragraphs (a), (b)(1) or (b)(2) of this section, the licensee must notify the NRC as soon as practical and in all cases within 8 hours of the occurrence of any of the following:

(i) Any event or condition that results in—

(A) The condition of the commercial nuclear plant, including its principal safety barriers, being seriously degraded; or

(B) The commercial nuclear plant being in an unanalyzed condition ~~not analyzed under § 53.450~~ that significantly degrades plant safety.

Commented [A396]: Edited to generalize the requirement and reflect that 53.450 does not require an analysis of normal operations.

(ii) Any event or condition that results in valid actuation of an SR system, except when the actuation results from and is part of a pre-planned sequence during testing or reactor operation.

(iii) Any event or condition that at the time of discovery could have prevented the fulfilment of the safety functions identified under~~defined in~~ § 53.230. Events covered may include one or more procedural errors, equipment failures, and/or discovery of design, analysis, fabrication, construction, and/or procedural inadequacies. However, individual component failures need not be reported pursuant to this paragraph if other equipment was operable and available to perform the required safety function.

(iv) Any event requiring the transport of a radioactively contaminated person to an offsite medical facility for treatment.

(v) Any event that results in a major loss of emergency assessment capability, offsite response capability, or offsite communications capability (e.g., significant portion of control room indication, Emergency Notification System, or offsite notification system).

(c) *Follow-up Notification*: With respect to the notifications made under paragraphs (a) and (b) of this section, in addition to making the required initial notification, each licensee, must during the course of the event—

(1) Immediately Report: (i) any further degradation in the level of safety of the plant or other worsening plant conditions, including those that require the declaration of any of the Emergency Classes, if such a declaration has not been previously made, or

(ii) any change from one Emergency Class to another, or

(iii) a termination of the Emergency Class.

(2) Immediately Report: (i) the results of ensuing evaluations or assessments of plant conditions,

(ii) the effectiveness of response or protective measures taken, and

(iii) important information related to plant behavior that is not understood.

(3) Maintain an open, continuous communication channel with the NRC Operation Center upon request by the NRC.

[81] Other requirements for immediate notification of the NRC by licensed operating commercial nuclear plants are contained elsewhere in this chapter, in particular §§ 20.1906, 20.2202, 72.216, 73.71, and 73.77 of this chapter.

§ 53.1640 Licensee event report system.

(a) *Reportable events*.

(1) Each holder of~~commercial nuclear plant licensee holding~~ an operating license~~OL~~ under ~~Framework A of~~ this part or a combined license~~COL~~ under ~~Framework A of~~ this part after the Commission makes the finding under § 53.1452(g), must submit a Licensee Event Report (LER) for any event of the type described in this paragraph within 60 days after discovery of the event. In the case of an invalid actuation reported under

§ 53.1640(a)(2), other than automatic reactor shutdown when the reactor is critical, the licensee may, at its option, provide a telephone notification to the NRC Operations Center within 60 days after discovery of the event instead of submitting a written LER. Unless otherwise specified in this section, the licensee must report an event if it occurred within 3 years of the date of discovery regardless of the plant mode or power level, and regardless of the significance of the structure, system, or component that initiated the event.

(2) The licensee must report—

(i)(A) The completion of any commercial nuclear plant shutdown required by the plant's Technical Specifications.

(B) Any operation or condition which was prohibited by the plant's Technical Specifications except when—

(1) The Technical Specification is administrative in nature;

(2) The event consisted solely of a case of a late surveillance test where the oversight was corrected, the test was performed, and the equipment was found to be capable of performing its specified safety functions; or

(3) The Technical Specification was revised prior to discovery of the event such that the operation or condition was no longer prohibited at the time of the event.

(C) Any deviation from the plant's Technical Specifications authorized underpursuant to § 53.740(h).

(ii) Any event or condition that resulted in—

(A) The condition of the commercial nuclear plant, including its principal safety barriers, being seriously degraded; or

(B) The commercial nuclear plant being in an unanalyzed condition not analyzed under § 53.450 that significantly degrades plant safety.

(iii) Any natural phenomena or other external condition that posed an actual threat to the safety of the commercial nuclear plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the commercial nuclear plant.

(iv) Any event or condition that resulted in ~~inadvertent operation~~manual or automatic actuation of any ~~SSC~~ system classified as safety-related (SR) for an identified safety function under § 53.460 or the unplanned sole reliance on an SR system for those systems that are in constant operation, except when—

Commented [A397]: Edited to align with the usage of "actuation" in paragraphs 53.1640(a)(2)(A) and (B), as well as the usages of "system(s)" later in this sentence. This better follows the parallel usages in 50.73 and avoids a reading of "operation of a structure" for "operation of any SSC."

(A) The actuation resulted from and was part of a pre-planned sequence during testing; or

(B) The actuation was invalid and—

(*1*) Occurred while the system was properly removed from service; or

(*2*) Occurred after the safety function had been already completed.

(v) Any event or condition that could have prevented the fulfillment of the safety functions ~~listed in~~identified under § 53.230.

Commented [A398]: Edited to reflect the fact that 53.230 does not provide an exhaustive list of safety functions but instead would require an applicant to identify them.

(vi) Events covered in paragraph (a)(2)(v) of this section may include one or more procedural errors, equipment failures, and/or discovery of design, fabrication, construction, and/or procedural inadequacies. However, individual component failures need not be reported pursuant to paragraph (a)(2)(v) of this section if any other equipment was operable and available to perform the required safety function.

(vii)(A) Any event or condition that as a result of a single cause could have prevented the fulfillment of any of the safety functions ~~listed in~~identified under § 53.230.

(B) Events covered in paragraph (a)(2)(vii)(A) of this section may include cases of procedural error, equipment failure, and/or discovery of a design, analysis, fabrication, construction, and/or procedural inadequacy. However, licensees are not required to

report an event pursuant to paragraph (a)(2)(vii)(A) of this section if the event results from—

(*1*) A shared dependency among trains or channels that is a natural or expected consequence of the approved plant design; or

(*2*) Normal and expected wear or degradation.

(viii)(A) Any airborne radioactive release that, when averaged over a time period of 1-hour, resulted in airborne radionuclide concentrations in an unrestricted area that exceeds 20 times the applicable concentration limits specified in appendix B to 10 CFR part 20, table 2, column 1.

(B) Any liquid effluent release that, when averaged over a time period of 1-hour, exceeds 20 times the applicable concentrations specified in appendix B to 10 CFR part 20, table 2, column 2, at the point of entry into the receiving waters (i.e., unrestricted area) for all radionuclides except tritium and dissolved noble gases.

(ix) Any event that posed an actual threat to the safety of the commercial nuclear plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the plant, including fires, toxic gas releases, or radioactive releases.

(b) *Contents*. The LER must contain—

(1) A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.

(2)(i) A clear, specific narrative description of what occurred so that knowledgeable readers conversant with the design of commercial nuclear plants, but not familiar with the details of a particular plant, can understand the complete event.

(ii) The narrative description must include the following specific information as appropriate for the particular event:

(A) Plant operating conditions before the event.

(B) Status of systems, structures, or components that were inoperable at the start of the event and that contributed to the event.

(C) Dates and approximate time of the occurrences.

(D) The cause of each component or system failure or personnel error, if known.

(E) The failure mode, mechanism, and effect of each failed component, if known.

(F) [Reserved]

(G) For failures of components with multiple functions, include a list of systems or secondary functions that were also affected.

(H) For failure that rendered a component or system classified as SR or NSRSS inoperable, an estimate of the elapsed time from the discovery of the failure until the component or system was returned to service.

(I) The method of discovery of each component or system failure or procedural error.

(J) For each human performance related root cause, the licensee must discuss the cause(s) and circumstances.

(K) Automatically and manually initiated safety system responses.

(L) The manufacturer and model number (or other identification) of each component that failed during the event.

(3) An assessment of the safety consequences and implications of the event. This assessment must include—

(i) The availability of systems or components that could have performed the same function as the components and systems that failed during the event, and

(ii) For events that occurred when the reactor was shut down, the availability of systems or components that are needed to shut down the reactor and maintain safe shutdown conditions, remove residual heat, control the release of radioactive material, or mitigate the consequences of an accident.

(4) A description of any corrective actions planned as a result of the event, including those to reduce the probability of similar events occurring in the future.

(5) Reference to any previous similar events at the same plant that are known to the licensee.

(6) The name and contact information of a person within the licensee's organization who is knowledgeable about the event and can provide additional information concerning the event and the plant's characteristics.

(c) *Supplemental Information*: The Commission may require the licensee to submit specific additional information beyond that required by paragraph (b) of this section if the Commission finds that supplemental material is necessary for complete understanding of an unusually complex or significant event. These requests for supplemental information will be made in writing and the licensee must submit, as specified in § 53.040, the requested information as a supplement to the initial LER.

(d) *Submission of Reports*: LERs must be prepared on Form NRC 366 and submitted to the NRC, as specified in § 53.040.

(e) *Report Legibility*: The reports and copies that licensees are required to submit to the Commission under the provisions of this section must be of sufficient quality to permit legible reproduction and micrographic processing.

(f) [Reserved]

(g) [Reserved]. ~~*Reportable Occurrences*: The requirements contained in this section replace all existing requirements for licensees to report "Reportable Occurrences."~~

Commented [A399]: Deleted as there are no existing requirements for this section to replace - the original paragraph this is derived from specified that the existing requirements were in individual plant TS. Since there are no current licensees under part 53, this is unnecessary.

§ 53.1645 Reports of radiation exposure to members of the public.

(a) Each holder of an OL, and each holder of a COL after the Commission has made the finding under § 53.1452(g), must submit a report to the Commission annually that specifies the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents and the dose in unrestricted areas due to direct radiation exposure from contained radiation sources during the previous 12 months. In addition, the report shall include an estimate of the dose received by the maximally exposed member of the public in an unrestricted area from effluents and direct radiation from contained sources during the previous 12 months and include any other information as may be required by the Commission to estimate maximum potential annual radiation doses to the public. The report must be submitted as specified in § 53.040, and the time between submission of the reports must be no longer than 12 months. If the TEDE to members of the public in unrestricted areas during the reporting period is greater than the established ~~ALARA~~ design objectives under § 53.425(c) or 10 mrem/year TEDE, the report must specify the causes for exceeding the ~~ALARA~~ design objective and describe any corrective actions. On the basis of these reports and any additional information the Commission may obtain from the licensee or others, the Commission may require the licensee to take action as the Commission deems appropriate.

(b) If during any calendar quarter the radiation exposure to a member of the public in the unrestricted areas, calculated on the same basis as the respective ~~ALARA~~ design objective exposure, exceeds one-half of the annual ~~ALARA~~ design objective exposure, the licensee must investigate the causes, define and initiate a program of

corrective actions, and submit a report of the causes and actions as specified in § 53.040. ~~The report shall specify the causes for exceeding one-half the annual ALARA design objective exposure in a quarter and describe corrective actions that the licensee will take to maintain radiation exposure to levels within the ALARA design objectives for the remainder of the year.~~ The report shall be submitted within 30 days from the end of the quarter when one-half of the annual ~~ALARA~~ design objective exposure was exceeded.

Commented [A400]: Edited to actually require identifying the causes and initiate the program of corrective actions, as is done under section IV.A of appendix I to part 50.

§ 53.1650 Facility information and verification.

(a) In response to a written request by the Commission, each applicant for a CP or license and each recipient of a CP or a license must submit facility information, as described in § 75.10 of this chapter, on International Atomic Energy Agency (IAEA) Design Information Questionnaire forms and site information on DOC/NRC Form AP-A and associated forms;

(b) As required by the Additional Protocol, must submit location information described in § 75.11 of this chapter on DOC/NRC Form AP-1 and associated forms; and (c) Must permit verification thereof by the IAEA and take other action as necessary to implement the US/IAEA Safeguards Agreement, as described in ~~P~~part 75 of this chapter.

§ 53.1660 Financial requirements.

Sections 53.1670 through 53.1700 set out the requirements and procedures related to financial qualifications and related reporting requirements.

§ 53.1670 Financial qualifications.

Except for an electric utility applicant for a license to operate a commercial nuclear plant, an applicant for a CP, OL, or COL under this part must possess or have reasonable assurance of obtaining the funds necessary for the activities for which the permit or license is sought.

§ 53.1680 Annual financial reports.

~~With respect to any commercial nuclear plant of a type described in § 53.020,~~ ~~e~~Each licensee and each holder of a CP must submit its annual financial report, including the certified financial statements, to the Commission, as specified in § 53.040, upon issuance of the report. However, licensees and holders of a CP who submit a Form 10-Q with the Securities and Exchange Commission or a Form 1 with FERC need not submit the annual financial report or the certified financial statement under this ~~paragraph~~section.

Commented [A401]: Deleted as unnecessary. The source for this text is the 50.71(b) text regarding facilities described in 50.21(b) and 50.22, which correspond to Class 104(b) and Class 103 licensed facilities, respectively. All facilities licensed under part 53 will be Class 103 licensees so this is surplusage.

§ 53.1690 Licensee's change of status; financial qualifications.

(a) An electric utility licensee holding an OL or COL (including a renewed license) for a commercial nuclear plant, no later than seventy-five (75) days prior to ceasing to be an electric utility in any manner not involving a license transfer under § 53.1399 or § 53.1456 must provide the NRC with the financial qualifications information that would be required for obtaining an initial OL or COL under ~~Framework A of~~ this part. The financial qualifications information must address the first full 5 years of operation after the date the licensee ceases to be an electric utility.

(b)(1) Any holder of a license for a commercial nuclear plant issued under this part must notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code by or against—

Commented [A402]: Inserted to eliminate operators and senior operators from coverage under this requirement.

(i) The licensee;

(ii) An entity (as 11 U.S.C. 101(14) defines that term) controlling the licensee or listing the license or licensee as property of the estate; or

(iii) An affiliate (as 11 U.S.C. 101(2) defines that term) of the licensee.

(2) This notification must indicate—

(i) The bankruptcy court in which the petition for bankruptcy was filed; and

(ii) The date of the filing of the petition.

§ 53.1700 Creditor regulations.

(a) Pursuant to section 184 of the Act~~EA~~, the Commission consents, without individual application, to the creation of any mortgage, pledge, or other lien upon any facility not owned by the United States which is the subject of a license or upon any leasehold or other interest in such facility; provided—

(1) That the rights of any creditor so secured may be exercised only in compliance with and subject to the same requirements and restrictions as would apply to the licensee pursuant to the provisions of the license, the Act~~EA~~, and regulations issued by the Commission ~~pursuant to~~under the Act~~EA~~; and

(2) That no creditor so secured may take possession of the facility pursuant to the provisions of this section prior to either the issuance of a license from the Commission authorizing such possession or the transfer of the license.

(b) Any creditor so secured may apply for transfer of the license covering such facility by filing an application for transfer of the license ~~pursuant to~~under § 53.1570. The Commission will act upon such application ~~pursuant to~~under Subpart I of this part.

(c) Nothing contained in this regulation shall be deemed to affect the means of acquiring, or the priority of, any tax lien or other lien provided by law.

(d) As used in this section—

License includes any license under ~~Framework A of~~ this part, which may be issued by the Commission with regard to a facility;

Creditor includes, without implied limitation, the trustee under any mortgage, pledge or lien on a facility made to secure any creditor, any trustee or receiver of the facility appointed by a court of competent jurisdiction in any action brought for the benefit

Commented [A403]: This conflicts with the definition of "license" in 53.020. It's not absolutely incorrect to set up conflicting definitions of terms used in specific sections but it is a bad practice.

of any creditor secured by such mortgage, pledge or lien, any purchaser of such facility at the sale thereof upon foreclosure of such mortgage, pledge, or lien or upon exercise of any power of sale contained therein, or any assignee of any such purchaser.

Facility includes, but is not limited to, a site which is the subject of an early site permit under ~~Framework A of~~ this part, and a reactor manufactured under an manufacturing license~~ML~~ under ~~Framework A of~~ this part.

~~**§ 53.1710 Financial protection.**~~

~~Sections 53.1720 and 53.1730 set out the requirements and procedures related to licensees obtaining and maintaining insurance to cover stabilization and decontamination activities in the event of an accident and financial protection in accordance with Part 140, "Financial Protection Requirements and Indemnity Agreements," of this chapter.~~

Commented [A404]: Deleted as unnecessary with the deletion of 53.1730.

§ 53.1720 Insurance required to stabilize and decontaminate plant following an accident.

Each commercial nuclear plant licensee under ~~Framework A of~~ this part must take reasonable steps to obtain insurance available at reasonable costs and on reasonable terms from private sources or to demonstrate that it possesses an equivalent amount of protection covering the licensee's obligation, in the event of an accident at the licensee's ~~commercial~~ nuclear reactor, to stabilize and decontaminate the plant and the plant site at which such an accident may occur, provided that—

(a) The insurance required by this section must have a minimum coverage limit for each commercial nuclear plant site of $1.06 billion, an amount based on plant-specific estimates of costs to stabilize and decontaminate a plant, or whatever amount of insurance is generally available from private sources, whichever is less. The required insurance must clearly state that, as and to the extent provided in paragraph (d)~~(1)~~ of

Commented [A405]: Deleted to follow the corresponding text in 50.54(w)(1) and reflect that the terms of paragraph (d)(1) include exceptions provided for in paragraphs (d)(3) and (d)(4).

this section, any proceeds must be payable first for stabilization of the plant and next for decontamination of the plant and the plant site. If a licensee's coverage falls below the required minimum, the licensee must within 60 days take all reasonable steps to restore its coverage to the required minimum. The required insurance may, at the option of the licensee, be included within policies that also provide coverage for other risks, including, but not limited to, the risk of direct physical damage.

(b)(1) With respect to policies issued or annually renewed, the proceeds of such required insurance must be dedicated, as and to the extent provided in this paragraph, to reimbursement or payment on behalf of the insured of reasonable expenses incurred or estimated to be incurred by the licensee in taking action to fulfill the licensee's obligation, in the event of an accident at the licensee's plant, to ensure that the plant is in, or is returned to, and maintained in, a safe and stable condition and that radioactive contamination is removed or controlled such that personnel exposures are consistent with the occupational exposure limits in 10 CFR part 20. These actions must be consistent with any other obligation the licensee may have under this chapter and must be subject to paragraph (d) of this section. As used in this section, an "accident" means an event that involves the release of radioactive material from its intended place of confinement within the commercial nuclear plant such that there is a present danger of release off site in amounts that would pose a threat to the public health and safety.

(2) The stabilization and decontamination requirements set forth in paragraph (d) of this section must apply uniformly to all insurance policies required under this section.

(c) The licensee shall report to the NRC on April 1 of each year the current levels of this insurance or financial security it maintains and the sources of this insurance or financial security.

(d)(1) In the event of an accident at the licensee's plant, whenever the estimated costs of stabilizing the licensed plant and of decontaminating the plant and the plant site exceed one tenth of the minimum insurance under paragraph (a) of this section, the proceeds of the insurance required by this section must be dedicated to and used, first, to ensure that the licensed plant is in, or is returned to, and can be maintained in, a safe and stable condition so as to prevent any significant risk to the public health and safety and, second, to decontaminate the plant and the plant site in accordance with the licensee's cleanup plan as approved by order of the Director, Office of Nuclear Reactor Regulation. This priority on insurance proceeds must remain in effect for 60 days or, upon order of the Director, for such longer periods, in increments not to exceed 60 days except as provided for activities under the cleanup plan required in paragraphs (d)(3) and (d)(4) of this section, as the Director may find necessary to protect the public health and safety. Actions needed to bring the plant to and maintain the plant in a safe and stable condition may include one or more of the following, as appropriate:

(i) Shutdown of the reactor(s) and other processes at the plant;

(ii) Establishment and maintenance of long-term cooling with stable decay heat removal;

(iii) Maintenance of sub-criticality;

(iv) Control of radioactive releases; and

(v) Securing of structures, systems, or components to minimize radiation exposure to onsite personnel or to the offsite public or to facilitate later decontamination or both.

(2) The licensee must inform the Director, Office of Nuclear Reactor Regulation in writing when the plant is and can be maintained in a safe and stable condition so as to prevent any significant risk to the public health and safety. Within 30 days after the

licensee informs the Director that the plant is in this condition, or at such earlier time as the licensee may elect or the Director may for good cause direct, the licensee must prepare and submit a cleanup plan for the Director's approval. The cleanup plan must identify and contain an estimate of the cost of each cleanup operation that will be required to decontaminate the reactor sufficiently to permit the licensee either to resume operation of the reactor or to apply to the Commission under subpart G of this part for authority to decommission the reactor and to surrender the license voluntarily. Cleanup operations may include one or more of the following, as appropriate:

(i) Processing any contaminated materials generated by the accident and by decontamination operations to remove radioactive materials;

(ii) Decontamination of surfaces inside the plant buildings to levels consistent with the Commission's occupational exposure limits in 10 CFR part 20, and decontamination or disposal of equipment;

(iii) Decontamination or removal and disposal of internal parts, damaged fuel from the reactor coolant or fuel systems, or related process or waste systems; and

(iv) Cleanup of the reactor coolant or fuel systems or related process or waste systems.

(3) Following review of the licensee's cleanup plan, the Director will order the licensee to complete all operations that the Director finds are necessary to decontaminate the reactor sufficiently to permit the licensee either to resume operation of the reactor or to apply to the Commission under subpart G of this part for authority to decommission the reactor and to surrender the license voluntarily. The Director must approve~~s~~ or disapprove~~s~~, in whole or in part for stated reasons, the licensee's estimate of cleanup costs for such operations. Such order may not be effective for more than one

year, at which time it may be renewed. Each subsequent renewal order, if imposed, may be effective for not more than 6 months.

(4) Of the balance of the proceeds of the required insurance not already expended to place the plant in a safe and stable condition ~~pursuant to~~under paragraph (b)(1) of this section, an amount sufficient to cover the expenses of completion of those decontamination operations that are the subject of the Director's order must be dedicated to such use, provided that, upon certification to the Director of the amounts expended previously and from time to time for stabilization and decontamination and upon further certification to the Director as to the sufficiency of the dedicated amount remaining, policies of insurance may provide for payment to the licensee or other loss payees of amounts not so dedicated, and the licensee may proceed to use in parallel (and not in preference thereto) any insurance proceeds not so dedicated for other purposes.

~~**§ 53.1730 Financial protection requirements.**~~

~~Commercial nuclear plant licensees must satisfy the applicable provisions of Part 140, "Financial Protection Requirements and Indemnity Agreements," of this chapter.~~

Commented [A406]: Deleted as unnecessary. The requirements of part 140 are self-executing on applicants for and holders of licenses to operate nuclear reactors and would be extended to cover part 53 by this rulemaking. Part 140 compliance is an element of the necessary findings for a OL applicant under 53.1387 and is an area of review for COL applicants under 53.1422. Part 53 should require no further notice than parts 50 and 52 and there is no corresponding requirement to this in either.

~~**Subpart K — Quality Assurance Criteria for Commercial Nuclear Plants**~~

~~**§ 53.1800 General provisions.**~~

~~(a) Commercial nuclear plants and manufactured reactors include SSCs that prevent or mitigate the consequences of LBEs, including DBAs, as described in § 53.240, that could cause undue risk to the health and safety of the public. This subpart establishes QA requirements for the design, manufacture, construction, and operation of those SSCs classified as SR under Framework A of this part. The pertinent requirements of this subpart apply to all activities affecting the SR functions of those SSCs; these~~

activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

(b) As used in this subpart, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. QA includes quality control, which comprises those QA actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

§ 53.1805 Organization.

The applicant[9] must establish and execute the QAP. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the QAP, or any part thereof, but must retain responsibility for the QAP. The authority and duties of persons and organizations performing activities affecting the SR functions of SSCs must be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the QA functions. The QA functions are those of assuring that an appropriate QAP is established and effectively executed; and verifying, such as by checking, auditing, and inspecting, that activities affecting the SR functions have been correctly performed. The persons and organizations performing QA functions must have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. The persons and organizations performing QA functions must report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided. Because of the many

variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the QAP may take various forms, provided that the persons and organizations assigned the QA functions have the required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the QAP at any location where activities subject to this subpart are being performed, must have direct access to the levels of management necessary to perform this function.

[9] While the term "applicant" is used in these criteria, the requirements are applicable after such a person has received a license to construct and operate a commercial nuclear plant or manufacturing facility or has received an early site permit, design approval, design certification, or ML, as applicable. These criteria will also be used for guidance in evaluating the adequacy of QAPs in use by holders of CPs, OLs, early site permits, design approvals, COLs, and MLs.

§ 53.1810 Quality assurance program.

The applicant must establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a QAP which complies with the requirements of this Subpart. The program must be documented by written policies, procedures, or instructions and must be carried out throughout the plant life in accordance with those policies, procedures, or instructions. The applicant must identify the SSCs to be covered by the QAP and the major organizations participating in the program, together with the designated functions of these organizations. The QAP must provide control over activities affecting the quality of the identified SSCs. Activities affecting quality must be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied. The program must take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test. The program must provide for

indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. The applicant must regularly review the status and adequacy of the QAP. Management of other organizations participating in the QAP must regularly review the status and adequacy of that part of the QAP which they are executing.

§ 53.1815 Design control.

(a) Measures must be established to assure that applicable regulatory requirements and the functional design criteria, as specified in the license application, for those SSCs to which this subpart applies are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures must also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the SR functions of the SSCs.

(b) Measures must be established for the identification and control of design interfaces and for the coordination among participating design organizations. These measures must include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

(c) The design control measures must provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program.

(d) The verifying or checking process must be performed by individuals or groups other than those who performed the original design but who may be from the same

organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it must include suitable qualifications testing of a prototype unit under the most adverse design conditions. Design control measures must be applied to items such as the following: reactor physics, stress, thermal hydraulic, and accident analyses; compatibility of materials; accessibility for ISI, maintenance, and repair; and delineation of acceptance criteria for inspections and tests.

(e) Design changes, including field changes, must be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.

§ 53.1820 Procurement document control.

Measures must be established to assure that applicable regulatory requirements, functional design criteria, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents must require contractors or subcontractors to provide a QAP consistent with the pertinent provisions of this subpart.

§ 53.1825 Instructions, procedures, and drawings.

Activities affecting quality must be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and must be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily

~~accomplished.~~

~~§ 53.1830 Document control.~~

~~Measures must be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents must be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.~~

~~§ 53.1835 Control of purchased material, equipment, and services.~~

~~Measures must be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements must be available at the commercial nuclear plant site or manufacturing facility prior to installation or use of such material and equipment. This documentary evidence must be retained at the commercial nuclear plant site or manufacturing facility and must be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment. The effectiveness of the control of quality by contractors and subcontractors must be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.~~

§ 53.1840 Identification and control of materials, parts, and components.

Measures must be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures must assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective material, parts, and components.

§ 53.1845 Control of special processes.

Measures must be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

§ 53.1850 Inspection.

A program for inspection of activities affecting quality must be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Such inspection must be performed by individuals other than those who performed the activity being inspected. Examinations, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the applicant's designated representative and beyond which work must not

proceed without the consent of its designated representative are required, the specific hold points must be indicated in appropriate documents.

§ 53.1855 Test control.

A test program must be established to assure that all testing required to demonstrate that SSCs will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. The test program must include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during commercial nuclear plant and manufacturing facility operation, of SSCs. Test procedures must include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results must be documented and evaluated to assure that test requirements have been satisfied.

§ 53.1860 Control of measuring and test equipment.

Measures must be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specific periods to maintain accuracy within necessary limits.

§ 53.1865 Handling, storage, and shipping.

Measures must be established to control the handling, storage, shipping, cleaning, and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, must be specified and provided.

§ 53.1870 Inspection, test, and operating status.

~~Measures must be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the commercial nuclear plant. These measures must provide for the identification of items which have satisfactorily passed required inspections and tests where necessary to preclude inadvertent bypassing of such inspections and tests. Measures must also be established for indicating the operating status of SSCs of the commercial nuclear plant, such as by tagging valves and switches, to prevent inadvertent operation.~~

~~§ 53.1875 Nonconforming materials, parts, or components.~~

~~Measures must be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.~~

~~§ 53.1880 Corrective action.~~

~~Measures must be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material, and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures must assure that the cause of the condition is determined and corrective action is taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.~~

~~§ 53.1885 Quality assurance records.~~

~~Sufficient records must be maintained to furnish evidence of activities affecting~~

~~quality. The records must include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records must also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records must, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records must be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant must establish requirements concerning record retention, such as duration, location, and assigned responsibility.~~

~~§ 53.1890 Audits.~~

~~A comprehensive system of planned and periodic audits must be carried out to verify compliance with all aspects of the QAP and to determine the effectiveness of the program. The audits must be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including reaudit of deficient areas, must be taken where indicated.~~

Subparts K through W~~L and M~~ [Reserved]

~~Subpart N — Siting Requirements~~

~~§ 53.3505 Scope.~~

~~The siting requirements in this subpart apply to applications for an early site permit, CP, OL, or COL under Framework B of this part.~~

~~§ 53.3510 Definitions.~~

~~For the purposes of this subpart—~~

Ground Motion Response Spectra means the free-field GMRS resulting from the geologic investigations and evaluations of the site vicinity and region.

Probabilistic Seismic Hazard Analysis means an analytical methodology that incorporates uncertainty into estimates of an annual frequency of exceedance for certain ground motion parameters (e.g., peak ground acceleration, peak ground velocity, response spectral values) at a site.

Response spectrum means a plot of the maximum responses (acceleration, velocity, or displacement) of idealized single-degree-of-freedom oscillators as a function of the natural frequencies of the oscillators for a given damping value. The response spectrum is calculated for a specified vibratory motion input at the oscillators' supports.

Safe Shutdown Earthquake Ground Motion means, for applicants and licensees that do not use the seismic design criteria in § 53.4733, the vibratory ground motion for which certain SSCs must be designed pursuant to appendix S to 10 CFR part 50 to remain functional.

Surface deformation means distortion of geologic strata at or near the ground surface by the processes of folding or faulting as a result of various earth forces. Tectonic surface deformation is associated with earthquake processes.

§ 53.3515 Factors to be considered when evaluating sites.

(a) Population density and use characteristics of the site environs, including the exclusion area, population distribution, and site-related characteristics must be evaluated to determine whether individual as well as societal risk of potential plant accidents is low, and that physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans are identified.

(b) The nature and proximity of constructed hazards (e.g., airports, dams, transportation routes, military and chemical facilities) must be evaluated to establish site

characteristics for use in determining whether a plant design can accommodate commonly occurring hazards, and whether the risk of other hazards is very low.

(c) The Commission will take the following factors into consideration in determining the acceptability of a site for a commercial nuclear plant:

(1) Physical characteristics of the site, including seismology, meteorology, geology, and hydrology.

(2) Geologic and seismic siting criteria set forth in § 53.3525 to obtain the geologic and seismic data necessary to determine the suitability of the proposed site and the plant design bases.

(3) Meteorological characteristics of the site that are necessary for safety analysis or that may have an impact upon plant design (such as maximum probable wind speed and precipitation) must be identified and characterized.

(4) Factors important to hydrological radionuclide transport (such as soil, sediment, and rock characteristics, adsorption and retention coefficients, groundwater velocity, and distances to the nearest surface body of water) must be obtained from on-site measurements. The maximum probable flood along with the potential for seismically induced floods discussed in § 53.3525(c)(3) must be estimated using historical data.

§ 53.3520 Non-seismic siting criteria.

Applications for site approval for commercial nuclear plants must demonstrate that the proposed site demonstrates compliance with the following criteria:

(a) Every site must have an exclusion area and a low population zone, as defined in § 53.020.

(b) The population center distance, as defined in § 53.020, must be at least one and one-third times the distance from the reactor to the outer boundary of the low population zone. In applying this guide, the boundary of the population center must be

determined upon consideration of population distribution. Political boundaries are not controlling in the application of this guide.

(c) Site atmospheric dispersion characteristics must be evaluated and dispersion parameters established such that—

(1) Radiological effluent release limits associated with normal operation from the type of facility proposed to be located at the site can be met for any individual located offsite, and

(2) Radiological dose consequences of postulated accidents demonstrate compliance with the criteria set forth in § 53.4730(a)(1)(vi) for the type of facility proposed to be located at the site.

(d) The physical characteristics of the site, including meteorology, geology, seismology, and hydrology must be evaluated and site characteristics established such that potential threats from such physical characteristics will pose no undue risk to the type of facility proposed to be located at the site.

(e) Potential hazards associated with nearby transportation routes and industrial and military facilities must be evaluated, and site characteristics established such that potential hazards from such routes and facilities will pose no undue risk to the type of facility proposed to be located at the site.

(f) Site characteristics must be such that adequate security plans and measures can be developed.

(g) Physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans must be identified.

(h) Reactor sites should be located away from very densely populated centers. Areas of low population density are, generally, preferred. However, in determining the acceptability of a particular site located away from a very densely populated center but

not in an area of low density, consideration will be given to safety, environmental, economic, or other factors, which may result in the site being found acceptable.[10]

[10] Examples of these factors include, but are not limited to, such factors as the higher population density site having superior seismic characteristics, better access to skilled labor for construction, better rail and highway access, shorter transmission line requirements, or less environmental impact on undeveloped areas, wetlands, or endangered species, etc. Some of these factors are included in, or impact, the other criteria included in this section.

§ 53.3525 Geologic and seismic siting criteria.

This section sets forth the principal geologic and seismic considerations that guide the Commission in its evaluation of the suitability of a proposed site and adequacy of the design bases established in consideration of the geologic and seismic characteristics of the proposed site, such that, there is a reasonable assurance that a commercial nuclear plant can be constructed and operated at the proposed site without undue risk to the health and safety of the public. Related engineering design requirements are included in either appendix S to 10 CFR part 50 or § 53.4733.

(a) *Commencement of construction*. The investigations required in paragraph (b) of this section are not considered "construction" as defined in § 53.020.

(b) *Geological, seismological, and engineering characteristics*. The geological, seismological, and engineering characteristics of the site and its environs must be investigated in sufficient scope and detail to permit an adequate evaluation of the proposed site, to provide sufficient information to support evaluations performed to arrive at estimates of the GMRS, and to permit adequate engineering solutions to actual or potential geologic and seismic effects at the proposed site. The size of the region to be investigated and the type of data pertinent to the investigations must be determined based on the nature of the region that surrounds the proposed site. Data on the vibratory ground motion, tectonic surface deformation, nontectonic deformation, earthquake recurrence rates, fault geometry and slip rates, site subsurface material properties, and seismically induced floods and water waves must be obtained by reviewing pertinent

literature and carrying out field investigations. However, each applicant must investigate all geologic and seismic factors (for example, volcanic activity) that may affect the design and operation of the proposed commercial nuclear plant irrespective of whether such factors are explicitly included in this section.

(c) *Geologic and seismic siting factors.* The geologic and seismic siting factors considered for design must include a determination of the GMRS for the site, the potential for surface tectonic and nontectonic deformations, the design bases for seismically induced floods and water waves, and other design conditions as stated in paragraph (c)(4) of this section.

(1) *Determination of the Ground Motion Response Spectra.* The GMRS for the site include both horizontal and vertical components that are established in the free-field and at the free ground surface. The GMRS are used to derive the Safe Shutdown Earthquake Ground Motion for use in demonstrating compliance with appendix S to 10 CFR part 50 or the DBGMs for use in demonstrating compliance with § 53.4733. The GMRS for the site are determined considering the results of the investigations required by paragraph (c) of this section. Uncertainties are inherent in such estimates and must be addressed through an appropriate analysis, such as a probabilistic seismic hazard analysis (PSHA). For applicants and licensees that do not use the seismic design alternatives in § 53.4733, paragraph IV(a)(1) of appendix S to 10 CFR part 50 identifies the minimum Safe Shutdown Earthquake Ground Motion for design.

(2) *Determination of the potential for surface tectonic and nontectonic deformations.* Sufficient geological, seismological, and geophysical data must be provided to clearly establish whether there is a potential for surface deformation.

(3) *Determination of design bases for seismically induced floods and water waves.* The size of seismically induced floods and water waves that could affect a site from either locally or distantly generated seismic activity must be determined.

(4) *Determination of siting factors for other design conditions.* Siting factors for other design conditions that must be evaluated include soil and rock stability, liquefaction potential, natural and artificial slope stability, cooling water supply, and remote-SR structure siting. Each applicant must evaluate all siting factors and potential causes of failure, such as the physical properties of the materials underlying the site, ground disruption, and vibratory ground motion that may affect the design and operation of the proposed commercial nuclear plant.

Subpart O — Construction and Manufacturing Requirements

§ 53.4100 Construction and manufacturing - scope and purpose.

This subpart applies to those construction and manufacturing activities authorized by a CP, COL, ML, or LWA issued under Framework B of this part.

§ 53.4105 Reporting of defects and noncompliance.

Each CP and ML issued under Framework B of this part is subject to the terms and conditions in this section, and each COL issued under Framework B of this part is subject to the terms and conditions in this section until the date that the Commission makes the finding under § 53.5052(g).

(a) *Definitions.* The definitions in § 21.3 of this chapter apply to this section.

(b) *Posting requirements.*

(1) Each individual, partnership, corporation, dedicating entity, or other entity subject to the regulations in this part must post current copies of this section and the regulations in part 21 of this chapter; Section 206 of the ERA; and procedures adopted under the regulations. These documents must be posted in a conspicuous position on

any premises within the United States where the activities subject to the license are conducted.

(2) If posting of these regulations or the procedures adopted under them is not practical, the licensee may, in addition to posting Section 206 of the ERA, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

(c) *Procedures*. The holder of a CP, COL, or ML subject to this section must adopt appropriate procedures to –

(1) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (c)(2) of this section, in all cases within 60 days of discovery, to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected.

(2) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from the discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer, or designated person as discussed in paragraph (d)(5) of this section. The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.

(3) Ensure that a director or responsible officer of the holder of a CP, COL, or ML subject to this section is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in paragraph (c)(1) or (c)(2) of

this section, if the construction or manufacture of a facility or activity, or a basic component supplied for such a facility or activity –

(i) Fails to comply with the ActEA or any applicable regulation, order, or license of the Commission relating to a substantial safety hazard;

(ii) Contains a defect; or

(iii) Underwent any significant breakdown in any portion of the QAP conducted under the requirements of subpart U to this part which could have produced a defect in a basic component. These breakdowns in the QAP are reportable whether or not the breakdown actually resulted in a defect in a design approved and released for construction, installation, or manufacture.

(d)(1) The holder of a CP, COL, or ML subject to this section that obtains information reasonably indicating that the facility or manufactured reactors fail to comply with the ActEA or any applicable regulation, order, or license of the Commission relating to a substantial safety hazard must notify the Commission of the failure to comply through a director, responsible officer, or designated person as discussed in paragraph (d)(5) of this section.

(2) The holder of a CP, COL, or ML subject to this section that obtains information reasonably indicating the existence of any defect found in the construction or manufacture, or any defect found in the final design of a facility as approved and released for construction or manufacture, must notify the Commission of the defect through a director, responsible officer, or designated person as discussed in paragraph (d)(5) of this section.

(3) The holder of a CP, COL, or ML subject to this part, who obtains information reasonably indicating that the QAP has undergone any significant breakdown discussed in paragraph (c)(3)(iii) of this section must notify the Commission of the breakdown in the

QAP through a director, responsible officer, or designated person as discussed in paragraph (d)(5) of this section.

(4) When acting as a dedicating entity, the holder of CP, COL, or ML subject to this section is responsible for identifying and evaluating deviations; reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and maintaining auditable records for the dedication process.

(5) The notification requirements of this paragraph apply to all defects and failures to comply associated with a substantial safety hazard regardless of whether extensive evaluation, redesign, or repair is required to conform to the criteria and bases stated in the Safety Analysis Report, CP, COL, or ML. Evaluation of potential defects and failures to comply and reporting of defects and failures to comply under this section satisfies the CP holder's, COL holder's, and ML holder's evaluation and notification obligations under 10 CFR part 21, and satisfies the responsibility of individual directors or responsible officers or holders of CP, COL, or ML subject to this section to report defects, and failures to comply associated with substantial safety hazards under section 206 of the ERA. The director or responsible officer may authorize an individual to provide the notification required by this section. However, this does not relieve the director or responsible officer of his or her responsibility under this section.

(e) *Notification – timing and where sent*. The notification required by paragraph (d) of this section must consist of –

(1) Initial notification by telephone, facsimile, or e-mail identified in appendix A to part 73 of this chapter to the NRC Operations Center within 2 days following receipt of information by the director or responsible corporate officer under paragraph (c)(3) of this section, on the identification of a defect or a failure to comply. If the CP, COL, or ML holder elects to use facsimile, verification that the facsimile has been received should be

made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in paragraph (c)(2) of this section.

(2) Written notification submitted to the NRC Document Control Desk by an appropriate method listed in § 53.040, with a copy to the appropriate NRC Regional Administrator at the address specified in appendix D to 10 CFR part 20 and a copy to the appropriate NRC resident inspector, if applicable, within 30 days following receipt of information by the director or responsible corporate officer under paragraph (c)(3) of this section, on the identification of a defect or failure to comply.

(f) *Content of notification*. The written notification required by paragraph (e)(2) of this section must clearly indicate that the written notification is being submitted under this section and include the following information, to the extent known:

(1) Name and address of the individual or individuals informing the Commission.

(2) Identification of the facility, the activity, or the basic component supplied for the facility or the activity within the United States which contains a defect or fails to comply.

(3) Identification of the firm constructing or manufacturing the facility or supplying the basic component which fails to comply or contains a defect.

(4) Nature of the defect or failure to comply and the safety hazard which is created or could be created by the defect or failure to comply.

(5) The date on which the information of a defect or failure to comply was obtained.

(6) In the case of a basic component which contains a defect or failure to comply, the number and location of these components in use at the facility subject to the regulations in this part.

(7) In the case of a completed reactor manufactured under Framework B of this part, the entities to which the reactor was supplied.

(8) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(9) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to other entities.

(g) *Procurement documents.* Each holder of a CP, COL, or ML subject to this section must ensure that each procurement document for a facility or a basic component specifies the provisions of 10 CFR part 21 or this section that apply, as applicable.

(h) *Coordination with 10 CFR part 21.* The requirements of this section are satisfied when the defect or failure to comply associated with a substantial safety hazard has been previously reported under 10 CFR part 21, under § 73.71 of this chapter, under this section, or under § 53.6340.

(i) *Records retention.* The holder of a CP, COL, or ML subject to this section must prepare and maintain records necessary to accomplish the purposes of this section, specifically –

(1) Retain procurement documents, which establish the requirements that facilities or basic components must satisfy in order to be considered acceptable, for the lifetime of the facility or basic component.

(2) Retain records of evaluations of all deviations and failures to comply under paragraph (c)(1) of this section for the longest of –

(i) Ten (10) years from the date of the evaluation;

(ii) Five (5) years from the date that an early site permit is referenced in an application for a COL; or

~~(iii) Five (5) years from the date of delivery of a manufactured reactor.~~

~~(3) Retain records of all interim reports to the Commission made under paragraph (c)(2) of this section, or notifications to the Commission made under paragraph (d) of this section for the minimum time periods stated in paragraph (i)(2) of this section;~~

~~(4) Suppliers of basic components must retain records of—~~

~~(i) All notifications sent to affected licensees or purchasers under paragraph (d)(4) of this section for a minimum of ten (10) years following the date of the notification;~~

~~(ii) The facilities or other purchasers to whom the basic components or associated services were supplied for a minimum of fifteen (15) years from the delivery of the basic component or associated services.~~

~~(5) Maintaining reports in accordance with this section satisfies the recordkeeping obligations under 10 CFR part 21 of the entities, including directors or responsible officers thereof, subject to this section.~~

~~§ 53.4110 Construction.~~

~~(a) *Management and control.* Licensees must ensure that the following plans, programs, and organizational units are developed and implemented to manage and control the construction activities:~~

~~(1) Programs to ensure that the construction of a commercial nuclear plant supports the eventual compliance with the plant's design basis, as documented in the plant's Safety Analysis Report.~~

~~(2) An organization, headed by qualified personnel, responsible for managing, controlling, and evaluating the adequacy of the construction activities.~~

(3) Procedures describing the qualifications for personnel in key positions in the licensee's management and control organization and the organizational responsibilities, authority, and interfaces with other parts of the licensee's organization.

(4) Procedures to evaluate the applicability of other national and international construction experience to the planned and ongoing construction activities and to ensure the applicable experience will be provided to those constructing the plant.

(5) An FFD program, under 10 CFR part 26.

(6) A QAP demonstrating compliance with the requirements of subpart U to be applied to the design, fabrication, construction, and testing of the SSCs.

(7) A radiation protection program, in accordance with 10 CFR part 20, that includes measures for monitoring the dose to individuals working with radioactive materials brought onto the site, as applicable.

(8) An information security program in accordance with §§ 73.21, 73.22, and 73.23 of this chapter, as applicable.

(b) *Construction activities.* No person may begin the construction of a commercial nuclear plant on a site on which the facility is to be operated under Framework B of this part until that person has been issued either a CP or COL, an early site permit authorizing activities under § 53.4740, or an LWA under Framework B of this part.

(1) Licensees must demonstrate compliance with the following requirements:

(i) As appropriate, considering the types and quantities of radioactive materials being brought onto the site—

(A) The licensee must maintain and follow an SNM MC&A program, a measurement control program, and other material control procedures that include corresponding record management requirements as required by the provisions of

§ 70.32 of this chapter. Prior to initial receipt of SNM onsite, the licensee must implement a SNM MC&A Program in accordance with 10 CFR part 74.

(B) Procedures must be in place to receive, possess, use, and store source, byproduct, and SNM in accordance with applicable portions of 10 CFR parts 30, 40, and 70.

(C) A plant staff training program associated with the receipt of radioactive material must be approved and implemented prior to initial receipt of byproduct, source, or SNM (excluding exempt quantities as described in § 30.18 of this chapter).

(ii) For construction of a commercial nuclear plant involving multiple reactor units, licensees must identify and manage potential hazards to the SSCs important to safety of operating nuclear facilities from construction activities, including controls that will be used during construction to assure the safety of the operating unit.

(iii) Procedures must be in place prior to the start of construction activities that describe how construction will be controlled so as not to impact other features important to the design, such as dewatering, slope stability, backfill, compaction, and seepage.

(iv) For LWA holders, a plan must be developed for redress of activities performed under the LWA should one of the following situations arise:

(A) LWA work activities are terminated by the holder of the LWA;

(B) The LWA is revoked by the NRC; or

(C) The Commission denies the associated CP or COL application.

(2) Onsite fresh fuel.

(i) Onsite fresh fuel must be protected and stored in compliance with § 73.67 of this chapter.

(ii) Before initial fuel load into the reactor, a cyber_security program that meets the requirements of § 73.54 or § 73.110 of this chapter, a physical security program that

meets the requirements of § 73.55 or § 73.100 of this chapter, and an access authorization program that meets the requirements of § 73.56 or § 73.120 of this chapter must be established, as applicable.

(iii) holders of an OL or a COL after the Commission makes the finding under § 53.5052(g) must implement fire protection measures for work and storage areas (including adjacent fire areas that could affect the work or storage area) before initial receipt of byproduct, source, or non-fuel SNM (excluding exempt quantities as described in § 30.18 of this chapter). The fire protection measures for areas associated with new fuel (including all fuel handling, fuel storage, and adjacent fire areas that could affect the new fuel) must be implemented before receipt of fuel. Prior to the receipt of fuel, a formal letter of agreement must be in place with the local fire department specifying the nature of arrangements in support of the fire protection program.

(c) *Inspection and acceptance*.

(1) The licensee must have a process for accepting individual or groups of SSCs upon completion of construction and protecting them from damage or tampering as other construction activities continue.

(2) The post construction acceptance process must address the ITAAC specified in the COL under § 53.5040 or the equivalent verifications needed to support the issuance of an OL under § 53.4987.

§ 53.4120 Manufacturing.

(a) *Management and control.* Holders of MLs must ensure that the following plans, programs, and organizational units are developed and implemented to manage and control the manufacturing activities within the scope of the ML:

(1) Programs to ensure that the manufacturing of a manufactured reactor or portions of a manufactured reactor complies with the design and analysis requirements

of subpart R of this part. The entity with design authority for the manufactured reactor covered by the ML must be identified in the license.

(2) An organizational and management structure responsible for managing, controlling, and evaluating the adequacy of the reactor design and manufacturing activities.

(3) Procedures describing the qualifications for personnel in key positions in the licensee's management and control organization and the organizational responsibilities, authority, and interfaces with other parts of the licensee's organization.

(4) A program to evaluate the applicability of other national and international design and manufacturing experience to the planned and ongoing manufacturing activities.

(5) An FFD program, in accordance with 10 CFR part 26.

(6) A QAP demonstrating compliance with the requirements of subpart U of this part, to be applied to the design, fabrication, construction, and testing of the SSCs of the manufactured reactor.

(7) A radiation protection program, in accordance with 10 CFR part 20, that includes measures for monitoring the dose to individuals if the manufacturing activities include working with radioactive materials.

(8) An information security program in accordance with § 73.21, 73.22 and 73.23 of this chapter, as applicable.

(b) *Manufacturing activities.* Holders of MLs must demonstrate compliance with the following requirements:

(1) The manufacturing process must be conducted within facilities for which the ML holder has the authority to establish controls on any activity that might affect

manufacturing. The licensee must establish access controls to the portions of each facility involved in the manufacturing processes governed by the ML.

(2) Manufacturing processes must be performed in accordance with the ML and the referenced codes and standards that have been endorsed or otherwise found acceptable by the NRC.

(3) A post-manufacturing inspection and acceptance process must be established and implemented before transporting a manufactured reactor or portions of a manufactured reactor for installation at a commercial nuclear plant. The process must consider the results of inspections, tests, and analyses that have been performed and the acceptance criteria that are necessary and sufficient to conclude that manufacturing activities have been completed in accordance with the ML.

(c) *Control of radioactive materials.* As appropriate considering the types and quantities of radioactive materials being brought into the manufacturing facility—

(1) Procedures must be in place to receive, transfer, possess, and use source, byproduct, and SNM in accordance with the applicable portions of 10 CFR parts 30, 40 and 70.

(2) A fire protection program must be established and implemented before the initial receipt of byproduct, source, or non-fuel SNM (excluding exempt quantities as described in § 30.18 of this chapter).

(3) An emergency plan appropriate for responding to the facility-specific hazards of an accidental release of radioactive material and to limit the health effects of the associated chemical hazards of licensed material must be approved and implemented prior to the receipt of byproduct, source, or SNM (excluding exempt quantities as described in § 30.18 of this chapter).

(4) A plant staff training program associated with the receipt of radioactive material must be approved and implemented before initial receipt of byproduct, source, or SNM (excluding exempt quantities as described in § 30.18 of this chapter).

(d) [Reserved]

(e) *Transportation*.

(1) A holder of an ML may not transport or allow to be removed from the places of manufacture the manufactured reactor or major portions thereof as identified in the ML except to the site of a licensee with a COL. The COL must authorize the construction of a commercial nuclear plant using the manufactured reactor(s).

(2) A holder of an ML must include, in any contract governing the transport of a manufactured reactor or major portions thereof as identified in the ML from the places of manufacture to any other location, a provision requiring that the person or entity transporting the manufactured reactor to comply with all NRC-approved shipping requirements in the ML.

(3) Procedures governing the preparation of the manufactured reactor or major portions thereof as identified in the ML for transport and the conduct of the transport must be documented and approved prior to transport. The procedures must implement the protective measures and restrictions described in the ML to protect the reactor from potential conditions that would adversely affect the safe operation of a commercial nuclear plant.

(f) *Acceptance and installation at the site*.

(1) Installation at the site must follow the regulations in § 53.4110.

(2) Upon arrival at the site, the manufactured reactor or portions of a manufactured reactor may not be installed in its final place of use unless the COL holder performs inspections, using approved procedures, and verifies it is in acceptable

condition in compliance with the ML. These inspections must confirm that all necessary interface requirements between the manufactured reactor or portions of a manufactured reactor and the remaining portions of the commercial nuclear plant are met.

Subpart P — Requirements for Operation

§ 53.4200 Operational objectives.

Each holder of an OL or COL under Framework B of this part must develop, implement, and maintain controls for plant SSCs, responsibilities of plant personnel, and plant programs during the operating life of each commercial nuclear plant. Each such licensee must maintain the capabilities, availability, and reliability of plant SSCs to ensure that these SSCs can perform their specified safety functions if called upon during design-basis events. Each such licensee must ensure that plant personnel have adequate knowledge and skills to perform their assigned duties. Each such licensee must implement plant programs during operations to ensure that plant safety is maintained during normal operations and design-basis events.

§ 53.4210 Maintenance, repair, and inspection programs.

The requirements of this section are applicable during all conditions of plant operation, including normal shutdown operations.

(a)(1) Each holder of an OL under Framework B of this part or a COL under Framework B of this part after the Commission makes the finding under § 53.5052(g) must monitor the performance or condition of SSCs against licensee-established goals, in a manner sufficient to provide reasonable assurance that these SSCs, as defined in paragraph (b) of this section, are capable of fulfilling their intended functions. These goals must be established commensurate with safety and, where practical, take into account industry-wide operating experience. When the performance or condition of an SSC does not satisfy licensee-established goals, appropriate corrective action must be

taken. For a commercial nuclear reactor for which the licensee has submitted the certifications specified in § 53.4670, this section will only apply to the extent that the licensee must monitor the performance or condition of all SSCs associated with the storage, control, and maintenance of spent fuel in a safe condition, in a manner sufficient to provide reasonable assurance that these SSCs are capable of fulfilling their intended functions.

(2) Monitoring as specified in paragraph (a)(1) of this section is not required for an SSC when the licensee has documented a demonstration that its performance or condition is being effectively controlled through the performance of appropriate preventive maintenance, such that the SSC remains capable of performing its intended function.

(3) Performance and condition monitoring activities and associated goals and preventive maintenance activities must be evaluated at appropriate times in the plant's operating cycle such that the interval between evaluations does not exceed 24 months. The evaluations must take into account, where practical, industry-wide operating experience. Adjustments must be made where necessary to ensure that the objective of preventing failures of SSCs through maintenance is appropriately balanced against the objective of minimizing unavailability of SSCs due to monitoring or preventive maintenance.

(4) Before performing maintenance activities (including but not limited to surveillance, post-maintenance testing, and corrective and preventive maintenance), the licensee must assess and manage the increase in risk that may result from the proposed maintenance activities. The scope of the assessment may be limited to SSCs that a risk-informed evaluation process has shown to be significant to public health and safety.

(b) The scope of the monitoring program specified in paragraph (a)(1) of this section must include—

(1) SR SSCs; and

(2) NSR SSCs—

(i) That are relied upon to mitigate accidents or transients or are used in plant emergency operating procedures;

(ii) Whose failure could prevent SR SSCs from fulfilling their SR function; or

(iii) Whose failure could cause a reactor scram or actuation of an SR system.

§ 53.4213 Technical specifications.

(a) Each OL or COL under Framework B of this part must include technical specifications in accordance with the requirements of this section. The technical specifications must be derived from the analyses and evaluation included in the Safety Analysis Report, and amendments thereto, submitted pursuant to § 53.4730(a)(23). The Commission may include such additional technical specifications as the Commission finds appropriate.

(b) Technical specifications must include items in the following categories:

(1) *Safety limits, limiting safety system settings, and limiting control settings.*

(i) Safety limits for commercial nuclear reactors are limits upon important process variables that are found to be necessary to reasonably protect the integrity of certain physical barriers that guard against the uncontrolled release of radioactivity. If any safety limit is exceeded, the reactor must be shut down. The licensee must notify the Commission, review the matter, and record the results of the review, including the cause of the condition and the basis for corrective action taken to preclude recurrence. Operation must not be resumed until authorized by the Commission. The licensee must notify the Commission as required by § 53.6330 and submit an LER to the Commission

as required by § 53.6340. Licensees must retain the record of the results of each review until the Commission terminates the license for the reactor.

(ii) Limiting safety system settings for nuclear reactors are settings for automatic protective devices related to those variables having significant safety functions. Where a limiting safety system setting is specified for a variable on which a safety limit has been placed, the setting must be so chosen that automatic protective action will correct the abnormal situation before a safety limit is exceeded. If, during operation, it is determined that the automatic safety system does not function as required, the licensee must take appropriate action, which may include shutting down the reactor. The licensee must notify the Commission, review the matter, and record the results of the review, including the cause of the condition and the basis for corrective action taken to preclude recurrence. The licensee must notify the Commission as required by § 53.6330 and submit an LER to the Commission as required by § 53.6340. Licensees must retain the records of the review for a period of 3 years following issuance of an LER.

(2) *Limiting conditions for operation*.

(i) Limiting conditions for operation are the lowest functional capability or performance levels of equipment required for safe operation of the facility. When a limiting condition for operation of a commercial nuclear reactor is not met, the licensee must shut down the reactor or follow any remedial action permitted by the technical specifications until the condition can be met. The licensee must notify the Commission if required by § 53.6330 and must submit an LER to the Commission as required by § 53.6340. Licensees must retain records associated with preparation of an LER for a period of 3 years following issuance of the report. For events which do not require an LER, the licensee must retain each record as required by the technical specifications.

(ii) A technical specification limiting condition for operation of a nuclear reactor must be established for each item satisfying one or more of the following criteria:

(A) *Criterion 1.* Installed instrumentation that is used to detect, and indicate in the control room, significant abnormal degradation of either a fission product barrier identified as part of § 53.4730(a)(36), or for water-cooled commercial nuclear reactors, the reactor coolant pressure boundary.

(B) *Criterion 2.* A process variable, design feature, or operating restriction that is an initial condition of a DBA or transient analysis that either assumes the failure of or presents a challenge to the integrity of a fission product barrier.

(C) *Criterion 3.* A structure, system, or component that is part of the primary success path and which functions or actuates to mitigate a DBA or transient that either assumes the failure of, presents a challenge to, or acts as a precursor to identifying an issue that would affect the integrity of a fission product barrier.

(D) *Criterion 4.* A structure, system, or component which operating experience or a risk evaluation has shown to be significant to public health and safety.

(3) *Surveillance requirements.* Surveillance requirements are requirements relating to test, calibration, or inspection to assure that the necessary quality of systems and components is maintained, that facility operation will be within safety limits, and that the limiting conditions for operation will be met.

(4) *Design features.* Design features to be included are those features of the facility such as materials of construction and geometric arrangements, which, if altered or modified, would have a significant effect on safety and are not covered in categories described in paragraphs (b)(1), (2), and (3) of this section.

(5) *Administrative controls.* Administrative controls are the provisions relating to organization and management, procedures, recordkeeping, review and audit, and

reporting necessary to assure operation of the facility in a safe manner. Administrative controls for commercial nuclear plants subject to §§ 53.800 through 53.820 must address the requirements of § 53.805. Each licensee must submit any reports to the Commission pursuant to approved technical specifications as specified in § 53.040.

(6) *Decommissioning*. This paragraph applies only to commercial nuclear reactors that have submitted the certifications required by § 53.4670. Technical specifications involving safety limits, limiting safety system settings, and limiting control system settings; limiting conditions for operation; surveillance requirements; design features; and administrative controls must be developed on a case-by-case basis.

(7) *Initial notification*. Reports made to the Commission by licensees in response to the requirements of this section must be made as follows:

(i) Licensees that have an installed Emergency Notification System must make the initial notification to the NRC Operations Center in accordance with § 53.6330.

(ii) All other licensees must make the initial notification by telephone to the Administrator of the appropriate NRC Regional Office listed in appendix D to 10 CFR part 20.

(8) *Written Reports*. Holders of an OL or COL under Framework B of this part must submit written reports to the Commission in accordance with § 53.6340 for events described in paragraphs (b)(1) and(b)(2) of this section. For all licensees, the Commission may require Special Reports as appropriate.

(c) At the initiative of the Commission or the licensee, any license may be amended to include technical specifications of the scope and content which would be required if a new license were being issued.

(d) The provisions of this section apply to each OL or COL under Framework B of this part for which the authority to operate the reactor has been removed by license amendment, order, or regulation.

§ 53.4215 Response to seismic events.

If vibratory ground motion exceeding that of the OBE Ground Motion or significant plant damage due to vibratory ground motion occurs, the licensee must shut down the commercial nuclear plant. If SSCs necessary for the safe shutdown of the commercial nuclear plant are not available after the occurrence of this vibratory ground motion, the licensee must consult with the Commission and must propose a plan for the timely, safe shutdown of the commercial nuclear plant. Prior to resuming operations, the licensee must demonstrate to the Commission that those features necessary for continued operation without undue risk to the health and safety of the public or necessary to maintain the licensing basis of the commercial nuclear plant were either not functionally damaged or have been repaired.

§ 53.4220 General staffing, training, personnel qualifications, and human factors engineering requirements.

The rules in §§ 53.725 through 53.830 apply under Framework B of this part.

§ 53.4300 Programs.

(a) The required plant programs under Framework B must include but are not necessarily limited to the programs described in the following sections of this subpart. Licensees may combine, separate, and otherwise organize programs and related documents as appropriate for the technologies and organizations associated with the commercial nuclear plant.

(b) In addition to the programs described in the following sections, programs must be provided for each commercial nuclear plant, if necessary, such that, when

~~combined with associated design features and human actions, plant safety will be maintained during normal operations and design basis events.~~

~~§ 53.4310 Radiation protection.~~

~~(a) Each holder of an OL or COL under Framework B of this part must develop, implement, and maintain a Radiation Protection Program for operations that is commensurate with the scope and extent of licensed activities under Framework B of this part and includes measures for limiting and monitoring radioactive plant effluents and limiting and monitoring the dose to individuals working with radioactive materials in accordance with 10 CFR part 20.~~

~~(b) Each holder of an OL or COL under Framework B of this part must develop, implement, and maintain a program for the control of radioactive effluents and for keeping the doses to members of the public from radioactive effluents as low as is reasonably achievable. The program must be contained in an ODCM, must be implemented by procedures, and must include remedial actions to be taken whenever the program limits are exceeded. The ODCM must —~~

~~(1) Contain the methodology and parameters used in the calculation of offsite doses resulting from radioactive gaseous and liquid effluents, in the calculation of gaseous and liquid effluent monitoring alarm and trip setpoints, and in the conduct of the radiological environmental monitoring program; and~~

~~(2) Contain the radioactive effluent controls and radiological environmental monitoring activities, and descriptions of the information that should be included in the Annual Radiological Environmental Operating, and Radioactive Effluent Release Reports required by § 53.6345.~~

~~(c) Each holder of an OL or COL under Framework B of this part must develop, implement, and maintain a Process Control Program that identifies the administrative~~

and operational controls for solid radioactive waste processing, process parameters, and surveillance requirements sufficient to ensure compliance with the requirements of 10 CFR part 20, 10 CFR part 61, and 10 CFR part 71.

§ 53.4320 Emergency preparedness.

Each holder of an OL or COL under Framework B of this part must comply with the requirements of § 53.855.

§ 53.4330 Security programs.

(a) *Physical Protection Program.* Each holder of an OL or COL under Framework B of this part must develop, implement, and maintain a physical protection program demonstrating compliance with the following requirements:

(1) The licensee must implement security requirements for the protection of SNM based on the type, enrichment, and quantity in accordance with 10 CFR part 73, as applicable, and implement security requirements for the protection of Category 1 and Category 2 quantities of radioactive material in accordance with 10 CFR part 37, as applicable; and

(2) The licensee must demonstrate compliance with the provisions set forth in either § 73.55 or § 73.100 of this chapter, unless the licensee meets the following criterion:

(i) The radiological consequences from a design-basis threat initiated event involving the loss of engineered systems for decay heat removal and possible breaches in physical structures surrounding the reactor, spent fuel, and other inventories of radioactive materials result in offsite doses below the values in § 53.4730(a)(1)(vi).

(ii) The applicant must perform a site-specific analysis, including identification of target sets, to demonstrate that the criterion in § 53.4330(a)(2)(i) is satisfied. The

analysis must assume that licensee mitigation and recovery actions, including any operator actions, are unavailable or ineffective. The licensee must maintain the analysis until the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.4670.

(b) *Fitness for Duty*. Each holder of an OL or COL under Framework B of this part must develop, implement, and maintain an FFD program that demonstrates compliance with the requirements in 10 CFR part 26.

(c) *Access Authorization*. Each holder of an OL or COL under Framework B of this part must develop, implement, and maintain an access authorization program that demonstrates compliance with the requirements in § 73.120 of this chapter if the criterion in § 53.4330(a)(2)(i) is satisfied, or the requirements in § 73.56 of this chapter if the criterion is not satisfied.

(d) *Cyber security*. Each holder of an OL or COL under Framework B of this part must develop, implement, and maintain a cyber security program that demonstrates compliance with the requirements in § 73.54 or § 73.110 of this chapter.

(e) *Information Security*. Each holder of an OL or COL under Framework B of this part must develop, implement, and maintain an information protection system that demonstrates compliance with the requirements of §§ 73.21, 73.22, and 73.23 of this chapter, as applicable.

§ 53.4340 Quality assurance.

Each holder of an OL or COL under Framework B of this part must develop, implement, and maintain a QAP in accordance with subpart U of this part. A written QAP manual must be developed and used to guide the conduct of the program in accordance with generally accepted consensus codes and standards that have been endorsed or otherwise found acceptable by the NRC.

§ 53.4350 Fire protection.

(a) *Fire protection plan.*

(1) Each holder of an OL or COL under Framework B of this part must have a fire protection plan that demonstrates compliance with the requirements in paragraph (c) of this section and describes the overall fire protection program for the facility; identifies the various positions within the licensee's organization that are responsible for the program; states the authorities that are delegated to each of these positions to implement those responsibilities; and outlines the plans for fire protection, fire detection and suppression capability; and limitation of fire damage.

(2) The fire protection plan must also describe specific features necessary to implement the program described in paragraph (a)(1) of this section such as the following: administrative controls and personnel requirements for fire prevention and manual fire suppression activities; automatic fire detection and automatic and manually operated fire suppression systems; and the means to limit fire damage to SSCs important to safety so that the capability to shut down the plant safely is ensured.

(3) Each applicant for a design approval or design certification under Framework B of this part must have a description and analysis of the fire protection design features for the standard plant necessary to demonstrate compliance with the requirements in paragraph (c) of this section.

(b) *Fire protection program.*

(1) Each holder of an OL or COL under Framework B of this part must develop a fire protection program. The program must establish the fire protection policy for the protection of SSCs important to safety at each commercial nuclear plant and the procedures, equipment, and personnel required to implement the program at the plant site.

(2) The fire protection program must be under the direction of an individual who has been delegated authority commensurate with the responsibilities of the position and who has available staff personnel knowledgeable in both fire protection and nuclear safety.

(3) The fire protection program must extend the concept of defense in depth to fire protection in fire areas containing structures, systems, or components important to safety, with the following objectives:

(i) To prevent fires from starting;

(ii) To detect rapidly, control, and extinguish promptly those fires that do occur; and

(iii) To provide protection for SSCs important to safety so that a fire that is not promptly extinguished by the fire suppression activities will not prevent the safe shutdown of the plant.

(4) The fire protection program must demonstrate compliance with the requirements in paragraph (c) of this section and be based on the analysis described in paragraph (d) of this section.

(c) *Fire protection program performance criteria.*

(1) SSCs important to safety must be designed and located to minimize, consistent with other safety requirements, the probability and effect of fires and explosions.

(2) Noncombustible and heat resistant materials must be used wherever practical throughout the facility, particularly in locations containing structures, systems, or components important to safety.

(3) Fire detection and suppression systems of appropriate capacity and capability must be provided and designed to minimize the adverse effects of fires on SSCs important to safety.

(4) Fire suppression systems must be designed to ensure that their rupture or inadvertent operation does not significantly impair the ability of SSCs important to safety to perform their safety functions.

(d) *Fire Hazards analysis.* A fire hazards analysis must be performed by qualified fire protection and reactor systems engineers to—

(1) Consider potential in situ and transient fire hazards;

(2) Determine the consequences of fire in any location in the plant on the ability to safely shut down the reactor and on the ability to minimize and control the release of radioactivity to the environment; and

(3) Specify measures for fire prevention, fire detection, fire suppression, fire containment, and alternative shutdown capability as required for each fire area containing structures, systems, or components important to safety.

§ 53.4360 Inservice inspection and inservice testing.

(a) Each boiling or pressurized water-cooled commercial nuclear plant licensee under Framework B of this part must demonstrate compliance with the requirements of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (BPV) Code and the ASME Operation and Maintenance of Nuclear Power Plants (OM) Code for ISI and IST as specified in § 50.55a of this chapter.

(b) Each non-light-water-cooled commercial nuclear plant licensee under Framework B of this part must develop, implement, and maintain programs for ISI and IST that demonstrate compliance with the requirements of § 53.880.

§ 53.4380 Environmental qualification of electric equipment important to safety for commercial nuclear plants.

(a) Each holder of an OL, COL, or ML under Framework B of this part, other than a commercial nuclear plant for which the certifications required under § 53. 4670 have been submitted, must develop, implement, and maintain a program for qualifying the electric equipment defined in paragraph (b) of this section. For an ML, only electric equipment defined in paragraph (b) of this section that is within the scope of the manufactured reactor must be included in the program.

(b) Electric equipment important to safety covered by this section is—

(1) SR electric equipment;[11]

(2) NSR electric equipment whose failure under postulated environmental conditions could prevent satisfactory accomplishment of safety functions by the SR equipment; and

(3) Certain post-accident monitoring equipment.[12]

(c) Requirements for (1) dynamic and seismic qualification of electric equipment important to safety, (2) protection of electric equipment important to safety against other natural phenomena and external events, and (3) environmental qualification of electric equipment important to safety located in a mild environment are not included within the scope of this section. A mild environment is an environment that would at no time be significantly more severe than the environment that would occur during normal plant operation, including AOOs.

(d) The licensee must prepare a list of electric equipment important to safety covered by this section. In addition, the licensee must include the information in paragraphs (d)(1), (2), and (3) of this section for this electric equipment important to safety in a qualification file. The licensee must keep the list and information in the file

current and retain the file in auditable form for the entire period during which the covered item is installed in the commercial nuclear plant or is stored for future use to permit verification that each item of electric equipment covered by this section that is important to safety meets the requirements of paragraph (j) of this section. Information to be developed and maintained includes—

(1) The performance specifications under conditions existing during and following DBAs;

(2) The voltage, frequency, load, and other electrical characteristics for which the performance specified in accordance with paragraph (d)(1) of this section can be ensured; and

(3) The environmental conditions, including temperature, pressure, humidity, radiation, chemicals, and submergence at the location where the equipment must perform as specified in accordance with paragraphs (d)(1) and (2) of this section.

(e) The electric equipment qualification program must include and be based on the following:

(1) *Temperature and pressure*. The time-dependent temperature and pressure at the location of the electric equipment important to safety must be established for the most severe DBA during or following which this equipment is required to remain functional.

(2) *Humidity*. Humidity during DBAs must be considered.

(3) *Chemical effects*. The composition of chemicals used must be at least as severe as that resulting from the most limiting mode of plant operation (e.g., containment spray, combustion products, fluid releases). If the composition of the chemical environment can be affected by equipment malfunctions, the most severe chemical environment that results from a single failure must be assumed.

(4) *Radiation*. The radiation environment must be based on the type of radiation, the total dose expected during normal operation over the installed life of the equipment, and the radiation environment associated with the most severe DBA during or following which the equipment is required to remain functional, including dose rate effects.

(5) *Aging*. Equipment qualified by test must be preconditioned by natural or artificial (accelerated) aging to its end-of-installed life condition. Consideration must be given to all significant types of degradation which can have an effect on the functional capability of the equipment. If preconditioning to an end-of-installed life condition is not practicable, the equipment may be preconditioned to a shorter designated life. The equipment must be replaced or refurbished at the end of this designated life unless ongoing qualification demonstrates that the item has additional life.

(6) *Submergence* (if subject to being submerged).

(7) *Synergistic effects*. Synergistic effects must be considered when these effects are believed to have a significant effect on equipment performance.

(8) *Margins*. Margins must be applied to account for unquantified uncertainty, such as the effects of production variations and inaccuracies in test instruments. These margins are in addition to any conservatisms applied during the derivation of local environmental conditions of the equipment unless these conservatisms can be quantified and shown to contain appropriate margins.

(f) Each item of electric equipment important to safety must be qualified by one of the following methods:

(1) Testing an identical item of equipment under identical conditions or under similar conditions with a supporting analysis to show that the equipment to be qualified is acceptable;

(2) Testing a similar item of equipment with a supporting analysis to show that the equipment to be qualified is acceptable;

(3) Experience with identical or similar equipment under similar conditions with a supporting analysis to show that the equipment to be qualified is acceptable; or

(4) Analysis in combination with partial type test data that supports the analytical assumptions and conclusions.

(g) [Reserved]

(h) [Reserved]

(i) [Reserved]

(j) A record of the qualification, including documentation in paragraph (d) of this section, must be maintained in an auditable form for the entire period during which the covered item is installed in the commercial nuclear plant or is stored for future use to permit verification that each item of electric equipment important to safety covered by this section —

(1) Is qualified for its application; and

(2) Meets its specified performance requirements when it is subjected to the conditions predicted to be present when it must perform its safety function up to the end of its qualified life.

(k) [Reserved]

(l) Replacement equipment must be qualified in accordance with the provisions of this section unless there are sound reasons to the contrary.

[11] SR electric equipment is referred to as "Class 1E" equipment in IEEE 323–1974. Copies of this standard may be obtained from the Institute of Electrical and Electronics Engineers, Inc., 345 East 47th Street, New York, NY 10017.

[12] Specific guidance concerning the types of variables to be monitored for light-water reactors is provided in Revision 2 of Regulatory Guide 1.97, "Instrumentation for Light-Water-Cooled Nuclear Power Plants to Assess Plant and Environs Conditions During and Following an Accident." The need for environmental qualification of post-accident monitoring equipment for non-light-water reactors is determined on a case-by-case basis considering factors such as the need for information to confirm plant status and/or to take additional on-site or off-site actions to protect public health and safety.

§ 53.4390 Procedures and guidelines.

(a) Each holder of an OL or COL under Framework B of this part must have a program for developing, implementing, and maintaining an integrated set of procedures, guidelines, and related supporting activities to support normal operations and respond to possible unplanned events.

(b) The program required by paragraph (a) of this section must include but is not limited to development, implementation, maintenance, and supporting activities of procedures and guidelines for the following:

(1) Plant operations;

(2) Maintenance activities under § 53.4210;

(3) Program requirements under this subpart;

(4) Emergency operating procedures if human intervention is needed to respond to DBAs identified in accordance with the requirements of § 53.4730(a)(5)(ii); and

(5) Procedures that describe how the licensee will address the following areas if the licensee is notified of a potential aircraft threat:

(i) Verification of the authenticity of threat notifications;

(ii) Maintenance of continuous communication with threat notification sources;

(iii) Contacting all onsite personnel and applicable offsite response organizations;

(iv) Onsite actions necessary to enhance the capability of the facility to mitigate the consequences of an aircraft impact;

(v) Measures to reduce visual discrimination of the site relative to its surroundings or individual buildings within the protected area;

(vi) Dispersal of equipment and personnel, as well as rapid entry into site protected areas for essential onsite personnel and offsite responders who are necessary to mitigate the event; and

(vii) Recall of site personnel.

§ 53.4400 Integrity assessment program.

(a) Each holder of an OL or COL licensee under Framework B of this part must develop, implement, and maintain an integrity assessment program to monitor, evaluate, and manage—

(1) The effects of plant aging on SSCs identified in § 53.4400(b). The program may refer to surveillances, tests, and inspections conducted for specific SSCs in accordance with other requirements in Framework B of this part or conducted in accordance with applicable consensus codes and standards endorsed or otherwise found acceptable by the NRC;

(2) Cyclic or transient load limits to ensure that SSCs are maintained within the applicable design limits; and

(3) Degradation mechanisms related to chemical interactions, operating temperatures, effects of irradiation, and other environmental factors to ensure that the capabilities, availability, and reliability of SSCs demonstrate compliance with the principal design criteria for the commercial nuclear plant.

(b) Plant SSCs within the scope of this section are—

(1) SR SSCs; and

(2) NSR SSCs—

(i) That are relied upon to mitigate accidents or transients or are used in plant emergency operating procedures;

(ii) Whose failure could prevent SR SSCs from fulfilling their SR function; or

(iii) Whose failure could cause a reactor scram or actuation of an SR system.

§ 53.4410 Primary containment leakage rate testing program.

Primary reactor containments for water-cooled commercial nuclear plants licensed under Framework B of this part, other than facilities for which the certifications required under § 53.4670 have been submitted, must be subject to the requirements set forth in appendix J to 10 CFR part 50.

§ 53.4420 Mitigation of beyond-design-basis events.

(a) *Applicability.*

(1) Each holder of an OL under Framework B of this part and each holder of a COL under Framework B of this part for which the Commission has made the finding under § 53.5052(g) must comply with the requirements of this section until submittal of the licensee's certifications described in § 53.4670(a).

(2)(i) Once the certifications described in § 53.4670(a) have been submitted by a licensee subject to the requirements of this section, that licensee need only comply with the requirements of paragraphs (b) through (d) and (f) of this section associated with spent fuel pool cooling capabilities, if the licensee relies on active cooling or submergence of spent reactor fuel in a water-filled spent fuel pool to protect public health and safety.

(ii) Holders of OLs or COLs for which the certifications described in § 53.4670(a) have been submitted need not demonstrate compliance with the requirements of this section except for the requirements of paragraph (b)(2) associated with spent fuel pool cooling capabilities, if the licensee relies on active cooling or submergence of spent reactor fuel in a water-filled spent fuel pool to protect public health and safety, once the decay heat of the fuel in the spent fuel pool can be removed solely by passive cooling mechanisms such that sufficient time is available for the licensee to obtain off-site resources to sustain the spent fuel pool cooling function indefinitely, as demonstrated by an analysis performed and retained by the licensee.

~~(iii) Holders of OLs or COLs for which the certifications described in § 53.4670(a) have been submitted need not demonstrate compliance with the requirements of this section once all irradiated fuel has been permanently removed from the spent fuel pool(s).~~

~~(b) *Strategies and guidelines.* Each applicant or licensee must develop, implement, and maintain —~~

~~(1) *Mitigation strategies for beyond-design-basis external events.* Strategies and guidelines to mitigate beyond-design-basis external events from natural phenomena that are developed assuming damage states that would immediately challenge the safety functions of the commercial nuclear plant. These strategies and guidelines must be capable of being implemented site-wide and must include the following:~~

~~(i) Maintaining or restoring the capabilities to shut down the reactor and control reactivity, to remove decay heat from the reactor fuel and spent fuel stored on site, and to control the release of radioactive material; and~~

~~(ii) The acquisition and use of offsite assistance and resources to support the safety functions required by paragraph (b)(1)(i) of this section indefinitely, or until sufficient site functional capabilities can be maintained without the need for the mitigation strategies; and~~

~~(2) *Extensive damage mitigation guidelines.* Strategies and guidelines to maintain or restore the capabilities to perform the functions required by paragraph (b)(1)(i) of this section under the circumstances associated with loss of large areas of the plant impacted by the event, due to explosions or fire, to include strategies and guidelines in the following areas:~~

~~(i) Firefighting;~~

~~(ii) Operations to mitigate fuel damage; and~~

~~(iii) Actions to minimize radiological release.~~

~~(c) *Equipment.*~~

~~(1) The equipment relied on for the mitigation strategies and guidelines required by paragraph (b)(1) of this section must have sufficient capacity and capability to perform the functions required by paragraph (b)(1) of this section.~~

~~(2) The equipment relied on for the mitigation strategies and guidelines required by paragraph (b)(1) of this section must be reasonably protected from the effects of natural phenomena that are equivalent in magnitude to the phenomena assumed for developing the design basis of the facility.~~

~~(d) *Training requirements.* Each licensee must provide for the training of personnel that perform activities in accordance with the capabilities required by paragraphs (b)(1) and (2) of this section.~~

~~(e) *Spent fuel pool monitoring.* In order to support effective prioritization of event mitigation and recovery actions, each licensee that relies on active cooling or submergence of spent reactor fuel in a water-filled spent fuel pool to protect public health and safety must provide reliable means to remotely monitor wide-range water level for each spent fuel pool at its site until 5 years have elapsed since all of the fuel within that spent fuel pool was last used in a reactor vessel.~~

~~(f) *Documentation of changes.*~~

~~(1) A licensee may make changes in the implementation of the requirements in this section without NRC approval, provided that before implementing each such change, the licensee demonstrates that the provisions of this section continue to be met and maintains documentation of changes until the requirements of this section no longer apply.~~

(2) Changes in the implementation of requirements in this section subject to change control processes in addition to paragraph (f) of this section must be processed via their respective change control processes unless the changes being evaluated impact only the implementation of the requirements of this section.

Subpart Q — Decommissioning

§ 53.4600 Scope and purpose.

This subpart establishes the requirements related to decommissioning for applicants for or holders of an OL or COL under Framework B. The requirements related to maintaining financial assurance for decommissioning are in §§ 53.4610 through 53.4660. The requirements for transitioning from operations to decommissioning and for the release of property and termination of the license are in §§ 53.4670 through 53.4680.

§ 53.4610 Financial assurance for decommissioning.

(a) This section establishes requirements for indicating to the NRC how an applicant for or holder of an OL or COL under Framework B of this part will provide reasonable assurance that funds will be available for the decommissioning process. Reasonable assurance consists of a series of steps as provided in paragraph (b) of this section and §§ 53.4620, 53.4630, and 53.4640. Funding for the decommissioning of commercial nuclear plants may also be subject to the regulation of Federal or State government agencies (e.g., FERC and State PUCs) that have jurisdiction over rate regulation. The requirements of this subpart, in particular § 53.4620, are in addition to, and not a substitution for, other requirements, and are not intended to be used by themselves or by other agencies to establish rates.

(b) Each applicant for an OL or COL under Framework B of this part must prepare a plan and an associated decommissioning report that ensures and documents that adequate funding will be available to decommission the facility. Each holder of an

~~OL or COL must implement and maintain the plan.~~

~~(1)(i) Before the Commission issues an OL under Framework B of this part, the applicant must update the decommissioning report to certify that it has provided financial assurance for decommissioning in the amount proposed in the application and approved by the NRC in accordance with § 53.4620.~~

~~(ii) No later than 30 days after the Commission issues the notice of intended operation under § 53.5052 for a COL under Framework B of this part, the licensee must update the decommissioning report to certify that it has provided financial assurance for decommissioning in the amount proposed in the application and approved by the NRC in accordance with § 53.4620.~~

~~(2) The amount of financial assurance for decommissioning to be provided must be based on a site-specific cost estimate for decommissioning the facility in accordance with § 53.4620.~~

~~(3) The amount of financial assurance for decommissioning to be provided must be adjusted annually using a rate at least equal to that stated in § 53.4630.~~

~~(4) The amount of financial assurance for decommissioning to be provided must be covered by one or more of the methods described in § 53.4640 as acceptable to the NRC. A copy of the financial instrument obtained to satisfy the requirements of § 53.4640 must be submitted to the NRC as part of the application for an OL under Framework B of this part; however, an applicant for or holder of a COL need not obtain such financial instrument or submit a copy to the Commission except as provided in § 53.4660(b).~~

~~§ 53.4620 Cost estimates for decommissioning.~~

~~Cost estimates for decommissioning must be site-specific. Site-specific DCEs must account for the engineering, labor, equipment, transportation, disposal, and related~~

charges needed to support termination of the license. They must include the costs for decontaminating SSCs and the site environs; removal of contaminated components and materials from the plant and the site environs; disposal of removed components and materials in appropriate facilities; and any other activities supporting the release of the property and termination of the license. They must also address the approach to annual adjustments required by § 53.4630. Finally, site-specific DCEs must include plans for adjusting levels of funds assured for decommissioning to demonstrate that a reasonable level of assurance will be provided that funds will be available when needed to cover the cost of decommissioning.

§ 53.4630 Annual adjustments to cost estimates for decommissioning.

Each holder of an OL or COL under Framework B of this part must annually adjust the cost estimate for decommissioning to account for escalation in labor, energy, and waste burial costs. Licensees may elect to use either a site-specific adjustment factor, approved as part of the plan and associated decommissioning report required by § 53.4610, in paragraph (a) of this section or the generic adjustment factor in paragraph (b) of this section.

(a) A site-specific adjustment factor must address the estimated contributions and escalation of costs for the following aspects of decommissioning:

(1) Labor, materials, and services;

(2) Energy and waste transportation; and

(3) Radioactive waste burial or other disposition.

(b) A generic adjustment factor must be at least equal to 0.65 L + 0.13 E + 0.22 B, where L and E are escalation factors for labor and energy, respectively, and are to be taken from regional data of U.S. Department of Labor Bureau of Labor Statistics and B is

an escalation factor for waste burial and is to be taken from NRC report NUREG-1307, "Report on Waste Burial Charges."

§ 53.4640 Methods for providing financial assurance for decommissioning.

Financial assurance for decommissioning is to be provided by the following methods.

(a) *Prepayment*. Prepayment is the deposit made preceding the start of operation or the transfer of a license under § 53.6070 into an account segregated from licensee assets and outside the administrative control of the licensee and its subsidiaries or affiliates of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, or Government fund with payment by certificate of deposit, deposit of government or other securities, or other method acceptable to the NRC. This trust, escrow account, Government fund, or other type of agreement must be established in writing and maintained at all times in the United States with an entity that is an appropriate State or Federal government agency, or an entity whose operations in which the prepayment deposit is managed are regulated and examined by a Federal or State agency. A licensee that has prepaid funds based on a site-specific cost estimate under § 53.4620 may take credit for projected earnings on the prepaid decommissioning trust funds, using up to a 2 percent annual real rate of return through the time of termination of the license. A licensee may use a credit of greater than 2 percent if the licensee's rate-setting authority has specifically authorized a higher rate. Actual earnings on existing funds may be used to calculate future fund needs.

(b) *External sinking fund*. An external sinking fund is a fund established and maintained by setting funds aside periodically in an account segregated from licensee assets and outside the administrative control of the licensee and its subsidiaries or

affiliates in which the total amount of funds would be sufficient to pay decommissioning costs. An external sinking fund may be in the form of a trust, escrow account, or Government fund, with payment by certificate of deposit, deposit of Government or other securities, or other method acceptable to the NRC. This trust, escrow account, Government fund, or other type of agreement must be established in writing and maintained at all times in the United States with an entity that is an appropriate State or Federal government agency, or an entity whose operations in which the external sinking fund is managed are regulated and examined by a Federal or State agency. A licensee that has collected funds based on a site-specific cost estimate under § 53.4620 may take credit for projected earnings on the external sinking funds using up to a 2 percent annual real rate of return from the time of future funds' collection through the time of termination of the license. A licensee may use a credit of greater than 2 percent if the licensee's rate-setting authority has specifically authorized a higher rate. Actual earnings on existing funds may be used to calculate future fund needs. A licensee whose rates for decommissioning costs cover only a portion of these costs may make use of this method only for the portion of these costs that are collected in one of the manners described in this paragraph. This method may be used as the exclusive mechanism relied upon for providing financial assurance for decommissioning in the following circumstances:

(1) By a licensee that recovers, either directly or indirectly, the estimated total cost of decommissioning through rates established by "cost of service" or similar ratemaking regulation. Public utility districts, municipalities, rural electric cooperatives, and State and Federal agencies, including associations of any of the foregoing, that establish their own rates and are able to recover their cost of service allocable to decommissioning, are deemed to satisfy this condition.

(2) By a licensee whose source of revenues for its external sinking fund is a

"non-bypassable charge," the total amount of which will provide funds estimated to be needed for decommissioning pursuant to § 53.4620, § 53.4660, or § 53.6075.

(c) *A surety method, insurance, or other guarantee method*.

(1) These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended, or, if written for a specified term, such as 5 years, must be renewed automatically, unless 90 days or more prior to the renewal day the issuer notifies the NRC, the beneficiary, and the licensee of its intention not to renew. The surety or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the NRC within 30 days after receipt of notification of cancellation.

(ii) The surety or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the NRC. An acceptable trustee includes an appropriate State or Federal government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(2) A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A to 10 CFR part 30.

(3) For commercial companies that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix C to 10 CFR part 30. For

commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in appendix D to 10 CFR part 30. A guarantee by the applicant or licensee may not be used in any situation in which the applicant or licensee has a parent company holding majority control of voting stock of the company.

(d) *Funding method for Federal licensees.* For a Federal licensee, a statement of intent containing a cost estimate for decommissioning and indicating that funds for decommissioning will be obtained when necessary.

(e) *Contractual funding method.* Contractual obligation(s) on the part of a licensee's customer(s), the total amount of which over the duration of the contract(s) will provide the licensee's total share of uncollected funds estimated to be needed for decommissioning pursuant to § 53.4620, § 53.4660, or § 53.6075. To be acceptable to the NRC as a method of decommissioning funding assurance, the terms of the contract(s) must include provisions that the buyer(s) of electricity or other products will pay for the decommissioning obligations specified in the contract(s), notwithstanding the operational status either of the licensed plant to which the contract(s) pertains or force majeure provisions. All proceeds from the contract(s) for decommissioning funding will be deposited to the external sinking fund. The NRC reserves the right to evaluate the terms of any contract(s) and the financial qualifications of the contracting entity or entities offered as assurance for decommissioning funding.

(f) *Other funding mechanisms.* Any other mechanism, or combination of mechanisms, that provides, as determined by the NRC upon its evaluation of the specific circumstances of each licensee submittal, assurance of decommissioning funding equivalent to that provided by the mechanisms specified in paragraphs (a) through (e) of this section. Licensees who do not have sources of funding described in paragraph (b) of

this section may use an external sinking fund in combination with a guarantee mechanism, as specified in paragraph (c) of this section, provided that the total amount of funds estimated to be necessary for decommissioning is assured.

§ 53.4645 Limitations on the use of decommissioning trust funds.

(a)(1) Decommissioning trust funds may be used by licensees if—

(i) The withdrawals are for expenses for decommissioning activities consistent with the definition of decommissioning in § 53.020;

(ii) The expenditure would not reduce the value of the decommissioning trust below an amount necessary to place and maintain the reactor in a safe storage condition if unforeseen conditions or expenses arise; and

(iii) The withdrawals would not inhibit the ability of the licensee to complete funding of any shortfalls in the decommissioning trust needed to ensure the availability of funds to ultimately release the site and terminate the license.

(2) Initially, 3 percent of the amount determined in accordance with § 53.4620 may be used for decommissioning planning. For licensees that have submitted the certifications required under § 53.4670 and commencing 90 days after the NRC has received the PSDAR required by § 53.4660, an additional 20 percent may be used. An updated site-specific DCE must be submitted to the NRC prior to the licensee using any funding in excess of these amounts.

(b) Licensees that are not "electric utilities" as defined in § 53.020 that use prepayment or an external sinking fund to provide financial assurance must provide in the terms of the arrangements governing the trust, escrow account, or Government fund, used to segregate and manage the funds that—

(1) The trustee, manager, investment advisor, or other person directing investment of the funds—

(i) Is prohibited from investing the funds in securities or other obligations of the licensee or any other owner or operator of any commercial nuclear plant or their affiliates, subsidiaries, successors or assigns, or in a mutual fund in which at least 50 percent of the fund is invested in the securities of a licensee or parent company whose subsidiary is an owner or operator of a foreign or domestic commercial nuclear plant. However, the funds may be invested in securities tied to market indices or other non-nuclear sector collective, commingled, or mutual funds, provided that no more than 10 percent of trust assets may be indirectly invested in securities of any entity owning or operating one or more commercial nuclear plants.

(ii) Is obligated at all times to adhere to a standard of care set forth in the trust, which either shall be the standard of care, whether in investing or otherwise, required by State or Federal law or one or more State or Federal regulatory agencies with jurisdiction over the trust funds, or, in the absence of any such standard of care, whether in investing or otherwise, that a prudent investor would use in the same circumstances. The term "prudent investor," shall have the same meaning as set forth in FERC's "Regulations Governing Nuclear Plant Decommissioning Trust Funds" at 18 CFR 35.32(a)(3), or any successor regulation.

(2) The licensee, its affiliates, and its subsidiaries are prohibited from being engaged as investment manager for the funds or from giving day-to-day management direction of the funds' investments or direction on individual investments by the funds, except in the case of passive fund management of trust funds where management is limited to investments tracking market indices.

(3) The trust, escrow account, Government fund, or other account used to segregate and manage the funds may not be amended in any material respect without written notification to the Director, Office of Nuclear Reactor Regulation, or Director,

Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the proposed effective date of the amendment. The licensee must provide the text of the proposed amendment and a statement of the reason for the proposed amendment. The trust, escrow account, Government fund, or other account may not be amended if the person responsible for managing the trust, escrow account, Government fund, or other account receives written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period.

(4) Except for withdrawals being made under paragraph (a) of this section or for payments of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, no disbursement or payment may be made from the trust, escrow account, Government fund, or other account used to segregate and manage the funds until written notice of the intention to make a disbursement or payment has been given to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the date of the intended disbursement or payment. The disbursement or payment from the trust, escrow account, Government fund or other account may be made following the 30-working day notice period if the person responsible for managing the trust, escrow account, Government fund, or other account does not receive written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period. Disbursements or payments from the trust, escrow account, Government fund, or other account used to segregate and manage the funds, other than for payment of ordinary administrative costs (including taxes) and other incidental

expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, are restricted to decommissioning expenses or transfer to another financial assurance method acceptable under § 53.4640 until final decommissioning has been completed. After decommissioning has begun and withdrawals from the decommissioning fund are made under paragraph (a) of this section, no further notification need be made to the NRC.

(c) Licensees that are "electric utilities" under § 53.020 that use prepayment or an external sinking fund to provide financial assurance must include a provision in the terms of the trust, escrow account, Government fund, or other account used to segregate and manage funds that except for withdrawals being made under paragraph (a) of this section or for payments of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, no disbursement or payment may be made from the trust, escrow account, Government fund, or other account used to segregate and manage the funds until written notice of the intention to make a disbursement or payment has been given the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the date of the intended disbursement or payment. The disbursement or payment from the trust, escrow account, Government fund or other account may be made following the 30-working day notice period if the person responsible for managing the trust, escrow account, Government fund, or other account does not receive written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period. Disbursements or payments from the trust, escrow account, Government fund, or other account used to segregate and manage the funds, other than

for payment of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, are restricted to decommissioning expenses or transfer to another financial assurance method acceptable under § 53.4640 until final decommissioning has been completed. After decommissioning has begun and withdrawals from the decommissioning fund are made under paragraph (a) of this section, no further notification need be made to the NRC.

(d) A licensee that is not an "electric utility" under § 53.020 and using a surety method, insurance, or other guarantee method to provide financial assurance must provide that the trust established for decommissioning costs to which the surety or insurance is payable contains in its terms the requirements in § 53.4645(b)(1), (2), (3), and (4).

§ 53.4650 NRC oversight.

The NRC reserves the right to take the following steps in order to ensure a licensee's adequate accumulation of decommissioning funds: review, as needed, the rate of accumulation of decommissioning funds and, either independently or in cooperation with FERC and the licensee's State PUC, take additional actions as appropriate on a case-by-case basis, including modification of a licensee's schedule for the accumulation of decommissioning funds.

§ 53.4660 Reporting and recordkeeping requirements.

(a) Each holder of an OL under Framework B of this part or holder of a COL under Framework B of this part after the date that the Commission has made the finding under § 53.5052(g) must report, at least once every 2 years, by March 31, on the status of its certification of decommissioning funding for each reactor or part of a reactor that it owns. The information in this report must include, at a minimum, the amount of

decommissioning funds estimated to be required pursuant to §§ 53.4620 and 53.4630; the amount of decommissioning funds accumulated to the end of the calendar year preceding the date of the report; a schedule of the annual amounts remaining to be collected; the assumptions used regarding rates of escalation in decommissioning costs, rates of earnings on decommissioning funds, and rates of other factors used in funding projections; any contracts upon which the licensee is relying pursuant to § 53.4640(e); any modifications occurring to a licensee's current method of providing financial assurance since the last submitted report; and any material changes to trust agreements. If any of the preceding items is not applicable, the licensee should so state in its report. Any licensee for a plant that is within 5 years of the projected end of its operation, or where conditions have changed such that it will close within 5 years (before the end of its licensed life), or that has already closed (before the end of its licensed life), or that is involved in a merger or an acquisition must submit this report annually.

(b) Each holder of a COL under Framework B of this part must, 2 years before and 1 year before the scheduled date for initial loading of fuel, submit a report to the NRC containing a certification updating the DCEs and a copy of the financial instrument to be used to satisfy § 53.4640. No later than 30 days after the Commission publishes notice in the Federal Register under § 53.5052(a), the licensee must submit an updated decommissioning report required under § 53.4610(b)(1)(ii), including a copy of the financial instrument obtained to satisfy § 53.4640.

(c) Each licensee must keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Commission. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Commission considers important to decommissioning consists of—

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when significant contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee must substitute appropriate records of available information concerning these areas and locations.

(3) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(4) Records of—

(i) The licensed site area, as originally licensed and any revisions, which must include a site map and any acquisition or use of property outside the originally licensed site area for the purpose of receiving, possessing, or using licensed materials;

(ii) The licensed activities carried out on the acquired or used property; and

(iii) The release and final disposition of any property recorded in paragraph (c)(4)(i) of this section, the historical site assessment performed for the release, radiation surveys performed to support release of the property, submittals to the NRC made in accordance with § 53. 4670, and the methods employed to ensure that the property met

the radiological criteria of 10 CFR part 20, subpart E, at the time the property was released.

(d) Each holder of an OL or COL under Framework B of this part must at or about 5 years prior to the projected end of operations submit a preliminary DCE which includes an up-to-date assessment of the major factors that could affect the cost to decommission.

(e) Prior to or within 2 years following permanent cessation of operations, the licensee must submit a PSDAR to the NRC, and a copy to the affected State(s). The PSDAR must contain a description of the planned decommissioning activities along with a schedule for their accomplishment, a discussion that provides the reasons for concluding that the environmental impacts associated with site-specific decommissioning activities will be bounded by appropriate previously issued environmental impact statements, and a site-specific DCE, including the projected cost of managing irradiated fuel.

(f) For decommissioning activities that delay completion of decommissioning by including a period of storage or surveillance, the licensee must provide a means of adjusting cost estimates and associated funding levels over the storage or surveillance period.

(g) After submitting its site-specific DCE required by paragraph (e) of this section, and until the licensee has completed its final radiation survey and demonstrated that residual radioactivity has been reduced to a level that permits termination of its license, the licensee must annually submit to the NRC, by March 31, a financial assurance status report. The report must include the following information, current through the end of the previous calendar year:

(1) The amount spent on decommissioning, both cumulative and over the

previous calendar year, the remaining balance of any decommissioning funds, and the amount provided by other financial assurance methods being relied upon;

(2) An estimate of the costs to complete decommissioning, reflecting any difference between actual and estimated costs for work performed during the year, and the decommissioning criteria upon which the estimate is based;

(3) Any modifications occurring to a licensee's current method of providing financial assurance since the last submitted report; and

(4) Any material changes to trust agreements or financial assurance contracts.

(5) If the sum of the balance of any remaining decommissioning funds, plus earnings on such funds calculated at not greater than a 2 percent real rate of return, together with the amount provided by other financial assurance methods being relied upon, does not cover the estimated cost to complete the decommissioning, the financial assurance status report must include additional financial assurance to cover the estimated cost of completion.

(h) After submitting its site-specific DCE required by paragraph (e) of this section, the licensee must annually submit to the NRC, by March 31, a report on the status of its funding for managing irradiated fuel. The report must include the following information, current through the end of the previous calendar year:

(1) The amount of funds accumulated to cover the cost of managing the irradiated fuel;

(2) The projected cost of managing irradiated fuel until title to the fuel and possession of the fuel is transferred to the Secretary of Energy; and

(3) If the funds accumulated do not cover the projected cost, a plan to obtain additional funds to cover the cost.

§ 53.4670 Termination of license.

~~For each holder of an OL or COL under Framework B of this part —~~

~~(a)(1) When the licensee has determined to permanently cease operations the licensee must, within 30 days, submit a written certification to the NRC, consistent with the requirements of § 53.040(b)(8);~~

~~(2) When appropriate to support decommissioning activities and the eventual permanent removal of fuel from the reactor vessel, the licensee must develop defueled technical specifications by reviewing the operational technical specifications and determining which specifications no longer apply during decommissioning and which ones should remain applicable in accordance with § 53.4213(b)(6). The licensee must make the appropriate submittals to the NRC in accordance with § 53.6010 to request changes to the technical specifications; and~~

~~(3)(i) Once fuel has been permanently removed from the reactor vessel, the licensee must submit a written certification to the NRC that meets the requirements of § 53.040(b)(9); and~~

~~(ii) The licensee must establish and maintain staffing consisting of certified fuel handlers, as defined under § 53.020, and other non-licensed personnel with appropriate qualifications, and in sufficient numbers, to ensure support for facility operations and radiological control activities, as required by the facility defueled technical specifications. These personnel must be subject to the training requirements of § 53.830.~~

~~(b) Upon docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessel, or when a final legally effective order to permanently cease operations has come into effect, the license issued under Framework B of this part no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor vessel.~~

~~(c) Decommissioning will be completed within 60 years of permanent cessation~~

~~of operations. Completion of decommissioning beyond 60 years will be approved by the Commission only when necessary to protect public health and safety. Factors that will be considered by the Commission in evaluating an alternative that provides for completion of decommissioning beyond 60 years of permanent cessation of operations include unavailability of waste disposal capacity and other site-specific factors affecting the licensee's capability to carry out decommissioning, including presence of other nuclear facilities at the site.~~

~~(d)(1) Prior to or within 2 years following permanent cessation of operations, the licensee must submit a PSDAR and site-specific DCE in accordance with § 53.4660(e).~~

~~(2) The NRC shall notice receipt of the PSDAR and make the PSDAR available for public comment. The NRC shall also schedule a public meeting readily accessible to individuals in the vicinity of the licensee's facility upon receipt of the PSDAR. The NRC shall publish a notice in the Federal Register and in a forum, such as local newspapers, that is readily accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.~~

~~(e) Licensees must not perform any major decommissioning activities, as defined in § 53.020, until 90 days after the NRC has received the licensee's PSDAR submittal and until certifications of permanent cessation of operations and permanent removal of fuel from the reactor vessel, as required under paragraph (a) of this section, have been submitted.~~

~~(f) Licensees must not perform any decommissioning activities, as defined in § 53.020, that—~~

~~(1) Foreclose release of the site for possible unrestricted use;~~

~~(2) Result in significant environmental impacts not previously reviewed; or~~

(3) Result in there no longer being reasonable assurance that adequate funds will be available for decommissioning.

(g) In taking actions permitted under § 53.6040 following submittal of the PSDAR, the licensee must notify the NRC in writing, and send a copy to the affected State(s), before performing any decommissioning activity inconsistent with, or making any significant schedule change from, those actions and schedules described in the PSDAR, including changes that increase the decommissioning cost by more than 20 percent from the previously provided DCE.

(h) Licensees may use decommissioning trust funds consistent with the limitations of § 53.4645(a). Licensees must report on the status of decommissioning trust funds consistent with the requirements of § 53.4660(g).

(i) Licensees must submit an application for termination of license in accordance with § 53.4670. The application for termination of license must be accompanied or preceded by a license termination plan to be submitted for NRC approval.

(1) The license termination plan must be a supplement to the FSAR or equivalent and must be submitted at least 2 years before termination of the license date.

(2) The license termination plan must include—

(i) A site characterization;

(ii) Identification of remaining dismantlement activities;

(iii) Plans for site remediation;

(iv) Detailed plans for the final radiation survey;

(v) A description of the end use of the site, if restricted;

(vi) An updated site-specific estimate of remaining decommissioning costs;

(vii) A supplement to the environmental report, pursuant to § 51.53 of this chapter, describing any new information or significant environmental change associated

~~with the licensee's proposed termination activities; and~~

~~(viii) Identification of parts, if any, of the facility or site that were released for use before approval of the license termination plan.~~

~~(3) The NRC shall notice receipt of the license termination plan and make the license termination plan available for public comment. The NRC shall also schedule a public meeting readily accessible to individuals in the vicinity of the licensee's facility upon receipt of the license termination plan. The NRC shall publish a notice in the Federal Register and in a forum, such as local newspapers, that is readily accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.~~

~~(j) If the license termination plan demonstrates that the remainder of decommissioning activities will be performed in accordance with the regulations in this chapter, will not be inimical to the common defense and security or to the health and safety of the public, and will not have a significant effect on the quality of the environment and after notice to interested persons, the Commission shall approve the plan, by license amendment, subject to such conditions and limitations as it deems appropriate and necessary and authorize implementation of the license termination plan.~~

~~(k) The Commission shall terminate the license if it determines that—~~

~~(1) The remaining dismantlement has been performed in accordance with the approved license termination plan, and~~

~~(2) The final radiation survey and associated documentation, including an assessment of dose contributions associated with parts released for use before approval of the license termination plan, demonstrate that the facility and site have met the criteria for decommissioning in 10 CFR part 20, subpart E.~~

~~§ 53.4675 Program requirements during decommissioning.~~

~~(a) Licensees that have submitted the certifications required under § 53.4670 must maintain a decommissioning fire protection program to address the potential for fires that could cause the release or spread of radioactive materials.~~

~~(1) The objectives of the decommissioning fire protection program are to~~

~~(i) Reasonably prevent these fires from occurring;~~

~~(ii) Rapidly detect, control, and extinguish those fires that do occur and that could result in a radiological hazard; and~~

~~(iii) Ensure that the risk of fire induced radiological hazards to the public, environment, and plant personnel is minimized.~~

~~(2) The licensee must assess the decommissioning fire protection program on a regular basis. The licensee must revise the decommissioning fire protection program documentation as appropriate throughout the various stages of facility decommissioning.~~

~~(3) The licensee may make changes to the decommissioning fire protection program without NRC approval if these changes do not reduce the effectiveness of fire protection for SSCs that could result in a radiological hazard, taking into account the decommissioning plant conditions and activities.~~

~~(b) [Reserved]~~

~~§ 53.4680 Release of part of a commercial nuclear plant or site for unrestricted use.~~

~~(a) Prior written NRC approval is required to release part of a commercial nuclear plant or site for unrestricted use at any time before receiving approval of a license termination plan. Section 53.4660 specifies recordkeeping requirements associated with partial release. Holders of an OL or COL under Framework B of this part seeking NRC review and approval shall—~~

~~(1) Evaluate the effect of releasing the property to ensure that—~~

(i) The dose to individual members of the public does not exceed the limits and standards of 10 CFR part 20, subpart D;

(ii) There is no reduction in the effectiveness of emergency planning or physical security;

(iii) Effluent releases remain within license conditions;

(iv) The environmental monitoring program and offsite dose calculation manual are revised to account for the changes;

(v) The siting criteria of 10 CFR part 100 continue to be met; and

(vi) All other applicable statutory and regulatory requirements continue to be met.

(2) Perform a historical site assessment of the part of the commercial nuclear plant or site to be released; and

(3) Perform surveys adequate to demonstrate compliance with the radiological criteria for unrestricted use specified in § 20.1402 of this chapter for impacted areas.

(b) For release of non-impacted areas, the licensee may submit a written request for NRC review and approval of the release if a license amendment is not otherwise required. The request submittal must include —

(1) The results of the evaluations performed in accordance with paragraphs (a)(1) and (a)(2) of this section;

(2) A description of the part of the commercial nuclear plant or site to be released;

(3) The schedule for release of the property;

(4) The results of the evaluations performed in accordance with § 53.6040; and

(5) A discussion that provides the reasons for concluding that the environmental impacts associated with the licensee's proposed release of the property will be bounded by appropriate previously issued environmental impact statements.

(c) After receiving a request from the licensee for NRC approval of the release of a non-impacted area, the NRC shall—

(1) Determine whether the licensee has adequately evaluated the effect of releasing the property as required by paragraph (a)(1) of this section;

(2) Determine whether the licensee's classification of any release areas as non-impacted is adequately justified; and

(3) If determining that the licensee's submittal is adequate, inform the licensee in writing that the release is approved.

(d) For release of impacted areas, the licensee must submit an application for amendment of its license for the release of the property. The application must include—

(1) The information specified in paragraphs (b)(1) through (b)(3) of this section;

(2) The methods used for and results obtained from the radiation surveys required to demonstrate compliance with the radiological criteria for unrestricted use specified in § 20.1402 of this chapter; and

(3) A supplement to the environmental report, under § 51.53 of this chapter, describing any new information or significant environmental change associated with the licensee's proposed release of the property.

(e) After receiving a license amendment application from the licensee for the release of an impacted area, the NRC shall—

(1) Determine whether the licensee has adequately evaluated the effect of releasing the property as required by paragraph (a)(1) of this section;

(2) Determine whether the licensee's classification of any release areas as non-impacted is adequately justified;

(3) Determine whether the licensee's radiation survey for an impacted area is adequate; and

(4) If determining that the licensee's submittal is adequate, approve the licensee's amendment application.

(f) The NRC shall notice receipt of the release approval request or license amendment application and make the approval request or license amendment application available for public comment. Before acting on an approval request or license amendment application submitted in accordance with this section, the NRC shall conduct a public meeting readily accessible to individuals in the vicinity of the licensee's facility for the purpose of obtaining public comments on the proposed release of part of the commercial nuclear plant or site. The NRC shall publish a document in the Federal Register and in a forum, such as local newspapers, which is readily accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.

Subpart R — Licenses, Certifications, and Approvals

§ 53.4700 Filing of application for licenses, certifications, or approvals; oath or affirmation.

(a) *Serving of applications*.

(1) Each filing of an application for a standard design approval, standard design certification, or license under Framework B of this part, and any amendments to the applications, must be submitted to the NRC under § 53.040, as applicable.

(2) Each applicant for a CP, early site permit, COL, or ML under Framework B of this part must, upon notification by the presiding officer designated to conduct the public hearing required by the ActEA, update the application and serve the updated copies of the application or parts of it, eliminating all superseded information, together with an index of the updated application, as directed by presiding officer. Any subsequent amendment to the application must be served on those served copies of the application

and must be submitted to the NRC as specified in § 53.040, as applicable.

(3) The applicant must make a copy of the updated application available at the public hearing for the use of any other parties to the proceeding and must certify that the updated copies of the application contain the current contents of the application submitted in accordance with the requirements under Framework B of this part.

(4) At the time of filing an application, the Commission will make available at the NRC Web site, http://www.nrc.gov, a copy of the application, subsequent amendments, and other records pertinent to the matter that is the subject of the application for public inspection and copying.

(5) The serving of copies required by this section must not occur until the application has been docketed under § 2.101(a) of this chapter. Copies must be submitted to the Commission, as specified in § 53.040, as applicable, to enable the Director, Office of Nuclear Reactor Regulation to determine whether the application is sufficiently complete to permit docketing.

(b) *Oath or affirmation.* Each application for a standard design approval, standard design certification, or license, including, whenever appropriate, a CP or early site permit, or amendment of it, and each amendment of each application must be executed in a signed original by the applicant or duly authorized officer thereof under oath or affirmation.

(c) [Reserved]

(d) [Reserved]

(e) *Filing fees.* Each application for a standard design approval, standard design certification, or commercial nuclear plant license under Framework B of this part, including, whenever appropriate, a CP, COL, OL, ML, or early site permit, other than a license exempted from 10 CFR part 170, must be accompanied by the fee prescribed in

10 CFR part 170. No fee will be required to accompany an application for renewal, amendment, or termination of a CP, OL, COL, or ML, except as provided in § 170.21 of this chapter.

(f) *Environmental report*. An application for a CP, OL, early site permit, design certification, COL, or ML for a commercial nuclear plant must be accompanied by an environmental report required under subpart A of 10 CFR part 51.

§ 53.4701 Requirement for license.

Except as provided in § 53.4720, no person within the United States may transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, or use any utilization facility except as authorized by a license issued by the Commission.

§ 53.4703 Combining applications and licenses.

(a) An applicant may combine several applications in one application for different kinds of licenses under the regulations in this chapter.

(b) The Commission may combine in a single license the activities of an applicant which would otherwise be licensed separately.

§ 53.4706 Elimination of repetition.

An applicant may incorporate by reference in its application information contained in previous applications, statements, or reports filed with the Commission, provided, however, that such references are clear and specific.

§ 53.4709 Contents of applications; general information.

Each application must include, unless otherwise indicated in this subpart:

(a) Name of applicant;

(b) Address of applicant;

(c) Description of business or occupation of applicant;

(d)(1) If applicant is an individual, the citizenship of applicant;

(2) If applicant is a partnership, the name, citizenship and address of each partner and the principal location where the partnership does business;

(3) If applicant is a corporation or an unincorporated association, the following information:

(i) The State where it is incorporated or organized and the principal location where it does business;

(ii) The names, addresses and citizenship of its directors and of its principal officers; and

(iii) Whether it is owned, controlled, or dominated by an alien, a foreign corporation, or foreign government, and if so, give details; or

(4) If the applicant is acting as agent or representative of another person in filing the application, identify the principal and furnish information required under this paragraph with respect to such principal;

(e) The class and type of license applied for, the use to which the facility will be put, the period of time for which the license is sought, and a list of other licenses, except operator's licenses, issued or applied for in connection with the proposed facility;

(f) [Reserved]

(g)(1) If the application is for an OL or COL for a commercial nuclear plant, or if the application is for an early site permit for a commercial nuclear plant and contains plans for coping with emergencies under § 53.4756(b)(2)(ii), radiological emergency response plans of State, local, and participating Tribal governmental entities in the United States that are wholly or partially within the plume exposure pathway EPZ,[13] and, for applicants choosing to comply with § 50.47 of this chapter and appendix E to 10 CFR part 50, the plans of State governments wholly or partially within the ingestion pathway EPZ.[14] If the application is for an early site permit that, under § 53.4756(b)(2)(i),

proposes major features of the emergency plans describing the EPZs, then the descriptions of the EPZs must demonstrate compliance with the requirements of this paragraph. Generally, for applicants choosing to follow § 50.47 of this chapter and appendix E to 10 CFR part 50, the plume exposure pathway EPZ for a commercial nuclear plant must consist of an area about 10 miles (16 km) in radius and the ingestion pathway EPZ must consist of an area about 50 miles (80 km) in radius. The exact size and configuration of the EPZs surrounding a particular commercial nuclear plant must be determined in relation to the local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. The size of the EPZs also may be determined on a case-by-case basis for gas-cooled reactors and for reactors with an authorized power level less than 250 MW thermal. The plans for the ingestion pathway must focus on such actions as are appropriate to protect the food ingestion pathway.

(2) [Reserved]

(h) [Reserved]

(i) A list of the names and addresses of such regulatory agencies as may have jurisdiction over the rates and services incident to the proposed activity, and a list of trade and news publications which circulate in the area where the proposed activity will be conducted and which are considered appropriate to give reasonable notice of the application to those municipalities, private utilities, public bodies, and cooperatives, which might have a potential interest in the facility; and

(j) If the application contains Restricted Data or other defense information, confirmation that all Restricted Data and other defense information are separated from the unclassified information.

(k) [Reserved]

[13] EPZs are discussed in NUREG-0396, EPA 520/1-78-016, "Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light-Water Nuclear Power Plants," December 1978.

[14] If the State, local and participating Tribal emergency response plans have been previously provided to the NRC for inclusion in the facility docket, the applicant need only provide the appropriate reference to satisfy this requirement.

§ 53.4712 Environmental conditions.

(a) Each CP, early site permit, and COL under Framework B of this part may include conditions to address environmental issues during construction. These conditions are to be set out in an attachment to the license, which is incorporated in and made a part of the license. These conditions will be derived from information contained in the environmental report submitted pursuant to § 51.50 of this chapter as analyzed and evaluated in the NRC record of decision and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data and any conditions and monitoring requirement for the protection of the nonaquatic environment.

(b) Each license authorizing operation of a commercial nuclear plant, including a COL, under Framework B of this part, and each license for a commercial nuclear plant for which the certification of permanent cessation of operations required under § 53.4670 has been submitted may include conditions to address environmental issues during operation and decommissioning. These conditions are to be set out in an attachment to the license which is incorporated in and made a part of the license. These conditions will be derived from information contained in the environmental report or the supplement to the environmental report submitted under §§ 51.50 and 51.53 of this chapter as analyzed and evaluated in the NRC record of decision and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data and any conditions and monitoring requirement for the protection of the nonaquatic environment.

§ 53.4715 Agreement limiting access to classified information.

As part of its application and in any event before the receipt of Restricted Data or classified National Security Information or the issuance of a license or standard design approval under Framework B of this part, or before the Commission has adopted a final standard design certification rule under Framework B of this part, the applicant must agree in writing that it will not permit any individual to have access to any facility or to possess Restricted Data or classified National Security Information until the individual or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. The agreement of the applicant becomes part of the license or standard design approval.

§ 53.4718 Ineligibility of certain applicants.

Any person who is a citizen, national, or agent of a foreign country, or any corporation, or other entity which the Commission knows or has reason to believe is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government, shall be ineligible to apply for and obtain a license.

§ 53.4720 Exceptions and exemptions from licensing requirements.

Nothing in this part shall be deemed to require a license for—

(a) The manufacture, production, or acquisition by the Department of Defense of any utilization facility authorized pursuant to section 91 of the ActEA, or the use of such facility by the Department of Defense or by a person under contract with and for the account of the Department of Defense;

(b) Except to the extent that the Department of Energy facilities of the types subject to licensing pursuant to section 202 of the ERA are involved—

~~(1)(i) The processing, fabrication or refining of SNM or the separation of SNM, or the separation of SNM from other substances by a prime contractor of the Department of Energy under a prime contract for—~~

~~(A) The performance of work for the Department of Energy at a United States government-owned or controlled site;~~

~~(B) Research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or~~

~~(C) The use or operation of a utilization facility in a United States owned vehicle or vessel; or~~

~~(ii) The processing, fabrication or refining of SNM or the separation of SNM, or the separation of SNM from other substances by a prime contractor or subcontractor of the Commission or the Department of Energy under a prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety; or~~

~~(2)(i) The construction or operation of a utilization facility for the Department of Energy at a United States government-owned or controlled site, including the transportation of the utilization facility to or from such site and the performance of contract services during temporary interruptions of such transportation; or the construction or operation of a utilization facility for the Department of Energy in the performance of research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof; or the use or operation of a utilization facility for the Department of Energy in a United States government-owned~~

vehicle or vessel; provided that such activities are conducted by a prime contractor of the Department of Energy under a prime contract with the Department of Energy; or

(ii) The construction or operation of a utilization facility by a prime contractor or subcontractor of the Commission or the Department of Energy under his prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety; or

(c) The transportation or possession of any utilization facility by a common or contract carrier or warehouse employee in the regular course of carriage for another or storage incident thereto.

§ 53.4721 Public inspection of applications.

Applications and documents submitted to the Commission in connection with applications may be made available for public inspection in accordance with the provisions of the regulations contained in 10 CFR part 2.

§ 53.4724 Relationship between sections.

(a) *Limited work authorization.* (1) An application for an LWA under Framework B of this part may be submitted as part of an application for an early site permit, CP, or COL under Framework B of this part as required in § 53.4740(a)(2).

(2) [Reserved]

(b) *Early site permit.*

(1) A holder of an early site permit may request an LWA.

(2) An application for a CP or COL under Framework B of this part may, but need not, reference an early site permit.

(c) *Standard design approval.* An application for a standard design approval under Framework B of this part may, but need not, reference an OL or custom COL under Framework B of this part that is essentially the same as the standard design for which approval is being requested.

(d) *Standard design certification.* An application for a standard design certification under Framework B of this part may, but need not, reference an OL or custom COL under Framework B of this part that is essentially the same as the standard design for which certification is being requested.

(e) *Manufacturing license.*

(1) A manufactured reactor manufactured under an ML issued under Framework B of this part may only be transported to and installed at a site for which a COL under Framework B of this part has been issued.

(2) An ML applicant under Framework B of this part may reference a standard design certification or a standard design approval under Framework B of this part in its application.

(f) *Construction permit.* An application for a CP may, but need not, reference a standard design certification or standard design approval issued under Framework B of this part, respectively, and may also reference an early site permit issued under Framework B of this part. In the absence of a demonstration that an entity other than the one originally sponsoring a standard design certification is qualified to supply a design, the Commission will entertain an application for a CP that references a standard design certification issued under Framework B of this part only if the entity that sponsored the certification supplies the design for the applicant's use.

(g) *Operating license.*

(1) An application for an OL under Framework B of this part may, but need not, reference an early site permit, standard design certification, or standard design approval issued under Framework B of this part. In the absence of a demonstration that an entity other than the one originally sponsoring a standard design certification is qualified to supply a design, the Commission will entertain an application for an OL that references a standard design certification issued under Framework B of this part only if the entity that sponsored the certification supplies the design for the applicant's use.

(2) The holder of a CP must, at the time of submission of the FSAR, file an application for an OL.

(h) *Combined licenses.* An application for a COL under Framework B of this part may, but need not, reference an early site permit, standard design certification, standard design approval, or ML issued under Framework B of this part. In the absence of a demonstration that an entity other than the one originally sponsoring and obtaining a standard design certification is qualified to supply a design, the Commission will entertain an application for a COL that references a standard design certification issued under Framework B of this part only if the entity that sponsored the certification supplies the design for the applicant's use.

§ 53.4730 General technical requirements.

(a) *Purpose and applicability.* The Safety Analysis Report in an application for a CP, OL, early site permit, COL, standard design approval, standard design certification, or ML must include, to the extent required by §§ 53.4909, 53.4969, 53.4756, 53.5016, 53.4809, 53.4839, and 53.4879, respectively, the information specified in this section:

(1) *Site safety analysis.* A description of the site that includes—

(i) The boundaries of the site;

(ii) The proposed general location of each facility on the site;

(iii) The seismic, meteorological, hydrologic, and geologic characteristics of the proposed site with appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area and with sufficient margin for the limited accuracy, quantity, and time in which the historical data have been accumulated;

(iv) The location and description of any nearby industrial, military, or transportation facilities and routes;

(v) The existing and projected future population profile of the area surrounding the site; and

(vi) A description and safety assessment of the site on which the facility is to be located. The assessment must contain an analysis and evaluation of the major SSCs of the commercial nuclear plant that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in paragraphs (a)(1)(vi)(A), (a)(1)(vi)(B), and (a)(1)(vi)(C) of this section. In performing this assessment, an applicant must consider circumstances involving fuel or core damage or potential for large radiological releases from sources other than the reactor system. The applicant must perform an evaluation of the postulated fission product release, using the expected demonstrable barrier leak rate(s) and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with site characteristics or postulated site parameters for the license, certification, or approval being sought, including site meteorology, to evaluate the offsite radiological consequences. Applications must be based on either a mechanistic source term that is derived from physically representative models of the facility response for the circumstances involving fuel or core damage, or a bounding assessment assuming severe plant conditions such as those assessed as required by § 53.4730(a)(5)(v). A design specific fission product

release must be developed and provided for all applications. The assessment must specify any barrier(s) that are relied on for radionuclide retention. Site characteristics must comply with subpart N of this part. The analysis and evaluation must determine that—

(A) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem TEDE;

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE; and

(C) The design demonstrates acceptable dose consequence criteria are met, provided that dose consequence criteria more restrictive than those in (A) and (B) are applicable.

(2) *Facility description.* A description and analysis of the SSCs of the facility with emphasis upon performance requirements; the bases, with technical justification therefor, upon which these requirements have been established; and the evaluations required to show that safety functions will be accomplished. Reactors must reflect through their design, construction, and operation an extremely low probability for accidents that could result in the release of significant quantities of radioactive fission products. The SSC and facility descriptions must be sufficient to permit understanding of the system designs and their relationship to safety evaluations. All SSCs and facility design features must be discussed insofar as they are pertinent to the safety of the facility. These may include but are not limited to the following: the reactor core, reactor coolant system, instrumentation and control systems, electrical systems, and engineered

safety features. The following power reactor design characteristics and proposed operation will be taken into consideration by the Commission:

(i) Intended use of the reactor including the proposed maximum power level and the nature and inventory of contained radioactive materials;

(ii) The extent to which generally accepted engineering standards are applied to the design of the reactor;

(A) For codes or standards not previously endorsed or accepted by the NRC, a description and justification of the codes and standards to be used in the design of the SSCs important to safety must be provided, considering the materials, coolant, and service conditions of the design.

(B) For codes or standards previously endorsed or accepted by the NRC, a demonstration that the codes and standards to be used in the design of the SSCs important to safety will be used within their respective ranges of applicability.

(iii) The extent to which the reactor incorporates unique, unusual, or enhanced safety features having a significant bearing on the probability or consequences of accidental release of radioactive materials; and

(iv) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing the assessment of the safety features and barriers, an applicant must assume a fission product release as described in paragraph (a)(1)(vi) of this section assuming that the facility is operated at the ultimate power level contemplated.

(3) *Kinds and quantities of radioactive materials*. The kinds and quantities of radioactive materials expected to be produced in the operation and the means for

~~controlling and limiting radioactive effluents and radiation exposures within the limits set forth in 10 CFR part 20. A combination of design features and programmatic controls must, to the extent practical, be based upon sound radiation protection principles to achieve occupational doses that are as low as is reasonably achievable in accordance with 10 CFR part 20.~~

~~(4) *Design bases and principal design criteria*. Information describing the design of the facility, which must include—~~

~~(i) The principal design criteria for the facility. The principal design criteria must describe the necessary design, fabrication, construction, testing, and performance requirements for SSCs relied upon to accomplish the safety functions defined in § 53.020 and required to be included in the design under § 53.4730(a)(5)(ii). Appendix A to 10 CFR part 50, "General design criteria for nuclear power plants," establishes minimum requirements for the principal design criteria for water-cooled nuclear power plants similar in design and location to plants for which CPs have previously been issued by the Commission and provides guidance to applicants in establishing principal design criteria for other types of commercial nuclear reactors. Applicants for reactors that are not water-cooled must provide principal design criteria adapted for their designs.~~

~~(ii) The design bases and the relation of the design bases to the principal design criteria; and~~

~~(iii) Information relative to materials of construction, arrangement, and dimensions, sufficient to provide reasonable assurance that the design will conform to the design bases with adequate margin for safety.~~

~~(5) *Initiating events and accident analysis*.~~

~~(i)(A) A description identifying postulated initiating events for AOOs and DBAs using a risk-informed approach for systematically evaluating engineered systems.~~

(B) An analysis and evaluation model of the design and performance of SSCs with the objective of assessing the risk to public health and safety resulting from operation of the facility (to include the cumulative risk from all radionuclide sources on site licensed under Framework B of this part). This analysis and evaluation must include a determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of SSCs provided for the prevention of accidents and the mitigation of the consequences of accidents.

(ii) For DBAs —

(A) Acceptance criteria for safety-related SSCs to demonstrate that their performance during DBAs adequately mitigates the consequences of such events. Acceptance criteria must be associated with the performance of a safety function(s) for the design such that demonstrating compliance with the acceptance criteria can be shown to demonstrate compliance with the safety function(s) in order to demonstrate compliance with the requirements in paragraphs (a)(5)(i) and (ii) of this section.

(B) The analyses and evaluations required in paragraph (a)(5)(i) of this section must demonstrate that fission products are retained within specified barriers for each analyzed DBA or that the dose to an individual located at the exclusion area boundary or low population zone outer boundary remains below the reference values specified in paragraph (a)(1)(vi) of this section.

(C) SSCs credited to mitigate DBAs must be classified as safety related. Safety-related SSCs must be designed and located to withstand, without loss of safety function, the environments and conditions associated with the internal and external hazards associated with design-basis events, including DBAs.

(D) Applicants may elect to perform a single or multiple bounding analyses and evaluations to demonstrate the design appropriately mitigates the consequences of

~~accidents; in doing so, applicants must demonstrate that the bounding analyses or evaluations adequately envelope conditions for the full range of AOOs and DBAs with sufficient margin to account for uncertainties and differences between analytical assumptions and accident conditions.~~

~~(E) Limiting parameters that serve as acceptance criteria for the analyses of DBAs and provide the values associated with these parameters as part of the application. These acceptance criteria must demonstrate that the commercial nuclear reactor satisfies appropriate design-specific conditions and safety functions for DBAs (e.g., a fuel temperature limit below which radiological releases can be shown to be acceptable or a barrier can be shown to remain intact). The applicant or holder of a CP, OL, COL, or ML must file an annual report that describes each change to or error discovered in an evaluation model used to calculate DBA limiting parameters or in the application of such a model that affects these limiting parameters. The report must describe the nature of the change or error and its estimated effect on the safety analysis to the Commission. Such reports must be filed as specified in § 53.040, as applicable. If the change or error is significant, the applicant or licensee must provide this report within 30 days of identification and include with the report a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with other requirements in this section.~~

~~(F) An evaluation model is the calculational framework used to evaluate the behavior of the reactor system and calculated acceptance criteria for demonstrating safety during DBA conditions. It includes one or more computer programs and all other information necessary for application of the calculational framework, such as mathematical models used, assumptions included in the programs, procedure for treating the program input and output information, specification of those portions of~~

~~analysis not included in computer programs, values of parameters, and all other information necessary to specify the calculational procedure.~~

~~(iii) For normal operation and AOOs—~~

~~(A) Analyses that demonstrate that the radiological consequences of AOOs remain below the values specified in subpart D of 10 CFR part 20. SSCs required to mitigate the effects resulting from AOOs must be identified.~~

~~(B) Event sequences initiated from events identified as AOOs must not result in a more severe event (e.g., a DBA).~~

~~(C) Event sequences initiated from events identified as AOOs must not result in damage to an SSC that impairs the capability to perform other safety functions as identified in § 53.4730(a)(36), including but not limited to cooling to maintain the integrity of required systems and barriers.~~

~~(iv) For additional licensing basis events—~~

~~(A) In addition to the analysis of DBAs and AOOs required by § 53.4730(a)(1), applicants must perform assessments to identify design features or programmatic controls for enhancing the plant's capabilities to withstand, without undue risk, credible events that are either more severe than DBAs or that involve additional failures. Events include unlikely but credible events that could lead to situations beyond those considered for DBAs, multiple credible failures, including common cause failures, that prevent safety systems from performing one or more of their intended functions, or credible failure sequences that are not assessed within the scope of DBAs but are mitigated by other plant SSCs outside the scope of the credited safety function of those SSCs.~~

~~(B) For recognized initiators applicable to the design (e.g., reduction of risk from anticipated transients without scram (ATWS), loss of all alternating current power) or~~

~~complex accident sequences comparable to DBAs that may have substantial uncertainty associated with the sequence, and are of similar or greater consequence compared to a recognized initiator, design features or programmatic controls to establish supplementary protections to mitigate against these events.~~

~~(*1*) SSCs required to mitigate additional LBEs need not be classified as SR but must have appropriate treatments identified to ensure these SSCs function as specified in the analyses required in paragraph (a)(5)(iv)(A) of this section to mitigate these events.~~

~~(2) If an applicant elects to provide a bounding evaluation as described in paragraph (a)(5)(ii) of this section, that evaluation may be used to address any or all of the event(s) required as part this section provided the bounding evaluation is demonstrated to envelope these additional LBEs.~~

~~(C) For the events identified in paragraphs (a)(5)(iv)(A) and (B) of this section, performance, reliability, and availability targets for safety functions and a description of how they are met. Design standards must be identified for those SSCs performing safety functions to demonstrate that the SSCs will perform as intended.~~

~~(v) For severe accidents—~~

~~(A) A description and analysis of design features that prevent or mitigate accidents that could progress beyond the DBAs addressed in paragraph (a)(5)(ii) of this section. These accidents include those that would require analysis of how the design as a whole addresses the prevention and mitigation of severe accidents, including potential vulnerabilities to these events.~~

~~(B) [Reserved]~~

(C) In a light-water reactor, a description of how the design prevents and mitigates severe accidents based on conditions derived from operating experience and input from risk evaluations (those required in § 53.4730(a)(34)).

(D) For a non-light-water reactor design, identify severe accident conditions specific to the design and describe the measures provided in the design for preventing or mitigating such accidents, and describe the engineering judgment, insights from applicable operating experience, and input from risk evaluations described by paragraph (a)(34) of this section on which the conditions and measures are based.

(E) Descriptions of the safety features that will be engineered in the facility and any barriers that must be protected during various accidents to limit the release of radioactive material released to the environment.

(F) The applicant must perform an assessment of the severe accidents that could lead to fission product release, using the expected barrier leak rate(s) and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable site characteristics, including site meteorology, to evaluate the offsite radiological consequences.

(vi) Design features and related design criteria must be identified such that analyses demonstrate a low risk of permanent injury to the public due to the health effects of chemical hazards of licensed material.

(6) *Fire protection*. Information necessary to demonstrate compliance with § 53.4350.

(7) *Combustible gas control*. An analysis and description of the equipment and systems for combustible gas control as required by § 50.44 of this chapter.

(8) *Environmental qualification of electric equipment important to safety*. The following information must be included:

(i) A description of the program, and its implementation, required by § 53.4380(a) of this chapter for the environmental qualification of electric equipment important to safety; and

(ii) The list of electric equipment important to safety that is required by § 53.4380(d).

(9) *Role of personnel.* The following information must be included:

(i) A description of the completed assessments related to the role of personnel in ensuring safe operations considering the analyses required by § 53.730, which must include the following:

(A) Human factors engineering design requirements of § 53.730(a);

(B) Human system interface design requirements of § 53.730(b);

(C) Concept of operations of § 53.730(c); and

(D) Functional requirements analysis and function allocation of § 53.730(d);

(ii) A description of the program to be used for evaluating and applying operating experience as required by § 53.730(e);

(iii) A staffing plan and supporting analyses as required by § 53.730(f); and

(iv) The training, examination, and proficiency programs required by § 53.730(g).

(10) *Maintenance rule.* A description of the program, and its implementation, for monitoring the effectiveness of maintenance necessary to demonstrate compliance with the requirements of § 53.4210, as applicable.

(11) *Dose to members of the public.*

(i) Identify the appropriate as low as is reasonably achievable design objectives for the commercial nuclear plant, and the means to be employed, for keeping levels of radioactive material in effluents to unrestricted areas and the dose rate in unrestricted areas from the commercial nuclear plant within the design objectives during normal

reactor operations, including expected operational occurrences. The term "as low as is reasonably achievable" as used in this part means as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety and other societal and socioeconomic considerations, and in relation to the use of atomic energy in the public interest.[15]

(ii) Demonstrate that the design is adequate to satisfy the as low as is reasonably achievable design objectives during normal reactor operations, including AOOs, by providing an estimate of—

(A) The quantity of each of the principal radionuclides expected to be released annually to unrestricted areas in liquid effluents produced during normal reactor operations and the dose to the maximally exposed member of the public in unrestricted areas;

(B) The quantities of each of the principal radionuclides of the gases, halides, and particulates expected to be released annually to unrestricted areas in gaseous effluents produced during normal reactor operations and the dose to the maximally exposed member of the public in unrestricted areas; and

(C) The annual external radiation dose in unrestricted areas and the maximally exposed member of the public in unrestricted areas due to direct radiation from contained radiation sources from the commercial nuclear plant during normal reactor operations.

(12) *Post-accident radiation monitoring and protection*. The information necessary to demonstrate compliance with the technically relevant portions of the following requirements:

(i) A description of radiation and shielding design reviews of spaces around systems that may contain accident source term radioactive materials, how these

systems are designed as necessary to permit adequate access to important areas and to protect safety equipment from the radiation environment;

(ii) A description of the capability to promptly obtain and analyze samples from the reactor coolant system and containment that may contain accident source term radioactive materials without radiation exposures to any individual exceeding 5 rems to the whole body or 50 rems to the extremities. Materials to be analyzed and quantified include certain radionuclides that are indicators of the degree of core damage (e.g., noble gases, radioiodines and cesiums, and nonvolatile isotopes), hydrogen in the containment atmosphere, dissolved gases, chloride, and boron concentrations; and

(iii) A description of the capability for containment purging/venting designed to minimize the purging time consistent with ALARA principles for occupational exposure. Provide and demonstrate high assurance that the purge system will reliably isolate under accident conditions.

(13) [Reserved]

(14) *Earthquake engineering criteria*. The information necessary to demonstrate that the plant complies with the earthquake engineering criteria of appendix S to 10 CFR part 50 of this chapter in order to implement the principal design criterion corresponding to criterion 2 of appendix A to 10 CFR part 50. In implementing appendix S to 10 CFR part 50 under Framework B of this part, SSCs required to withstand the effects of the safe-shutdown earthquake ground motion or surface deformation must include all SR SSCs as defined in § 53.028. Alternatively, an applicant may propose the use of the seismic design criteria in § 53.4733.

(15) *Emergency plans*. Emergency plans complying with the requirements of § 53.4320.

(16) *State, participating Tribal, and local government cooperation in emergency planning.*

(i) All emergency plan certifications that have been obtained from the State, participating Tribal, and local governmental agencies with emergency planning responsibilities must state that—

(A) The proposed emergency plans are practicable;

(B) These agencies are committed to participating in any further development of the plans, including any required field demonstrations; and

(C) These agencies are committed to executing their responsibilities under the plans in the event of an emergency.

(ii) If certifications cannot be obtained after sustained, good faith efforts by the applicant, then the application must contain information, including a utility plan, sufficient to show that the proposed plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site.

(17) *Safety feature testing, analyses, operating experience, and prototypes.* Applications that propose nuclear reactor designs which differ significantly from light-water reactor designs that were licensed before 1997, or use simplified, inherent, passive, or other innovative means to accomplish their safety functions will be approved only if the requirements in § 53.090(c)(5) are met.

(18) *Quality assurance program.*

(i) A description of a QAP based on consideration of—

(A) Ensuring independence of the organization performing checking functions from the organization responsible for performing the functions;

(B) Performing QA/quality control functions at construction sites to the maximum feasible extent;

(C) Including QA personnel in the documented review of and concurrence in quality-related procedures associated with design, construction, and installation;

(D) Establishing criteria for determining QAP requirements;

(E) Establishing qualification requirements for QA and quality control personnel;

(F) Sizing the QA staff commensurate with its duties and responsibilities;

(G) Establishing procedures for maintenance of "as-built" documentation; and

(H) Providing a QA role in design and analysis activities.

(ii) A description of the QAP applied to the design and to be applied to the fabrication, construction, and testing of the SSCs of the facility. Subpart U under Framework B of this part sets forth the requirements for QAPs for commercial nuclear plants licensed under Framework B of this part. The description of the QAP for a commercial nuclear plant must include a discussion of how the applicable requirements of subpart U under Framework B of this part have been and will be satisfied, including a discussion of how the QAP will be implemented.

(19) *Organizational structure*. The applicant's organizational structure, allocations of responsibilities and authorities, and personnel qualifications requirements for operation.

(20) *Managerial and administrative controls*.

(i) Managerial and administrative controls to be used to assure safe operation. Subpart U under Framework B of this part sets forth the requirements for these controls for commercial nuclear plants. The information on the controls to be used for a commercial nuclear plant must include a discussion of how the applicable requirements of subpart U under Framework B of this part will be satisfied.

(ii) As applicable, provide a description of the management plan for design and construction activities, to include the following

(A) The organizational and management structure singularly responsible for direction of design and construction of the proposed plant;

(B) Technical resources directed by the applicant;

(C) Details of the interaction of entities responsible for design and construction within the applicant's organization and the manner by which the applicant will ensure close integration of the architect engineer and the commercial nuclear reactor vendor;

(D) Proposed procedures for handling the transition to operation; and

(E) The degree of top-level management oversight and technical control to be exercised by the applicant during design and construction, including the preparation and implementation of procedures necessary to guide the effort.

(21) *Preoperational testing and initial startup*. Plans for preoperational testing and initial operations.

(22) *Normal operations and maintenance*.

(i) Plans for the conduct of normal operations, including maintenance, surveillance, and periodic testing of SSCs; and

(ii) Plans for coping with emergencies, other than the plans required by § 53.4730(a)(15).

(23) *Technical specifications*.

(i) Proposed technical specifications in accordance with the requirements of § 53.4213. A summary statement of the bases or reasons for such specifications, other than those covering administrative controls, must also be included in the application, but must not become part of the technical specifications.

(ii) Each applicant for a design certification under § 53.4839 or ML under § 53.4879 must include in its application proposed generic technical specifications in

accordance with the requirements of § 53.4213 for the portion of the plant that is within the scope of the design certification or ML application.

(24) *Fitness-for-duty program.* A description of the FFD program required by 10 CFR part 26 and its implementation.

(25) *Multi-unit sites.* For commercial nuclear reactors to be operated on multi-unit sites, an evaluation of the potential hazards to the SSCs important to safety of operating units resulting from construction activities, as well as a description of the managerial and administrative controls to be used to provide assurance that the limiting conditions for operation are not exceeded as a result of construction activities at the multi-unit sites.

(26) *Technical qualifications.* The technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter.

(27) *Training program.* A description of the training programs required by § 53.830.

(28) *Physical security plan.*

(i) A physical security plan that describes how the applicant will demonstrate compliance with the requirements of § 53.4330 (and 10 CFR part 11, if applicable, including the identification and description of jobs as required by § 11.11(a) of this chapter, at the proposed facility). The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with the requirements of § 53.4330, and 10 CFR parts 11 and 73, if applicable; and

(ii) A description of the implementation of the physical security plan.

(29) *Safeguards, security, and related training and qualifications.*

(i) A safeguards contingency plan demonstrating compliance with the criteria set forth in appendix C to 10 CFR part 73. The safeguards contingency plan must include plans for dealing with threats, thefts, and radiological sabotage, as defined in

10 CFR part 73, relating to the SNM and nuclear facilities licensed under this chapter and in the applicant's possession and control. Each application for this type of license must include the information contained in the applicant's safeguards contingency plan.[16] (Implementing procedures required for this plan need not be submitted for approval).

(ii) A training and qualification plan that describes how the applicant will demonstrate compliance with the criteria set forth in § 73.100 of this chapter or appendix B to 10 CFR part 73;

(iii) A cyber security plan in accordance with the criteria set forth in § 73.54 or § 73.110 of this chapter;

(iv) A description of the implementation of the safeguards contingency plan, security training and qualification plan, and cyber security plan; and

(v) Each applicant who prepares a physical security plan, a safeguards contingency plan, a security training and qualification plan, or a cyber security plan must protect the plans and other related safeguards information against unauthorized disclosure under the requirements of §§ 73.21 and 73.22 of this chapter.

(30) *Operating experience*. The information necessary to demonstrate how operating experience insights have been incorporated into the plant design, as applicable.

(31) *Radiation protection program*. A description of the radiation protection program required by § 53.4310 and its implementation.

(32) *Criticality accident requirements*. The information included must demonstrate how the applicant will comply with requirements for criticality accidents in § 53.440(m).

(33) *Minimization of contamination*. The information required by § 20.1406 of this chapter.

(34) *Description of risk evaluation*. A description of the risk evaluation developed for the commercial nuclear plant and its results. The risk evaluation must be based on—

(i) A PRA; or

(ii) An alternative evaluation for risk insights, provided that—

(A) The analysis of a postulated bounding event demonstrates that the maximum consequence at any point within the area between the commercial nuclear plant's exclusion area boundary (EAB) and 16.1 kilometers (10 miles) from the EAB is less than 25 mSv (2.5 rem) TEDE in the first year following the release; and

(B) The identification of the postulated bounding event is determined by a systematic and comprehensive search for severe accident scenarios that includes—

(*1*) All radiological sources at the commercial nuclear plant;

(*2*) All plant operating states;

(*3*) Relevant internal and external hazards;

(*4*) Combinations of plant equipment failures including common-cause failures, hazard-induced equipment failures, and equipment failures caused by severe accident phenomena; and

(*5*) Human errors of commission and omission.

(35) *Aircraft impact assessment*.

(i) *Assessment requirements*.

(A) *Assessment*. Applicants must perform a design-specific assessment of the effects on the facility of the impact of a large, commercial aircraft. Using realistic analyses, the applicant must identify and incorporate into the design those design features and functional capabilities to show that, with reduced use of operator actions—

(*1*) The capability to remove heat from the reactor fuel is retained, or the SSCs associated with the confinement of radionuclides remains functional; and

(*2*) For facilities that rely on active cooling or submergence of spent reactor fuel in a water-filled spent fuel pool to protect public health and safety, spent fuel cooling or spent fuel pool integrity is maintained.

(B) *Aircraft impact characteristics*. The assessment must be based on the beyond-design-basis impact of a large, commercial aircraft used for long distance flights in the United States, with aviation fuel loading typically used in such flights, and an impact speed and angle of impact considering the ability of both experienced and inexperienced pilots to control large, commercial aircraft at the low altitude representative of a commercial nuclear plant's low profile.

(ii) *Content of application*. The Preliminary or Final Safety Analysis Report, as applicable, must include a description of—

(A) The design features and functional capabilities identified in § 53.4730(a)(35)(i)(A); and

(B) How the design features and functional capabilities identified in paragraph (i)(A) of this section satisfy the assessment requirements in paragraph (i)(A) of this section.

(36) *Containment requirements*. A description of the barriers to radionuclide release credited for the facility.

(i) Non-LWR applicants may elect to provide a functional containment; that is, those applicants may designate a set of barriers taken together that effectively limit the physical transport and release of radionuclides to the environment for events that demonstrate compliance with analysis requirements in § 53.4730(a)(1)(vi), (a)(5)(ii), and (a)(5)(iii). SSCs designated as part of the functional containment (and those SSCs that

~~support these designated SSCs) used in the analyses of DBAs must be classified as SR. These SR SSCs should be qualified to demonstrate they perform as assumed in the analyses (e.g., leakage testing if leakage is an assumption related to mitigating radionuclide release).~~

~~(ii) Water-cooled reactor applicants must have a primary containment to in part fulfill the function of barriers to radionuclide release, and this containment must—~~

~~(A) Demonstrate compliance with the requirements set forth in appendix J to 10 CFR part 50, including providing a description of the primary containment leakage rate testing program, and its implementation;~~

~~(B) If technically relevant, provide containment isolation systems that—~~

~~(*1*) Ensure all non-essential systems are isolated automatically by the containment isolation system;~~

~~(2) For each non-essential penetration (except instrument lines), have two isolation barriers in series;~~

~~(*3*) Do not result in reopening of the containment isolation valves upon reset of the isolation signal;~~

~~(*4*) Utilize a containment set point pressure for initiating containment isolation as low as is compatible with normal operation; and~~

~~(*5*) Include automatic closing on a high radiation signal for all systems that provide a path to the environs.~~

~~(C) Provide a capability for containment purging/venting designed to minimize the purging time consistent with ALARA principles for occupational exposure. Provide and demonstrate high assurance that the purge system will reliably isolate under accident conditions.~~

(37) *Water-cooled reactor requirements*. For applications for water-cooled commercial nuclear plants, the information must include—

(i) *Emergency core cooling systems*. Analysis and evaluation of emergency core cooling system (ECCS) cooling performance and the need for high-point vents following postulated loss-of-coolant accidents must be performed in accordance with the requirements of §§ 50.46 and 50.46a of this chapter, as applicable;

(ii) *Codes and standards*. For boiling and pressurized water-cooled reactors, a description of the program(s), and their implementation, necessary to ensure that the systems and components demonstrate compliance with the requirements of the ASME BPV Code and the ASME OM Code in accordance with § 50.55a of this chapter;

(iii) *Pressurized thermal shock and fracture toughness requirements*. A description of protection provided against pressurized thermal shock events, including projected values of the reference temperature for reactor vessel beltline materials as defined in §§ 50.60 and 50.61(b)(1) and (b)(2) of this chapter, as applicable;

(iv) *Anticipated transients without scram*. For light-water reactors, information demonstrating how the applicant will comply with requirements for reduction of risk from ATWS events in § 50.62 of this chapter;

(v) *Station blackout*. For light-water reactors, the coping analyses, and any design features necessary to address station blackout, as described in § 50.63 of this chapter;

(vi) *Reactor vessel material surveillance*. A description of the reactor vessel material surveillance program required by appendix H to 10 CFR part 50 and its implementation;

(vii) *Resolution of generic issues*. Proposed technical resolutions of all generic issues identified since July 21,1999, unresolved safety issues, and medium- and high-

priority generic safety issues identified before July 21,1999, that are relevant to the design. These issues are based upon the applicant's review of publicly available information published up to 6 months before the docket date of the application (for example, the issues listed in NRC's NUREG-0933, "Resolution of Generic Safety Issues."); and

(viii) *Requirements from light-water-reactor operating experience*. The information with respect to compliance with technically relevant portions of the following requirements:

(A) A description of the pressurizer heater power supply and associated motive and control power interfaces indicating how it is sufficient to establish and maintain natural circulation in hot standby conditions with only onsite power available (applicable to PWRs only);

(B) A description of the power supplies for pressurizer relief valves, block valves, and level indicators with provisions such that—

(*1*) Level indicators are powered from vital buses;

(*2*) Motive and control power connections to the emergency power sources are through devices qualified in accordance with requirements applicable to systems important to safety; and

(*3*) Electric power is provided from emergency power sources (Applicable to PWR's only); and

(C) A description of any test program and associated model development and tests conducted to qualify reactor coolant system relief and safety valves and, for PWR's, PORV block valves, for all fluid conditions expected under operating conditions, transients, and accidents. Consideration of ATWS conditions must be included in the

test program. Actual testing under ATWS conditions need not be carried out until subsequent phases of the test program are developed.

(b) [Reserved]

[15] A guide for the design objectives for satisfying the criteria as low as is reasonably achievable is that the dose to the maximally exposed member of the public in unrestricted areas not exceed 10 mrem/year TEDE. The 10 mrem/year dose criteria should not be construed as a dose limit.

[16] A physical security plan that contains all the information required in both § 73.55 or § 73.100 of this chapter and appendix C to 10 CFR part 73 satisfies the requirement for a contingency plan.

§ 53.4731 Risk-informed classification of structures, systems, and components.

(a) *Definitions.*

Risk-Informed Safety Class (RISC)–1 structures, systems, and components (SSCs) means SR SSCs that perform safety-significant functions.

Risk-Informed Safety Class (RISC)–2 structures, systems, and components (SSCs) means NSR SSCs that perform safety-significant functions.

Risk-Informed Safety Class (RISC)–3 structures, systems, and components (SSCs) means SR SSCs that perform low safety-significant functions.

Risk-Informed Safety Class (RISC)–4 structures, systems, and components (SSCs) means NSR SSCs that perform low safety-significant functions.

Safety-significant function means a function whose degradation or loss could result in a significant adverse effect on defense-in-depth, safety margin, or risk.

(b) *Applicability and scope of risk-informed treatment of SSCs and submittal/approval process.*

(1) This section describes alternative requirements for the SSCs of a commercial nuclear plant. Holders of a CP, OL, COL, or ML under Framework B of this part that develop a PRA in accordance with the requirements of § 53.4730(a)(34)(i) may voluntarily comply with the requirements in this section. Compliance with the requirements in this section may be proposed when applying for a standard design certification or approval, CP, OL, COL, or ML under Framework B of this part. For RISC–

3 and RISC-4 SSCs, the requirements in this section are an alternative to compliance with the following:

(i) 10 CFR part 21;

(ii) For licensees of facilities with high point vents under § 53.4730(a)(37)(i), that portion of § 50.46a(b) of this chapter that imposes QA requirements;

(iii) Section 53.4380;

(iv) Section 53.4105(b);

(v) For licensees of LWR facilities, the IST requirements in § 50.55a(f) of this chapter; and the ISI, and repair and replacement (with the exception of fracture toughness), requirements for ASME Class 2 and Class 3 SSCs in § 50.55a(g) of this chapter;

(vi) Section 53.4210, except for paragraph (a)(4);

(vii) Section 53.6330;

(viii) Section 53.6340;

(ix) Subpart U under Framework B of this part; and

(x) For licensees of water-cooled reactors, the Type B and Type C leakage testing requirements in both Options A and B of appendix J to 10 CFR part 50, for penetrations and valves satisfying the following criteria:

(A) Containment penetrations that are either 1-inch nominal size or less, or continuously pressurized; or

(B) Containment isolation valves that satisfy one or more of the following criteria:

(*1*) The valve is required to be open under accident conditions to prevent or mitigate core damage events;

(*2*) The valve is normally closed and in a physically closed, water-filled system;

(*3*) The valve is in a physically closed system whose piping pressure rating exceeds the containment design pressure rating and is not connected to the reactor coolant pressure boundary; or

(*4*) The valve is 1-inch nominal size or less.

(2) A licensee voluntarily choosing to implement this section must submit the following as part of its application for a CP, OL, COL, or ML under Framework B of this part or as an application for license amendment under § 53.6010:

(i) A description of the process for categorization of RISC–1, RISC–2, RISC–3 and RISC–4 SSCs;

(ii) A description of the measures taken to assure that the quality and level of detail of the systematic processes that evaluate the plant for internal and external events during normal operation, low power, and shutdown (including the plant-specific PRA, margins-type approaches, or other systematic evaluation techniques used to evaluate severe accident vulnerabilities) are adequate for the categorization of SSCs;

(iii) Results of the PRA review process conducted to demonstrate compliance with paragraph (c)(1)(i) of this section; and

(iv) A description of, and basis for acceptability of, the evaluations to be conducted to demonstrate compliance with paragraph (c)(1)(iv) of this section. The evaluations must include the effects of common cause interaction susceptibility, and the potential impacts from known degradation mechanisms for both active and passive functions, and address internally and externally initiated events and plant operating modes (e.g., full power and shutdown conditions).

(3) The Commission will approve a licensee's implementation of this section if it determines that the process for categorization of RISC–1, RISC–2, RISC–3, and RISC–

4 SSCs demonstrates compliance with the requirements of paragraph (c) of this section by issuing a license amendment approving the licensee's use of this section.

(4) An applicant choosing to implement this section must include the information in paragraph (b)(2) of this section as part of application. The Commission will approve an applicant's implementation of this section if it determines that the process for categorization of RISC-1, RISC-2, RISC-3, and RISC-4 SSCs demonstrates compliance with the requirements of paragraph (c) of this section.

(c) *SSC Categorization Process*.

(1) SSCs must be categorized as RISC-1, RISC-2, RISC-3, or RISC-4 SSCs using a categorization process that determines if an SSC performs one or more safety-significant functions and identifies those functions. The process must—

(i) Consider results and insights from the plant-specific PRA. This PRA must, at a minimum, model severe accident scenarios resulting from internal initiating events occurring at full power operation. The PRA must be of sufficient quality and level of detail to support the categorization process and must be subjected to a peer review process assessed against a standard or set of acceptance criteria that is endorsed by the NRC;

(ii) Determine SSC functional importance using an integrated, systematic process for addressing initiating events (internal and external), SSCs, and plant operating modes, including those not modeled in the plant-specific PRA. The functions to be identified and considered include design bases functions and functions credited for mitigation and prevention of severe accidents. All aspects of the integrated, systematic process used to characterize SSC importance must reasonably reflect the current plant configuration and operating practices, and applicable plant and industry operational experience;

(iii) Maintain defense in depth;

~~(iv) Include evaluations that provide reasonable confidence that for SSCs categorized as RISC–3, sufficient safety margins are maintained and that any potential increases in risk resulting from changes in treatment permitted by implementation of paragraphs (b)(1) and (d)(2) of this section are small; and~~

~~(v) Be performed for entire structures and systems, not for selected components within a structure or system.~~

~~(2) The SSCs must be categorized by an Integrated Decision-Making Panel (IDP) staffed with expert, plant-knowledgeable members whose expertise includes, at a minimum, PRA, safety analysis, plant operation, design engineering, and system engineering.~~

~~(d) *Alternative treatment requirements*.~~

~~(1) *RISC–1 and RISC–2 SSCs*. The licensee or applicant must ensure that RISC–1 and RISC–2 SSCs perform their functions consistent with the categorization process assumptions by evaluating treatment being applied to these SSCs to ensure that it supports the key assumptions in the categorization process that relate to their assumed performance.~~

~~(2) *RISC–3 SSCs*. The licensee or applicant must ensure, with reasonable confidence, that RISC–3 SSCs remain capable of performing their SR functions under design-basis conditions, including seismic conditions and environmental conditions and effects throughout their service life. The treatment of RISC–3 SSCs must be consistent with the categorization process. Inspection and testing, and corrective action must be provided for RISC–3 SSCs.~~

~~(i) *Inspection and testing*. Periodic inspection and testing activities must be conducted to determine that RISC–3 SSCs will remain capable of performing their SR functions under design-basis conditions.~~

(ii) *Corrective action.* Conditions that would prevent a RISC-3 SSC from performing its SR functions under design-basis conditions must be corrected in a timely manner. For significant conditions adverse to quality, measures must be taken to provide reasonable confidence that the cause of the condition is determined and corrective action taken to preclude repetition.

(e) *Feedback and process adjustment.*

(1) *RISC-1, RISC-2, RISC-3 and RISC-4 SSCs.* The licensee must review changes to the plant, operational practices, applicable plant and industry operational experience, and, as appropriate, update the PRA and SSC categorization and treatment processes. The licensee must perform this review in a timely manner but not less often than once every 48 months.

(2) *RISC-1 and RISC-2 SSCs.* The licensee must monitor the performance of RISC-1 and RISC-2 SSCs. The licensee must make adjustments as necessary to either the categorization or treatment processes so that the categorization process and results are maintained valid.

(3) *RISC-3 SSCs.* The licensee must consider data collected in paragraph (d)(2)(i) of this section for RISC-3 SSCs to determine if there are any adverse changes in performance such that the SSC unreliability values approach or exceed the values used in the evaluations conducted to demonstrate compliance with paragraph (c)(1)(iv) of this section. The licensee must make adjustments as necessary to the categorization or treatment processes so that the categorization process and results are maintained valid.

(f) *Program documentation, change control and records.*

(1) The licensee or applicant must document the basis for its categorization of any SSC under paragraph (c) of this section before removing any requirements under paragraph (b)(1) of this section for those SSCs.

(2) Following implementation of this section, licensees and applicants must update their FSAR to reflect which SSCs have been categorized as RISC-1, RISC-2, RISC-3, or RISC-4, in accordance with § 53.6045.

(3) When a licensee first implements this section for an SSC, changes to the FSAR for the implementation of the changes in accordance with paragraph (d) of this section need not include a supporting § 53.6050 evaluation of the changes directly related to implementation. Thereafter, changes to the programs and procedures for implementation of paragraph (d), as described in the FSAR, may be made if the requirements of this section and § 53.6050 continue to be met.

(4) When a licensee first implements this section for an SSC, changes to the QA plan for the implementation of the changes under paragraph (d) of this section need not include a supporting § 53.6065(d) review of the changes directly related to implementation. Thereafter, changes to the programs and procedures for implementation of paragraph (d), as described in the QA plan may be made if the requirements of this section and § 53.6065(d) continue to be met.

(g) *Reporting*. The licensee must submit an LER under § 53.6340 for any event or condition that prevented, or would have prevented, a RISC–1 or RISC–2 SSC from performing a safety-significant function.

§ 53.4733 Seismic design alternatives.

(a) *Purpose*. This section provides alternative seismic design requirements to those in appendix S to 10 CFR part 50. Applicants and licensees not using the seismic design alternatives in this section must demonstrate compliance with the requirements in

appendix S to 10 CFR part 50. SSCs important to safety must be able to withstand the effects of earthquakes, commensurate with their safety significance, without loss of capability to perform their safety functions.

(b) *Definitions.* For the purpose of this section —

Design-Basis Ground Motions (DBGMs) are the sets of vibratory ground motions for which certain SSCs must be designed to remain functional.

Operating basis earthquake (OBE) ground motion is the vibratory ground motion for which those features of the commercial nuclear plant necessary for continued operation without undue risk to the health and safety of the public are designed to remain functional. The OBE ground motion is used in § 53.4215, "Response to seismic events."

Response spectrum means a plot of the maximum responses (acceleration, velocity, or displacement) of idealized single-degree-of-freedom oscillators as a function of the natural frequencies of the oscillators for a given damping value. The response spectrum is calculated for a specified vibratory motion input at the oscillators' supports.

Surface deformation means distortion of geologic strata at or near the ground surface by the processes of folding or faulting as a result of various earth forces. Tectonic surface deformation is associated with earthquake processes.

(c) *Vibratory ground motion.*

(1) *Design-basis ground motions.*

(i) The DBGMs must be derived from the site GMRS developed in accordance with § 53.3525, by taking into consideration the principal design criteria for SSCs that are important to safety. The horizontal component of each DBGM in the free-field at the foundation level of the structures must be an appropriate response spectrum that is determined based on the risk-significance of SSCs and their safety functions. In view of

~~the limited data available on vibratory ground motion of strong earthquakes, it is acceptable that the design response spectra be smoothed spectra.~~

~~(ii) The commercial nuclear plant must be designed so that, if the DBGMs occur, the SSCs important to safety must remain functional and within applicable stress, strain, and deformation limits.~~

~~(iii) In addition to seismic loads, applicable concurrent normal operating, functional, and accident-induced loads must be taken into consideration in the design of the SSCs important to safety.~~

~~(iv) The design of the commercial nuclear plant must take into consideration the possible effects of seismic-induced ground disruption, such as fissuring, lateral spreads, differential settlement, liquefaction, and landsliding, on the facility foundations.~~

~~(v) The SSCs important to safety must be demonstrated through design, testing, or qualification methods to be able to fulfill those safety functions during and after the vibratory ground motion associated with the DBGMs.~~

~~(vi) The evaluation of SSCs required by this section must show that the SSCs are able to function during and following earthquake ground motions and must appropriately take into consideration soil-structure interaction effects and the expected duration of vibratory motion. It is permissible to design for strain limits in excess of yield strain in some of these SSCs that are important to safety during the DBGMs and under the postulated concurrent loads, provided the necessary safety functions are maintained.~~

~~(2) *Operating basis earthquake ground motion.* The OBE ground motion must be characterized by response spectra. The value of the OBE ground motion must be set to one-third or less of the DBGM response spectra.~~

(3) *Required seismic instrumentation.* Suitable instrumentation must be provided so that the seismic response of commercial nuclear plant SSCs important to safety can be evaluated promptly after an earthquake.

(d) *Surface deformation.*

(1) The potential for surface deformation must be considered in the design of the commercial nuclear plant by providing reasonable assurance that in the event of deformation, SSCs important to safety will remain functional.

(2) In addition to surface deformation induced loads, the design of SSCs must take into account, commensurate with safety significance, seismic loads, and applicable concurrent functional and accident induced loads.

(3) The design provisions for surface deformation must be based on its postulated occurrence in any direction and azimuth and under any part of the commercial nuclear plant, unless evidence indicates this assumption is not appropriate, and must take into consideration the estimated rate at which the surface deformation may occur.

(e) *Seismically induced floods and water waves and other design conditions.* Seismically induced floods and water waves from either locally or distantly generated seismic activity and other design conditions determined pursuant to § 53.3525 must be taken into consideration in the design of the commercial nuclear plant to prevent undue risk to the health and safety of the public.

§ 53.4740 Limited work authorizations.

(a) *Request for limited work authorization.*

(1) Any person to whom the Commission may otherwise issue either a license or permit related to a commercial nuclear plant may request an LWA allowing that person to perform the driving of piles, subsurface preparation, placement of backfill, concrete, or

permanent retaining walls within an excavation, installation of the foundation, including placement of concrete, any of which are for an SSC of the facility for which either a CP or COL is otherwise required under § 53.4110 of this part.

(2) An application for an LWA may be submitted as part of a complete application for a CP or COL in accordance with § 2.101(a)(1) through (a)(5) of this chapter, or as a partial application in accordance with § 2.101(a)(9) of this chapter. An application for an LWA by the holder of an early site permit must be submitted as a complete application in accordance with § 2.101(a)(1) through (a)(4) of this chapter.

(3) The application must include—

(i) A Safety Analysis Report required by § 53.4756, § 53.4909, or § 53.5016, as applicable, a description of the activities requested to be performed, and the design and construction information otherwise required by the Commission's rules and regulations to be submitted for a CP or COL under Framework B of this part but limited to those portions of the facility that are within the scope of the LWA;

(A) The Safety Analysis Report must demonstrate that activities conducted under the LWA will be conducted in compliance with the technically relevant Commission requirements in 10 CFR chapter I applicable to the design of those portions of the facility within the scope of the LWA.

(B) [Reserved]

(ii) An environmental report in accordance with § 51.49 of this chapter; and

(iii) A plan for redress of activities performed under the LWA, should limited work activities be terminated by the holder or the LWA be revoked by the NRC or upon effectiveness of the Commission's final decision denying the associated CP or COL application, as applicable.

(b) *Issuance of limited work authorization.*

(1) The Director, Office of Nuclear Reactor Regulation may issue an LWA only after—

(i) The NRC staff issues the final environmental impact statement for the LWA in accordance with subpart A of 10 CFR part 51;

(ii) The presiding officer makes the finding in § 51.105(c) or § 51.107(d) of this chapter, as applicable;

(iii) The Director determines that the applicable standards and requirements of the ActEA, and the Commission's regulations applicable to the activities to be conducted under the LWA, have been met. The applicant is technically qualified to engage in the activities authorized. Issuance of the LWA will provide reasonable assurance of adequate protection to public health and safety and will not be inimical to the common defense and security; and

(iv) The presiding officer finds that there are no unresolved safety issues relating to the activities to be conducted under the LWA that would constitute good cause for withholding the authorization.

(2) Each LWA will specify the activities that the holder is authorized to perform.

(c) *Effect of limited work authorization.* Any activities undertaken under an LWA are entirely at the risk of the applicant and, except as to the matters determined under paragraph (b)(1) of this section, the issuance of the LWA has no bearing on the issuance of a CP or COL with respect to the requirements of the ActEA and rules, regulations, or orders issued under the ActEA. The environmental impact statement for a CP or COL application for which an LWA was previously issued will not address, and the presiding officer will not consider, the sunk costs of the holder of the LWA in determining the proposed action (i.e., issuance of the CP or COL).

(d) *Implementation of redress plan*. If construction is terminated by the holder, the underlying application is withdrawn by the applicant or denied by the NRC, or the LWA is revoked by the NRC, then the holder must begin implementation of the redress plan in a reasonable time. The holder must also complete the redress of the site no later than 18 months after termination of construction, revocation of the LWA, or upon effectiveness of the Commission's final decision denying the associated CP application or the associated COL application, as applicable.

§ 53.4750 Early site permits.

Sections 53.4750 through 53.4798 set out the requirements and procedures applicable to Commission issuance of an early site permit for approval of a site for a commercial nuclear plant, which may consist of one or more reactor units separate from the filing of an application for a CP or COL for the facility.

Commented [A407]: This phrase is unnecessary due to the definition of "commercial nuclear plant" in 53.020.

§ 53.4753 Filing of applications.

Any person who may apply for a CP or for a COL under Framework B of this part, may file an application for an early site permit with the Director, Office of Nuclear Reactor Regulation. An application for an early site permit may be filed notwithstanding the fact that an application for a CP or a COL has not been filed in connection with the site for which a permit is sought.

§ 53.4754 Contents of applications for early site permits; general information.

The application must contain all of the information required by § 53.4709 (a) through (d) and (j).

§ 53.4756 Contents of applications for early site permits; technical information.

(a) The application must contain—

(1) A Site Safety Analysis Report that must include the following:

(i) The specific number, type, and thermal power level of the facilities, or range of possible facilities, for which the site may be used;

(ii) The anticipated maximum levels of radiological and thermal effluents each facility will produce;

(iii) The type of cooling systems, including intakes and outflows, where appropriate, that may be associated with each facility;

(iv) The information required by § 53.4730(a)(1)(i) through (v);

(v) A facility description that demonstrates compliance with the requirements associated with § 53.4730(a)(2) and the assessment required in § 53.4730(a)(1)(vi);

(vi) Information demonstrating that site characteristics are such that adequate security plans and measures can be developed;

(vii) A description of the QAP required by subpart U applied to site-related activities for the future design, fabrication, construction, and testing of the SSCs of a facility or facilities that may be constructed on the site; and

(viii) For water-cooled reactor applicants, the information necessary to address the requirements associated with § 53.4730(a)(37)(viii).

(2) A complete environmental report as required by § 51.50(b) of this chapter;

(b)(1) The Site Safety Analysis Report must identify physical characteristics of the proposed site, such as egress limitations from the area surrounding the site, that could pose a significant impediment to the development of emergency plans. If physical characteristics are identified that could pose a significant impediment to the development of emergency plans, the application must identify measures that would, when implemented, mitigate, or eliminate the significant impediment.

(2) The Site Safety Analysis Report may also—

(i) Propose major features of the emergency plans, in accordance with the pertinent standards of § 53.4320, such as the exact size and configuration of the EPZs, for review and approval by the NRC, in consultation with FEMA, as applicable, in the absence of complete and integrated emergency plans; or

(ii) Propose complete and integrated emergency plans for review and approval by the NRC, in consultation with FEMA, as applicable, in accordance with the applicable standards of § 53.4320. To the extent approval of emergency plans is sought, the application must contain the information required by § 53.4709(g).

(3) Emergency plans submitted under paragraph (b)(2)(ii) of this section must include the proposed inspections, tests, and analyses that the holder of a COL referencing the early site permit must perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will be operated in conformity with the emergency plans, the provisions of the ActEA, and the Commission's rules and regulations. Major features of an emergency plan submitted under paragraph (b)(2)(i) of this section may include proposed ITAAC.

(4) Under paragraphs (b)(1) and (b)(2)(i) of this section, the Site Safety Analysis Report must include, where appropriate, a description of contacts and arrangements made with Federal, State, participating Tribal and local governmental agencies with emergency planning responsibilities. The Site Safety Analysis Report must contain any certifications that have been obtained. If these certifications, where appropriate, cannot be obtained, the Site Safety Analysis Report must contain information, including a utility plan, sufficient to show that the proposed plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological

emergency at the site. Under the option set forth in paragraph (b)(2)(ii) of this section, the applicant must make good faith efforts, where appropriate, to obtain from the same governmental agencies certifications that—

(i) The proposed emergency plans are practicable;

(ii) These agencies are committed to participating in any further development of the plans, including any required field demonstrations; and

(iii) That these agencies are committed to executing their responsibilities under the plans in the event of an emergency.

(c) An applicant may request that an LWA under § 53.4740 be issued in conjunction with the early site permit. The application must include the information otherwise required by § 53.4740.

(d) Each applicant for an early site permit under Framework B of this part must protect safeguards information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

§ 53.4759 Review of applications.

(a) *Standards for review of applications.* Applications filed under Framework B of this part will be reviewed according to the applicable standards set out in Framework B of this part. In addition, the Commission must prepare an environmental impact statement during review of the application, in accordance with the applicable provisions of 10 CFR part 51. The Commission must determine, after consultation with FEMA as applicable, whether the information required of the applicant by § 53.4756(b)(1) shows that there is no significant impediment to the development of emergency plans that cannot be mitigated or eliminated by measures proposed by the applicant, whether any major features of emergency plans submitted by the applicant under § 53.4756(b)(2)(i) are acceptable in accordance with the applicable standards of § 53.4320, and whether

any emergency plans submitted by the applicant under § 53.4756(b)(2)(ii) provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

(b) *Administrative review of applications; hearings.* An early site permit application is subject to all procedural requirements in 10 CFR part 2, including the requirements for docketing in § 2.101(a)(1) through (4) of this chapter, and the requirements for issuance of a notice of hearing in § 2.104(a) and (d) of this chapter, provided that the designated sections may not be construed to require that the environmental report, or draft or final environmental impact statement include an assessment of the benefits of construction and operation of the reactor or reactors, or an analysis of alternative energy sources. The presiding officer in an early site permit hearing must not admit contentions proffered by any party concerning an assessment of the benefits of construction and operation of the reactor or reactors, or an analysis of alternative energy sources if those issues were not addressed by the applicant in the early site permit application. All hearings conducted on applications for early site permits filed under Framework B of this part are governed by the procedures contained in subparts C, G, L, and N of 10 CFR part 2, as applicable.

§ 53.4765 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application for an early site permit to the ACRS. The ACRS must report on those portions of the application which concern safety.

§ 53.4768 Issuance of early site permit.

(a) After conducting a hearing under § 53.4759(b) and receiving the report to be submitted by the ACRS under § 53.4765, the Commission may issue an early site permit, in the form the Commission deems appropriate, if the Commission finds that —

~~(1) An application for an early site permit demonstrates compliance with the applicable standards and requirements of the Act~~EA and the Commission's regulations;

~~(2) Notifications, if any, to other agencies or bodies have been duly made;~~

~~(3) There is reasonable assurance that the site is in conformity with the provisions of the Act~~EA and the Commission's regulations;

~~(4) The applicant is technically qualified to engage in any activities authorized;~~

~~(5) The proposed ITAAC, including any on emergency planning, are necessary and sufficient, within the scope of the early site permit, to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act~~EA, and the Commission's regulations;

~~(6) Issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public;~~

~~(7) Any significant adverse environmental impact resulting from activities requested under § 53.4756(c) can be redressed; and~~

~~(8) The findings required by subpart A of 10 CFR part 51 have been made.~~

~~(b) The early site permit must specify the site characteristics, design parameters, and terms and conditions of the early site permit the Commission deems appropriate. Before issuance of either a CP or COL referencing an early site permit, the Commission must find that any relevant terms and conditions of the early site permit have been met. Any terms or conditions of the early site permit that could not be met by the time of issuance of the CP or COL, must be set forth as terms or conditions of the CP or COL.~~

~~(c) The early site permit must specify those § 53.4740(b) activities requested under § 53.4756(c) that the permit holder is authorized to perform.~~

~~§ 53.4771 Extent of activities permitted.~~

If the activities authorized by § 53.4768(c) are performed and the site is not referenced in an application for a CP or a COL issued under Framework B of this part while the permit remains valid, then the early site permit remains in effect solely for the purpose of site redress, and the holder of the permit must redress the site under the terms of the site redress plan required by § 53.4756(c). If, before redress is complete, a use not envisaged in the redress plan is found for the site or parts thereof, the holder of the permit must carry out the redress plan to the greatest extent possible consistent with the alternate use.

§ 53.4774 Duration of permit.

(a) Except as provided in paragraph (b) of this section, an early site permit issued under this subpart may be valid for not less than 10, nor more than 20 years from the date of issuance.

(b) An early site permit continues to be valid beyond the date of expiration in any proceeding on a CP application or a COL application that references the early site permit and is docketed before the date of expiration of the early site permit, or, if a timely application for renewal of the permit has been docketed before the Commission has determined whether to renew the permit.

(c) An applicant for a CP or COL may, at its own risk, reference in its application a site for which an early site permit application has been docketed but not granted.

(d) Upon issuance of a CP or COL, a referenced early site permit is subsumed, to the extent referenced, into the CP or COL.

§ 53.4777 Limited work authorization after issuance of early site permit.

A holder of an early site permit may request an LWA under § 53.4756(c).

§ 53.4780 Transfer of early site permit.

An application to transfer an early site permit will be processed under § 53.6070.

§ 53.4783 Application for renewal.

(a) Not less than 12, nor more than 36 months before the expiration date stated in the early site permit, or any later renewal period, the permit holder may apply for a renewal of the permit. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application.

(b) Any person whose interests may be affected by renewal of the permit may request a hearing on the application for renewal. The request for a hearing must comply with § 2.309 of this chapter. If a hearing is granted, notice of the hearing will be published in accordance with § 2.309 of this chapter.

(c) An early site permit, either original or renewed, for which a timely application for renewal has been filed, remains in effect until the Commission has determined whether to renew the permit. If the permit is not renewed, it continues to be valid in certain proceedings in accordance with the provisions of § 53.4774(b).

(d) The Commission must refer a copy of the application for renewal to the ACRS. The ACRS must report on those portions of the application which concern safety and must apply the criteria set forth in § 53.4786.

§ 53.4786 Criteria for renewal.

(a) The Commission must grant the renewal if it determines that—

(1) The site complies with the Act<u>EA</u>, the Commission's regulations, and orders applicable and in effect at the time the site permit was originally issued; and

(2) Any new requirements the Commission may wish to impose—

(i) Are necessary for adequate protection to public health and safety or common defense and security;

(ii) Are necessary for compliance with the Commission's regulations and orders applicable and in effect at the time the site permit was originally issued; or

(iii) Will provide a substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementation of those requirements are justified in view of this increased protection.

(b) A denial of renewal for failure to comply with the provisions of § 53.4786(a) does not bar the permit holder or another applicant from filing a new application for the site which proposes changes to the site or the way that it is used to correct the deficiencies cited in the denial of the renewal.

§ 53.4789 Duration of renewal.

Each renewal of an early site permit may be for not less than 10, nor more than 20 years, plus any remaining years on the early site permit then in effect before renewal.

§ 53.4792 Use of site for other purposes.

A site for which an early site permit has been issued under this subpart may be used for purposes other than those described in the permit, including the location of other types of energy facilities. The permit holder must inform the Director, Office of Nuclear Reactor Regulation (Director), of any significant uses for the site, which have not been approved in the early site permit. The information about the activities must be given to the Director at least 30 days in advance of any actual construction or site modification for the activities. The information provided could be the basis for imposing new requirements on the permit, under the provisions of § 53.4798. If the permit holder informs the Director that the holder no longer intends to use the site for a commercial nuclear plant, the Director may terminate the permit.

§ 53.4798 Finality of early site permit determinations.

(a) *Commission finality.*

(1) While an early site permit is in effect under § 53.4774 or § 53.4789, the Commission may not change or impose new site characteristics, design parameters, or terms and conditions, including emergency planning requirements, on the early site permit unless the Commission —

(i) Determines that a modification is necessary to bring the permit or the site into compliance with the Commission's regulations and orders applicable and in effect at the time the permit was issued;

(ii) Determines the modification is necessary to assure adequate protection of the public health and safety or the common defense and security;

(iii) Determines that a modification is necessary based on an update under paragraph (b) of this section; or

(iv) Issues a variance requested under paragraph (d) of this section.

(2) In making the findings required for issuance of a CP or COL, or the findings required by § 53.5052(g), or in any enforcement hearing other than one initiated by the Commission under paragraph (a)(1) of this section, if the application for the CP or COL references an early site permit, the Commission must treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the early site permit, except as provided for in paragraphs (b), (c), and (d) of this section.

(i) If the early site permit approved an emergency plan (or major features thereof) that is in use by a licensee of a commercial nuclear plant, the Commission must treat as resolved changes to the early site permit emergency plan (or major features thereof) that are identical to changes made to the licensee's emergency plans in compliance with § 53.6065 occurring after issuance of the early site permit.

(ii) If the early site permit approved an emergency plan (or major features thereof) that is not in use by a licensee of a commercial nuclear plant, the Commission

must treat as resolved changes that are equivalent to those that could be made under § 53.6065 without prior NRC approval had the emergency plan been in use by a licensee.

(b) *Updating of early site permit emergency preparedness.* An applicant for a CP, OL, or COL who has filed an application referencing an early site permit issued under this subpart must update the emergency preparedness information that was provided under § 53.4756(b) and discuss whether the updated information materially changes the bases for compliance with applicable NRC requirements.

(c) *Hearings and petitions.*

(1) In any proceeding for the issuance of a CP, OL, or COL referencing an early site permit, contentions on the following matters may be litigated in the same manner as other issues material to the proceeding:

(i) The nuclear reactor proposed to be built does not fit within one or more of the site characteristics or design parameters included in the early site permit;

(ii) One or more of the terms and conditions of the early site permit have not been met;

(iii) A variance requested under paragraph (d) of this section is unwarranted or should be modified;

(iv) New or additional information is provided in the application that substantially alters the bases for a previous NRC conclusion or constitutes a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness; or

(v) Any significant environmental issue that was not resolved in the early site permit proceeding, or any issue involving the impacts of construction and operation of

~~the facility that was resolved in the early site permit proceeding for which significant new information has been identified.~~

~~(2) Any person may file a petition requesting that the site characteristics, design parameters, or terms and conditions of the early site permit should be modified, or that the permit should be suspended or revoked. The petition will be considered in accordance with § 2.206 of this chapter. Before construction commences, the Commission must consider the petition and determine whether any immediate action is required. If the petition is granted, an appropriate order will be issued. Construction under the CP or COL will not be affected by the granting of the petition unless the order is made immediately effective. Any change required by the Commission in response to the petition must demonstrate compliance with the requirements of paragraph (a)(1) of this section.~~

~~(d) *Variances.* An applicant for a CP, OL, or COL referencing an early site permit may include in its application a request for a variance from one or more site characteristics, design parameters, or terms and conditions of the early site permit, or from the Site Safety Analysis Report. In determining whether to grant the variance, the Commission must apply the same technically relevant criteria applicable to the application for the original or renewed early site permit. Once a CP or COL referencing an early site permit is issued, variances from the early site permit will not be granted for that CP or COL.~~

~~(e) *Early site permit amendment.* The holder of an early site permit may not make changes to the early site permit, including the Site Safety Analysis Report, without prior Commission approval. The request for a change to the early site permit must be in the form of an application for a license amendment and must demonstrate compliance with the requirements of §§ 53.6010 and 53.6020.~~

§ 53.4800 Standard design approvals.

Sections 53.4800 through 53.4821 set out procedures for the filing, NRC staff review, and referral to the ACRS of standard designs, or major portions thereof, for a commercial nuclear plant under Framework B of this part.

§ 53.4803 Filing of applications.

Any person may submit a proposed standard design for a commercial nuclear plant to the NRC staff for its review. The submittal may consist of either the final design for the entire facility or the final design for major portions thereof.

§ 53.4806 Contents of applications for standard design approvals; general information.

The application must contain all of the information required by § 53.4709(a) through (c) and (j).

§ 53.4809 Contents of applications for standard design approvals; technical information.

If the applicant seeks review of a major portion of a standard design, the application need only contain the information required by this section to the extent the requirements are applicable to the major portion of the standard design for which NRC staff approval is sought.

(a) The application must contain an FSAR that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the SSCs and of the facility, or major portion thereof, and must include the following information:

(1) The site parameters postulated for the design, and an analysis and evaluation of the design in terms of those site parameters;

(2) A facility description that demonstrates compliance with the requirements in § 53.4730(a)(2) and the assessment required in § 53.4730(a)(1)(vi);

(3) The information pertaining to design features that affect plans for coping with emergencies in the operation of the reactor facility or a major portion thereof;

(4) The list of electric equipment important to safety that is required by § 53.4380(d);

(5) Information demonstrating how the applicant will comply with the relevant requirements for criticality accidents in § 53.4730(a)(32);

(6) A description of the QAP, applied to the design of the SSCs of the facility. Subpart U sets forth the requirements for QAPs for commercial nuclear plants licensed under Framework B of this part. The description of the QAP for a commercial nuclear plant must include a discussion of how the applicable requirements of subpart U under Framework B of this part will be satisfied;

(7) A description, analysis, and evaluation of the interfaces between the standard design and the balance of the commercial nuclear plant;

(8) The information required by—

(i) Section 53.4730(a)(3) – kinds and quantities of radioactive materials;

(ii) Section 53.4730(a)(4) – design bases and principal design criteria;

(iii) Section 53.4730(a)(5) – initiating events and accident analysis;

(iv) Section 53.4730(a)(6) – fire protection;

(v) For applications under Framework B of this part that do not demonstrate compliance with the criteria in § 53.4730(a)(34)(ii)(A) and (B), § 53.4730(a)(7) – combustible gas control;

(vi) Paragraph§ 53.4730 (a)(8)(ii) – environmental qualification of electric equipment important to safety;

(vii) Section 53.4730(a)(11) – dose to members of the public;

(viii) Section 53.4730(a)(12) – post-accident radiation monitoring and protection;

~~(ix) Section 53.4730 (a)(14) – earthquake engineering criteria;~~

~~(x) Section 53.4730(a)(17) – safety feature testing, analyses, operating experience, and prototypes;~~

~~(xi) Section 53.4730(a)(26) – technical qualifications;~~

~~(xii) Section 53.4730(a)(30) – operating experience;~~

~~(xiii) Section 53.4730(a)(33) – minimization of contamination;~~

~~(xiv) Section 53.4730(a)(34) – description of risk evaluation;~~

~~(xv) Section 53.4730(a)(35) – aircraft impact assessment;~~

~~(xvi) Section 53.4730(a)(36) – containment requirements;~~

~~(9) For water-cooled reactor applicants, the information required by –~~

~~(i) Section 53.4730(a)(37)(i) – emergency core cooling systems;~~

~~(ii) Section 53.4730 (a)(37)(iii) – pressurized thermal shock and fracture toughness requirements;~~

~~(iii) Section 53.4730(a)(37)(iv) – anticipated transients without scram;~~

~~(iv) Section 53.4730(a)(37)(v) – station blackout;~~

~~(v) Section 53.4730(a)(37)(vii) – resolution of generic issues; and~~

~~(vi) Section 53.4730(a)(37)(viii) – requirements from light water reactor operating experience; and~~

~~(10) Information to address the following for the role of personnel in ensuring safe operations:~~

~~(i) A description of how the human factors engineering design requirements of § 53.730(a) will be addressed;~~

~~(ii) A description of how the human system interface design requirements of § 53.730(b) will be addressed;~~

(iii) A concept of operations that is of sufficient scope and detail to address the areas described under § 53.730(c); and

(iv) A functional requirements analysis and function allocation that is of sufficient scope and detail to address the areas described under § 53.730(d).

(b) [Reserved]

§ 53.4812 Review of applications.

Applications filed under Framework B of this part will be reviewed for compliance with the standards set out in 10 CFR parts 20, 53, and 73.

§ 53.4815 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application which concern safety.

§ 53.4818 Staff approval of design.

(a) Upon completion of its review of a submittal under §§ 53.4800 through 53.4821 and receipt of a report by the ACRS under § 53.4815, the NRC staff must publish a determination in the *Federal Register* as to whether or not the design is acceptable, subject to appropriate terms and conditions, and make an analysis of the design in the form of a report available at the NRC Web site, http://www.nrc.gov.

(b) A standard design approval issued under this section is valid for 15 years from the date of issuance and may not be renewed. A design approval continues to be valid beyond the date of expiration in any proceeding on an application for a CP, OL, COL, or ML under Framework B of this part that references the design approval and is docketed before the date of expiration of the design approval.

§ 53.4821 Finality of standard design approvals; information requests.

(a) An approved design must be used by and relied upon by the NRC staff and the ACRS in their review of any standard design certification or individual facility license

application under Framework B of this part that incorporates by reference a standard design approved under Framework B of this part unless there exists significant new information that substantially affects the earlier determination or other good cause.

(b) The determination and report by the NRC staff do not constitute a commitment to issue a permit or license, or in any way affect the authority of the Commission, Atomic Safety and Licensing Board Panel, or presiding officers in any proceeding under 10 CFR part 2.

(c) Except for information requests seeking to verify compliance with the current licensing basis of the standard design approval, information requests to the holder of a standard design approval must be evaluated before issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each evaluation performed by the NRC staff must be in accordance with § 53.6080 and must be approved by the Executive Director for Operations or authorized designee before issuance of the request.

(d) The Commission will require, before granting a CP, COL, OL, or ML that references a standard design approval, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if the information is necessary for the Commission to make its safety determination, including the determination that the application is consistent with the design approval information. This information may be acquired by appropriate arrangements with the design approval applicant.

§ 53.4830 Standard design certifications.

Sections 53.4830 through 53.4863 set forth the requirements and procedures applicable to the Commission's issuance of rules granting standard design certifications

for commercial nuclear plants under Framework B of this part separate from the filing of an application for a CP or COL for such a facility.

§ 53.4833 Filing of applications.

(a) An application for design certification may be filed notwithstanding the fact that an application for a CP, COL, or ML for such a facility has not been filed.

(b) The application must comply with the applicable filing requirements of § 53.040 and §§ 2.811 through 2.819 of this chapter.

§ 53.4836 Contents of applications for standard design certifications; general information.

The application must contain all of the information required by § 53.4709 (a) through (c) and (j).

§ 53.4839 Contents of applications for standard design certifications; technical information.

The application must contain a level of design information sufficient to enable the Commission to judge the applicant's proposed means of assuring that construction conforms to the design and to reach a final conclusion on all safety questions associated with the design before the certification is granted. The information submitted for a design certification must include performance requirements and design information sufficiently detailed to permit the preparation of acceptance and inspection requirements by the NRC. The Commission will require, before design certification, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if the information is necessary for the Commission to make its safety determination.

(a) *Final Safety Analysis Report.* Each application for a design certification must include an FSAR that describes the facility, presents the design bases and the limits on

its operation, and presents a safety analysis of the SSCs and of the facility as a whole, and must include the following information:

(1) The site parameters postulated for the design, and an analysis and evaluation of the design in terms of those site parameters;

(2) A facility description that demonstrates compliance with the requirements associated with § 53.4730(a)(2) and the assessment required in § 53.4730(a)(1)(vi);

(3) A representative conceptual design for those portions of the plant for which the application does not seek certification, to aid the NRC in its review of the FSAR and to permit assessment of the adequacy of the interface requirements in paragraph (a)(4) of this section;

(4) The interface requirements to be met by those portions of the plant for which the application does not seek certification. The interface requirements must be sufficiently detailed to allow completion of the FSAR;

(5) Justification that compliance with the interface requirements of paragraph (a)(4) of this section is verifiable through inspections, tests, or analyses. The method to be used for verification of interface requirements must be included as part of the proposed ITAAC required by § 53.4841(a)(2);

(6) A description of a design integrity assessment program that addresses the elements described in § 53.4400(d);

(7) A description of the QAP, applied to the design of the SSCs of the facility. Subpart U under Framework B of this part sets forth the requirements for QAPs for commercial nuclear plants licensed under Framework B of this part. The description of the QAP for a commercial nuclear plant must include a discussion of how the applicable requirements of subpart U under Framework B of this part were satisfied;

(8) The information required by —

(i) Section 53.4730(a)(3) – kinds and quantities of radioactive materials;

(ii) Section 53.4730(a)(4) – design bases and principal design criteria;

(iii) Section 53.4730(a)(5) – initiating events and accident analysis;

(iv) Section 53.4730(a)(6) – fire protection;

(v) For applications under Framework B of this part that do not demonstrate compliance with the criteria in § 53.4730(a)(34)(ii)(A) and (B), § 53.4730 (a)(7) – combustible gas control;

(vi) Section 53.4730(a)(8)(ii) – environmental qualification of electric equipment important to safety;

(vii) Section 53.4730(a)(11) – dose to members of the public;

(viii) Section 53.4730(a)(12) – post-accident radiation monitoring and protection;

(ix) Section 53.4730(a)(14) – earthquake engineering criteria;

(x) Section 53.4730(a)(17) – safety feature testing, analyses, operating experience, and prototypes;

(xi) Section 53.4730(a)(23)(ii) – technical specifications;

(xii) Section 53.4730(a)(26) – technical qualifications;

(xiii) Section 53.4730(a)(30) – operating experience;

(xiv) Section 53.4730(a)(32) – criticality accident requirements;

(xv) Section 53.4730(a)(33) – minimization of contamination;

(xvi) Section 53.4730(a)(34) – description of risk evaluation;

(xvii) Section 53.4730(a)(35) – aircraft impact assessment; and

(xviii) Section 53.4730(a)(36) – containment requirements.

(9) For water-cooled reactor applicants, the information required by –

(i) Section 53.4730(a)(37)(i) – emergency core cooling systems;

(ii) Section 53.4730(a)(37)(iii) – pressurized thermal shock and fracture toughness requirements;

(iii) Section 53.4730(a)(37)(iv) – anticipated transients without scram;

(iv) Section 53.4730(a)(37)(v) – station blackout;

(v) Section 53.4730(a)(37)(vii) – resolution of generic issues; and

(vi) Section 53.4730(a)(37)(viii) – requirements from light-water-reactor operating experience; and

(10) Information to address the following for the role of personnel in ensuring safe operations:

(i) A description of how the human factors engineering design requirements of § 53.730(a) will be addressed;

(ii) A description of how the human system interface design requirements of § 53.730(b) will be addressed;

(iii) A concept of operations that is of sufficient scope and detail to address the areas described under § 53.730(c); and

(iv) A functional requirements analysis and function allocation that is of sufficient scope and detail to address the areas described under § 53.730(d).

(b) [Reserved]

§ 53.4841 Contents of applications for standard design certifications; other application content.

(a) In addition to the FSAR, the application must also include the following:

(1) *Environmental report*. An environmental report as required by § 51.55 of this chapter.

(2) *Inspections, tests, analyses, and acceptance criteria*. The proposed ITAAC that are necessary and sufficient to provide reasonable assurance that, if the

inspections, tests, and analyses are performed and the acceptance criteria met, a facility that incorporates the design certification has been constructed and will be operated in conformity with the design certification, the provisions of the ActEA, and the Commission's rules and regulations; and

(3) *Safeguards information*. A description of the program to protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

(b) An application for certification of a modular nuclear power reactor design must describe and analyze the possible operating configurations of the reactor units with common systems, interface requirements, and system interactions. The final safety analysis must also account for differences among the configurations, including any restrictions that will be necessary during the construction and startup of a given unit to ensure the safe operation of any unit already operating.

§ 53.4842 Review of applications.

(a) *Standards for review of applications*. Applications filed under Framework B of this part will be reviewed for compliance with the standards set out in 10 CFR parts 20, 51, 53, and 73.

(b) *Administrative review of applications; hearings*.

(1) A standard design certification is a rule that will be issued in accordance with the provisions of subpart H of 10 CFR part 2, as supplemented by the provisions of this section. The Commission must initiate the rulemaking after an application has been filed under § 53.4833 and must specify the procedures to be used for the rulemaking. The notice of proposed rulemaking published in the *Federal Register* must provide an opportunity for the submission of comments on the proposed design certification rule. If, at the time a proposed design certification rule is published in the *Federal Register* under

this paragraph the Commission decides that a legislative hearing should be held, the information required by § 2.1502(c) of this chapter must be included in the *Federal Register* document for the proposed design certification.

(2) Following the submission of comments on the proposed design certification rule, the Commission may, at its discretion, hold a legislative hearing under the procedures in subpart O of 10 CFR part 2. The Commission must publish a document in the *Federal Register* of its decision to hold a legislative hearing. The document must contain the information specified in § 2.1502(c) of this chapter and specify whether the Commission or a presiding officer will conduct the legislative hearing.

(3) Notwithstanding anything in § 2.390 of this chapter to the contrary, proprietary information will be protected in the same manner and to the same extent as proprietary information submitted in connection with applications for licenses, provided that the design certification must be published in chapter I of this title.

(c) *Reference to an issued operating license or combined license*. In those cases where a design certification application is preceded by the issuance of an OL or custom COL for a commercial nuclear plant that is essentially the same as the standard design for which certification is being requested, the NRC review will follow the processes for referencing a standard design approval in § 53.4821, to the extent practicable.

§ 53.4845 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application which concern safety.

§ 53.4848 Issuance of standard design certification.

(a) After conducting a rulemaking proceeding under § 53.4842 on an application for a standard design certification and receiving the report to be submitted by the ACRS under § 53.4845, the Commission may issue a standard design certification in the form

~~of a rule for the design, which is the subject of the application, if the Commission determines that —~~

~~(1) The application demonstrates compliance with the applicable standards and requirements of the Act~~EA ~~and the Commission's regulations;~~

~~(2) Notifications, if any, to other agencies or bodies have been duly made;~~

~~(3) There is reasonable assurance that the standard design conforms with the provisions of the Act~~EA ~~and the Commission's regulations;~~

~~(4) The applicant is technically qualified;~~

~~(5) The proposed ITAAC are necessary and sufficient, within the scope of the standard design, to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will be operated in accordance with the design certification, the provisions of the Act~~EA, ~~and the Commission's regulations;~~

~~(6) Issuance of the standard design certification will not be inimical to the common defense and security or to the health and safety of the public;~~

~~(7) The findings required by subpart A of part 51 of this chapter have been made; and~~

~~(8) The applicant has implemented the QAP described or referenced in the Safety Analysis Report.~~

~~(b) The design certification rule must specify the site parameters, design characteristics, and any additional requirements and restrictions of the design certification rule.~~

~~(c) After the Commission has adopted a final design certification rule, the applicant must not permit any individual to have access to any facility or to possess restricted data or classified National Security Information until the individual and/or~~

facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95, as applicable.

§ 53.4851 Duration of certification.

(a) Except as provided in paragraph (b) of this section, a standard design certification issued under this subpart is valid for 15 years from the effective date of the rule.

(b) A standard design certification continues to be valid beyond the date of expiration in any proceeding on an application for a COL or an OL under Framework B of this part that references the standard design certification and is docketed either before the date of expiration of the certification, or, if a timely application for renewal of the certification has been filed, before the Commission has determined whether to renew the certification. A design certification also continues to be valid beyond the date of expiration in any hearing held under § 53.5052 before operation begins under a COL that references the design certification.

(c) An applicant for a CP, OL, COL, or ML under Framework B of this part may, at its own risk, reference in its application a design for which a design certification application has been docketed but not granted.

§ 53.4854 Application for renewal.

(a) Not less than 12 nor more than 36 months before the expiration of the initial 15-year period, or any later renewal period, any person may apply for renewal of the certification. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application. The Commission will require, before renewal of certification, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if this information is necessary for the

~~Commission to make its safety determination. Notice and comment procedures must be used for a rulemaking proceeding on the application for renewal. The Commission, in its discretion, may require the use of additional procedures in individual renewal proceedings.~~

~~(b) A design certification, either original or renewed, for which a timely application for renewal has been filed remains in effect until the Commission has determined whether to renew the certification. If the certification is not renewed, it continues to be valid in certain proceedings under § 53.4851.~~

~~(c) The Commission must refer a copy of the application for renewal to the ACRS. The ACRS must report on those portions of the application which concern safety and must apply the criteria set forth in § 53.4857.~~

~~§ 53.4857 Criteria for renewal.~~

~~(a) The Commission must issue a rule granting the renewal if the design, either as originally certified or as modified during the rulemaking on the renewal, complies with the Act~~EA and the Commission's regulations applicable and in effect at the time the certification was issued.

~~(b) The Commission may impose other requirements if it determines that—~~

~~(1) They are necessary for adequate protection to public health and safety or common defense and security;~~

~~(2) They are necessary for compliance with the Commission's regulations and orders applicable and in effect at the time the design certification was issued; or~~

~~(3) There is a substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementing those requirements are justified in view of this increased protection.~~

(c) In addition, the applicant for renewal may request an amendment to the design certification. The Commission must grant the amendment request if it determines that the amendment will comply with the ActEA and the Commission's regulations in effect at the time of renewal. If the amendment request entails such an extensive change to the design certification that an essentially new standard design is being proposed, an application for a design certification must be filed in accordance with this subpart.

(d) Denial of renewal does not bar the applicant, or another applicant, from filing a new application for certification of the design, which proposes design changes that correct the deficiencies cited in the denial of the renewal.

§ 53.4860 Duration of renewal.

Each renewal of certification for a standard design will be for not less than 10, nor more than 15 years.

§ 53.4863 Finality of standard design certifications.

(a)(1) While a standard design certification rule is in effect under § 53.4851, the Commission may not modify, rescind, or impose new requirements on the certification information, whether on its own motion or in response to a petition from any person, unless the Commission determines in a rulemaking that the change—

(i) Is necessary either to bring the certification information or the referencing plants into compliance with the Commission's regulations applicable and in effect at the time the certification was issued;

(ii) Is necessary to provide adequate protection of the public health and safety or the common defense and security;

(iii) Reduces unnecessary regulatory burden and maintains protection to public health and safety and the common defense and security;

(iv) Provides the detailed design information to be verified under those ITAAC which are directed at certification information (i.e., design acceptance criteria);

(v) Is necessary to correct material errors in the certification information;

(vi) Substantially increases overall safety, reliability, or security of facility design, construction, or operation, and the direct and indirect costs of implementation of the rule change are justified in view of this increased safety, reliability, or security; or

(vii) Contributes to increased standardization of the certification information.

(2)(i) In a rulemaking under § 53.4863(a)(1), the Commission will give consideration to whether the benefits justify the costs for plants that are already licensed or for which an application for a permit or license is under consideration.

(ii) The rulemaking procedures for changes under § 53.4863(a)(1) must provide for notice and opportunity for public comment.

(3) Any modification the NRC imposes on a design certification rule under paragraph (a)(1) of this section will be applied to all plants referencing the certified design, except those to which the modification has been rendered technically irrelevant by action taken under paragraphs (a)(4) or (b)(1) of this section.

(4) The Commission may not impose new requirements by plant-specific order on any part of the design of a specific plant referencing the design certification rule if that part was approved in the design certification while a design certification rule is in effect under § 53.4851, unless ——

(i) A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time the certification was issued, or to assure adequate protection of the public health and safety or the common defense and security; and

~~(ii) Special circumstances as defined in § 53.080 are present. In addition to the factors listed in § 53.080, the Commission must consider whether the special circumstances which § 53.080 requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the plant-specific order.~~

~~(5) Except as provided in § 2.335 of this chapter, in making the findings required for issuance of a COL, CP, OL, or ML, or for any hearing under § 53.5052, the Commission must treat as resolved those matters resolved in connection with the issuance or renewal of a design certification rule.~~

~~(b) An applicant who references a design certification rule may request an exemption from one or more elements of the certification information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 53.080. In addition to the factors listed in § 53.080, the Commission must consider whether the special circumstances that § 53.080 requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. The granting of an exemption on request of an applicant is subject to litigation in the same manner as other issues in the OL or COL hearing.~~

~~(c) The Commission will require, before granting a CP, COL, OL, or ML that references a design certification rule, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if the information is necessary for the Commission to make its safety determination, including the determination that the application is consistent with the certification information. This information may be acquired by appropriate arrangements with the design certification applicant.~~

~~§ 53.4870 Manufacturing licenses.~~

Sections 53.4870 through 53.4895 set out the requirements and procedures applicable to Commission issuance of a license under Framework B of this part authorizing manufacture of manufactured reactors to be installed at sites not identified in the ML application.

§ 53.4873 Filing of applications.

Any person, except one excluded by § 53.4718, may file an application for an ML under this section with the Director, Office of Nuclear Reactor Regulation.

§ 53.4876 Contents of applications for manufacturing licenses; general information.

Each application for an ML must include the information contained in § 53.4709(a) through (e), and (j).

§ 53.4879 Contents of applications for manufacturing licenses; technical information.

The application must contain an FSAR containing the information set forth in this section, with a level of design information sufficient to enable the Commission to judge the applicant's proposed means of assuring that its manufacturing conforms to the design and to reach a final conclusion on all safety questions associated with the design, permit the preparation of construction and installation specifications by an applicant who seeks to use the manufactured reactor, and permit the preparation of acceptance and inspection requirements by the NRC:

(a) The principal design criteria and design bases of the manufactured reactor required by § 53.4730(a)(4);

(b) A description and analysis of the SSCs of the reactor to be manufactured, with emphasis upon the materials of manufacture; performance requirements; the bases, with technical justification therefor, upon which the performance requirements have been

established; and the evaluations required to show that safety functions will be accomplished. The description must be sufficient to permit understanding of the system designs and their relationship to safety evaluations. All SSCs and manufactured reactor design features must be discussed insofar as they are pertinent to the safety of the manufactured reactor. These may include, but are not limited to, the following: the reactor core, reactor coolant system, instrumentation and control systems, electrical systems, and engineered safety features. The following power reactor design characteristics will be taken into consideration by the Commission:

(1) Intended use of the manufactured reactor, including the proposed maximum power level and the nature and inventory of contained radioactive materials;

(2) The extent to which generally accepted engineering standards are applied to the design of the manufactured reactor; and

(3) The extent to which the manufactured reactor incorporates unique, unusual, or enhanced safety features having a significant bearing on the probability or consequences of accidental release of radioactive materials.

(c) The safety features that are to be engineered into the manufactured reactor and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant must assume a fission product release as described in § 53.4730(a)(1)(vi) and that the manufactured reactor is operated at the ultimate power level contemplated;

(d) Information necessary to establish that the design of the reactor to be manufactured complies with the technical requirements in 10 CFR chapter I, including—

(1) A description and analysis of the fire protection design features for the manufactured reactor necessary to comply with the principal design criterion corresponding to criterion 3 of appendix A to 10 CFR part 50 and § 53.4350;

(2) [Reserved];

(3) Information demonstrating how the applicant will comply with requirements for criticality accidents in § 53.4730(a)(32);

(4) For applicants that seek to use risk-informed treatment of SSCs in accordance with § 53.4731, the information required by § 53.4731(b)(2);

(5) A description of the QAP applied to the design, and to be applied to the manufacture of, the SSCs of the manufactured reactor. Subpart U under Framework B of this part sets forth the requirements for QAPs for commercial nuclear plants licensed under Framework B of this part. The description of the QAP must include a discussion of how the applicable requirements of subpart U under Framework B of this part have been and will be satisfied;

(6) Proposed technical specifications applicable to the reactor being manufactured, prepared in accordance with the requirements of § 53.4730(a)(23);

(7) The site parameters postulated for the design, and an analysis and evaluation of the manufactured reactor design in terms of those site parameters;

(8) The interface requirements between the manufactured reactor and the remaining portions of the commercial nuclear plant. These requirements must be sufficiently detailed to allow for completion of the final safety analysis;

(9) Justification that compliance with the interface requirements of paragraph (d)(8) of this section is verifiable through inspections, tests, or analyses. The method to be used for verification of interface requirements must be included as part of the proposed ITAAC required by § 53.4882(a)(1);

(10) A representative conceptual design for a commercial nuclear plant using the manufactured reactor, to aid the NRC in its review of the final safety analysis required by this section and to permit assessment of the adequacy of the interface requirements in paragraph (d)(8) of this section;

(11) If the manufactured reactor is to be used in modular plant design, a description of the possible operating configurations with common systems, interface requirements, and system interactions. The final safety analysis must also account for differences among the configurations, including any restrictions that will be necessary during the construction and startup of a given unit to ensure the safe operation of any unit already operating;

(12) A description of the management plan for design and manufacturing activities, including the following—

(i) The organizational and management structure singularly responsible for direction of design and manufacture of the reactor;

(ii) Technical resources directed by the applicant, and the qualifications requirements;

(iii) Details of the interaction of design and manufacture within the applicant's organization and the manner by which the applicant will ensure close integration of the architect engineer and the nuclear steam supply vendor, as applicable;

(iv) Proposed procedures governing the preparation of the manufactured reactor for shipping to the site where it is to be operated, the conduct of shipping, and verifying the condition of the manufactured reactor upon receipt at the site; and

(v) The degree of top level management oversight and technical control to be exercised by the applicant during design and manufacture, including the preparation and implementation of procedures necessary to guide the effort.

~~(13) Necessary parameters to be used in developing plans for preoperational testing and initial operation; and~~

~~(14) The information required by—~~

~~(i) Section 53.4730(a)(3) – kinds and quantities of radioactive materials;~~

~~(ii) Section 53.4730(a)(5) – initiating events and accident analysis;~~

~~(iii) For applications under Framework B of this part that do not demonstrate compliance with the criteria in § 53.4730(a)(34)(ii)(A) and (B), § 53.4730(a)(7) – combustible gas control;~~

~~(iv) Section 53.4730(a)(8)(ii) – environmental qualification of electric equipment important to safety;~~

~~(v) Section 53.4730(a)(11) – dose to members of the public;~~

~~(vi) Section 53.4730(a)(12) – post-accident radiation monitoring and protection ;~~

~~(vii) Section 53.4730(a)(14) – earthquake engineering criteria;~~

~~(viii) Section 53.4730(a)(17) – safety feature testing, analyses, operating experience, and prototypes;~~

~~(ix) Section 53.4730(a)(26) – technical qualifications;~~

~~(x) Section 53.4730(a)(30) – operating experience;~~

~~(xi) Section 53.4730(a)(33) – minimization of contamination;~~

~~(xii) Section 53.4730(a)(34) – description of risk evaluation;~~

~~(xiii) For applicants that do not reference a standard design certification or standard design approval, § 53.4730(a)(35) – aircraft impact assessment; and~~

~~(xiv) Section 53.4730(a)(36) – containment requirements; and~~

~~(15) For water-cooled reactor applicants, the information required by—~~

~~(i) Section 53.4730(a)(37)(i) – emergency core cooling systems;~~

(ii) Section 53.4730(a)(37)(iii) – pressurized thermal shock and fracture toughness requirements;

(iii) Section 53.4730(a)(37)(iv) – anticipated transients without scram;

(iv) Section 53.4730(a)(37)(v) – station blackout;

(v) Section 53.4730(a)(37)(vii) – resolution of generic issues; and

(vi) Section 53.4730(a)(37)(viii) – requirements from light-water-reactor operating experience.

(e) The following information related to the deployment of a manufactured reactor:

(1) Procedures governing the preparation of the manufactured reactor or portions of the manufactured reactor for shipping to the site where it is to be operated, the conduct of shipping, and verifying the condition of the shipped items upon receipt at the site;

(2) Details of the interaction of the design, manufacture, and installation of a manufactured reactor within the applicant's organization and the manner by which the applicant will ensure close integration between the designer, contractors, and any facility in which the manufactured reactor is to be installed; and

(3) A description of the measures used for the control of interfaces, including the consideration of key site parameters, between the holder of the ML and the holder of the COL for the commercial nuclear plant at which the manufactured reactor is to be installed.

(f) The description of the FFD program and its implementation as required by § 53.4730(a)(24).

§ 53.4882 Contents of applications for manufacturing licenses; other application content.

(a) *Inspections, tests, analyses, and acceptance criteria.*

(1) The application must contain proposed inspections, tests, and analyses that the COL holder must perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met—

(i) The reactor has been manufactured in conformity with the ML; the provisions of the ActEA, and the Commission's rules and regulations; and

(ii) The manufactured reactor will be operated in conformity with the approved design and any license authorizing operation of the manufactured reactor.

(2) If the application references a standard design certification, the ITAAC contained in the certified design must apply to those portions of the facility design which are covered by the design certification.

(3) If the application references a standard design certification, the application may include a notification that a required inspection, test, or analysis in the design certification ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The *Federal Register* notification required by § 53.5022 must indicate that the application includes this notification.

(b) *Environmental report.*

(1) The application must contain an environmental report as required by § 51.54 of this chapter; and

(2) If the ML application references a standard design certification, the environmental report need not contain a discussion of severe accident mitigation design alternatives for the manufactured reactor as used in a commercial nuclear plant.

(c) *Safeguards information*. The application must contain a description of the program to protect safeguards information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

§ 53.4885 Review of applications.

(a) *Standards for review of applications*. Applications for MLs under Framework B of this part will be reviewed according to the applicable standards set out in this subpart as well as applicable standards in 10 CFR parts 20, 25, 26, 51, 53, 70, 71, 73, and 75.

(b) *Administrative review of applications, hearings.* A proceeding on an ML is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing in § 2.101(a)(1) through (4) of this chapter, and the requirements for issuance of a notice of proposed action in § 2.105 of this chapter, provided, however, that the designated sections may not be construed to require that the environmental report or draft or final environmental impact statement include an assessment of the benefits of constructing and/or operating the manufactured reactor or an evaluation of alternative energy sources. All hearings on MLs are governed by the hearing procedures contained in 10 CFR part 2, subparts C, E, G, L, and N.

§ 53.4886 Referral to Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application which concern safety.

§ 53.4887 Issuance of manufacturing license.

(a) After completing any hearing under § 53.4885(b) and receiving the report submitted by the ACRS, the Commission may issue an ML if the Commission finds that—

(1) Applicable standards and requirements of the ActEA and the Commission's regulations have been met;

~~(2) There is reasonable assurance that the manufactured reactor will be manufactured, and can be transported, incorporated into a commercial nuclear plant, and operated in conformity with the ML, the provisiosn of the ActEA, and the Commission's regulations;~~

~~(3) The proposed manufactured reactor can be incorporated into a commercial nuclear plant and operated at sites having characteristics that fall within the site parameters postulated for the design of the manufactured reactors without undue risk to the health and safety of the public;~~

~~(4) The applicant is technically qualified to design and manufacture the proposed manufactured reactor;~~

~~(5) The proposed ITAAC are necessary and sufficient, within the scope of the ML, to provide reasonable assurance that the manufactured reactor has been manufactured and will be operated in conformity with the license, the provisions of the ActEA, and the Commission's regulations;~~

~~(6) The issuance of a license to the applicant will not be inimical to the common defense and security or to the health and safety of the public; and~~

~~(7) The findings required by subpart A of 10 CFR part 51 have been made.~~

~~(b) Each ML issued under this subpart must specify—~~

~~(1) Terms and conditions as the Commission deems necessary and appropriate;~~

~~(2) Technical specifications for operation of the manufactured reactor as the Commission deems necessary and appropriate;~~

~~(3) Site parameters and design characteristics for the manufactured reactor; and~~

~~(4) The interface requirements to be met by the site-specific elements of the facility, such as the energy conversions systems and ultimate heat sink, not within the scope of the manufactured reactor.~~

§ 53.4888 Finality of manufacturing licenses.

(a)(1) Notwithstanding any provision in § 53.6090, during the term of an ML issued under Framework B of this part the Commission may not modify, rescind, or impose new requirements on the design of the manufactured reactor, or the requirements for the manufacture of the manufactured reactor, unless the Commission determines that a modification is necessary to bring the design of the reactor or its manufacture into compliance with the Commission's requirements applicable and in effect at the time the ML was issued, or to provide reasonable assurance of adequate protection to public health and safety or common defense and security.

(2) Any modification to the design of a manufactured reactor that is imposed by the Commission under paragraph (a)(1) of this section will be applied to all manufactured reactors manufactured under the license, including those that have already been transported and sited, except those manufactured reactors to which the modification has been rendered technically irrelevant by action taken under § 53.6030 or paragraph (b) of this section.

(3) In making the findings required under Framework B of this part for issuance of a COL, in any hearing under § 53.5052, or in any enforcement hearing other than one initiated by the Commission under paragraph (a)(1) of this section, for which a manufactured reactor manufactured under this subpart is referenced or used, the Commission must treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the ML, including the adequacy of design of the manufactured reactor, the costs and benefits of severe accident mitigation design alternatives, and the bases for not incorporating severe accident mitigation design alternatives into the design of the manufactured reactor to be manufactured.

(b) An applicant who references or uses a manufactured reactor manufactured under an ML under Framework B of this part may include in the application a request for a departure from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The Commission may grant a request only if it determines that the departure will comply with the requirements of § 53.080, and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure. The granting of a departure on request of an applicant is subject to litigation in the same manner as other issues in the COL hearing.

§ 53.4891 Duration of manufacturing licenses.

An ML issued under Framework B of this part is valid for not less than 5, nor more than 15 years from the date of issuance. Upon expiration of the ML, the manufacture of any uncompleted manufactured reactors must cease unless a timely application for renewal has been docketed with the NRC.

§ 53.4893 Transfer of manufacturing licenses.

An ML may be transferred under § 53.6070.

§ 53.4895 Renewal of manufacturing licenses.

(a)(1) Not less than 12 months, nor more than 5 years before the expiration of the ML, or any later renewal period, the holder of the ML issued under Framework B of this part may apply for a renewal of the license. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application.

(2) The filing of an application for a renewed license must be in accordance with subpart A of 10 CFR part 2 and § 53.4700.

(3) An ML issued under Framework B of this part, either original or renewed, for which a timely application for renewal has been filed, remains in effect until the Commission has made a final determination on the renewal application, provided, however, that the holder of an ML may not begin manufacture of a manufactured reactor less than 6 months before the expiration of the license.

(4) Any person whose interest may be affected by renewal of the license may request a hearing on the application for renewal. The request for a hearing must comply with § 2.309 of this chapter. If a hearing is granted, notice of the hearing will be published in accordance with § 2.104 of this chapter.

(5) The Commission must refer a copy of the application for renewal to the ACRS. The ACRS must report on those portions of the application which concern safety and must apply the criteria set forth in § 53.4885.

(b) The Commission may grant the renewal if the Commission determines—

(1) The ML complies with the ActEA and the Commission's regulations and orders applicable and in effect at the time the ML was originally issued; and

(2) Any new requirements the Commission may wish to impose are—

(i) Necessary for adequate protection to public health and safety or common defense and security;

(ii) Necessary for compliance with the Commission's regulations and orders applicable and in effect at the time the ML was originally issued; or

(iii) A substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementation of those requirements are justified in view of this increased protection.

(c) A renewed ML may be issued for a term of not less than 5, nor more than 15 years, plus any remaining years on the ML then in effect before renewal. The renewed license must be subject to the requirements of § 53.4888.

§ 53.4900 Construction permits.

Sections 53.4900 through 53.4948 set out the requirements and procedures applicable to Commission issuance of a CP for commercial nuclear plants. A CP for the construction of a commercial nuclear plant under Framework B of this part will be issued before the issuance of an OL if the application is otherwise acceptable and will be converted upon completion of the facility and Commission action into an OL as provided under §§ 53.4960 through 53.5005.

§ 53.4906 Contents of applications for construction permits; general information.

An application for a CP must include the information required by § 53.4709 and the following information:

(a) Information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, under the regulations in this chapter, the activities for which the permit is sought. As applicable, the following should be provided:

(1) The information that demonstrates that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs, including estimates of the total construction costs and related fuel cycle costs of the facility and must indicate the source(s) of funds to cover these costs;

(2) Each application for a CP submitted by a newly formed entity organized for the primary purpose of constructing and operating a facility must also include information showing—

(i) The legal and financial relationships the entity has or proposes to have with its stockholders or owners;

(ii) The stockholders' or owners' financial ability to demonstrate compliance with any contractual obligation to the entity which they have incurred or proposed to incur; and

(iii) Any other information considered necessary by the Commission to enable it to determine the applicant's financial qualification; and

(3) The Commission may request an established entity or newly formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding an applicant's ability to continue the conduct of the activities authorized by the cp and to decommission the facility.

(b) If the applicant proposes to construct or alter a facility, the application must state the earliest and latest dates for completion of the construction or alteration.

§ 53.4909 Contents of applications for construction permits; technical information.

(a) *Preliminary Safety Analysis Report.* Each application for a CP must include a PSAR. The PSAR must include the following information, at a level of detail sufficient to enable the Commission to reach a conclusion on safety matters that must be resolved by the Commission before issuance of a CP:

(1) A summary description and discussion of the facility, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations;

(2) A facility description that demonstrates compliance with the requirements associated with § 53.4730(a)(2). The assessment must contain an analysis and evaluation of the major SSCs of the facility which bear significantly on the acceptability

of the site under the site evaluation factors identified in subpart N, assuming that the facility will be operated at the ultimate power level which is contemplated by the applicant. With respect to operation at the projected initial power level, the applicant is required to submit information prescribed in paragraphs (a)(4) through (a)(8) of this section, as well as the information required by § 53.4909(a)(2), in support of the application for a CP, or a design approval.

(3) The description and assessment of the site required in § 53.4730(a)(1);

(4) An identification and justification for the selection of those variables, conditions, or other items which are determined as the result of preliminary safety analysis and evaluation to be probable subjects of technical specifications for the facility, with special attention given to those items which may significantly influence the final design;

(5) A preliminary plan for the applicant's organization, training of personnel, and conduct of operations.

(6) An identification of those SSCs of the facility, if any, which require research and development to confirm the adequacy of their design; identification and description of the research and development program which will be conducted to resolve any safety questions associated with such structures, systems, or components; and a schedule of the research and development program showing that such safety questions will be resolved at or before the latest date stated in the application for completion of construction of the facility;

(7) The information required by—

(i) Section 53.4730(a)(4) – design bases and principal design criteria;

(ii) Section 53.4730(a)(5) – initiating events and accident analysis;

(iii) For applications under Framework B of this part that do not satisfy the criteria in § 53.4730(a)(34)(ii)(A) and (B), the requirements of § 53.4730(a)(7) – combustible gas control;

(iv) Section 53.4730(a)(11) – dose to members of the public;

(v) Section 53.4730(a)(12) – post-accident radiation monitoring and protection;

(vi) Section 53.4730(a)(14) – earthquake engineering criteria;

(vii) Section 53.4730(a)(15) – emergency plans;

(viii) Section 53.4730(a)(18) – quality assurance program;

(ix) Section 53.4730 (a)(25) – multi-unit sites;

(x) Section 53.4730(a)(26) – technical qualifications;

(xi) Section 53.4730(a)(30) – operating experience;

(xii) Section 53.4730(a)(32) – criticality accident requirements;

(xiii) Section 53.4730(a)(34) – description of risk evaluation; and

(xiv) For applicants that do not reference a standard design certification, standard design approval, or manufactured reactor, the requirements of § 53.4730 (a)(35) – aircraft impact assessment; and

(xv) Section 53.4730(a)(24) – FFD requirements.

(8) For water-cooled reactor applicants, the information required by—

(i) Section 53.4730(a)(37)(i) – emergency core cooling systems;

(ii) Section 53.4730(a)(37)(ii) – codes and standards; and

(iii) Section 53.4730(a)(37)(viii) – requirements from light-water-reactor operating experience.

(9) A description of the program to protect safeguards information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

~~(b) [Reserved]~~

~~§ 53.4912 Contents of applications for construction permits; other application content.~~

~~(a) In addition to the PSAR, the application must include the following:~~

~~(1) An environmental report either under § 51.50(a) of this chapter if an LWA under § 53.4740 is not requested in conjunction with the CP application, or under §§ 51.49 and 51.50(a) of this chapter if an LWA is requested in conjunction with the CP application; or~~

~~(2) If the applicant wishes to request that an LWA under § 53.4740 be issued before issuance of the CP, the information otherwise required by § 53.4740, in accordance with either § 2.101(a)(1) through (a)(5), or § 2.101(a)(9) of this chapter.~~

~~(b) If the CP application references an early site permit, standard design approval, or standard design certification issued under Framework B of this part, then the following requirements apply:~~

~~(1) The PSAR need not contain information or analyses submitted to the Commission in connection with the referenced NRC approval, permit, or certification, provided, however, that the PSAR incorporates the material by reference and confirms that the site and design of the facility falls within parameter values postulated in the referenced NRC approval, permit, or certification.~~

~~(2) The PSAR must provide a means to demonstrate that all terms and conditions that have been included in the referenced NRC approval, permit, or certification will be satisfied by the date of issuance of the OL, as appropriate. If the PSAR does not demonstrate that each site characteristic falls within the corresponding postulated site parameter and each design characteristic of the facility falls within the corresponding postulated design parameter, the application must justify a departure,~~

variance, or exemption from the referenced NRC approval, license, or certification in regard to that particular site or design characteristic in compliance with the requirements of Framework B of this part.

(3) If a referenced early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the PSAR must include any new or additional information that updates and corrects the information that was provided under § 53.4756(b)(2) and discuss whether the new or additional information materially changes the bases for compliance with the applicable requirements.

§ 53.4915 Review of applications.

(a) *Standards for review of applications.* Applications filed under Framework B of this part will be reviewed according to the standards set out in 10 CFR parts 20, 51, 53, 73, and 140.

(b) *Administrative review of applications; hearings.* A proceeding on a CP application is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). All hearings on CP applications are governed by the procedures contained in 10 CFR part 2.

§ 53.4918 Finality of referenced NRC approvals, permits, and certifications.

If the application for a CP under this part references an early site permit, standard design approval, or standard design certification, the scope and nature of matters resolved for the application are governed by the relevant provisions addressing finality, including §§ 53.4798, 53.4821, and 53.4863.

§ 53.4924 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application that concern safety and must apply the

standards referenced in § 53.4915(a), in accordance with the finality provisions in § 53.4918.

§ 53.4927 Authorization to conduct limited work authorization activities.

(a) If the application does not reference an early site permit which authorizes the holder to perform the activities under § 53.4740, the applicant may not perform those activities without obtaining the separate authorization required by § 53.4740. Authorization may be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by § 53.4740(b)(1)(ii) and (iv), and the Director, Office of Nuclear Reactor Regulation makes the determination required by § 53.4740(b)(1)(iii).

(b) If, after an applicant has performed the activities permitted by paragraph (a) of this section, the application for the CP is withdrawn or denied, then the applicant must implement an approved site redress plan.

§ 53.4930 Exemptions, departures, and variances.

(a) Applicants for a CP under this subpart, or any amendment to a CP, may include in the application a request for an exemption from one or more of the Commission's regulations. The Commission may grant a request if it determines that the exemption complies with § 53.080.

(b) An applicant for a CP who has filed an application referencing an NRC approval, permit, or certification issued under Framework B of this part may include in the application a request for departures, variances, or exemptions related to the subject referenced NRC approval, permit, or certification. In determining whether to grant the departure, variance, or exemption, the Commission must apply the same technically relevant criteria as were applicable to the application for the original or renewed approval, license, or certification.

§ 53.4933 Issuance of construction permits.

(a) After conducting a hearing in accordance with § 53.4915(b) and receiving the report submitted by the ACRS, the Commission may issue a CP only if the Commission finds that—

(1) The applicant has described the proposed design of the facility, including, but not limited to the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the FSAR;

(3) Safety features or components, if any, which require research and development have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components; and

(4) On the basis of the foregoing, there is reasonable assurance that—

(i) Such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility; and

(ii) Taking into consideration the site criteria contained in subpart N, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

(b) A CP must contain the terms and conditions for the permit, as the Commission deems necessary and appropriate. The Commission may, in its discretion, incorporate in any CP provisions requiring the applicant to furnish periodic reports of the

progress and results of research and development programs designed to resolve safety questions.

§ 53.4936 Finality of construction permits.

Notwithstanding any provision in § 53.6090, a CP constitutes an authorization to proceed with construction but does not constitute Commission approval of the safety of any design feature or specification unless the applicant specifically requests such approval and such approval is incorporated in the permit. The applicant, at its option, may request such approvals in the CP or by amendment to the CP. If approved by the NRC and included in the permit, the NRC will consider modifications to the approved design features or specifications in accordance with § 53.6090.

§ 53.4942 Duration of construction permit.

(a) A CP will state the earliest and latest dates for completion of construction or alteration of the facility, not to exceed 40 years from date of issuance.

(b) If the proposed construction or alteration of the facility is not completed by the latest completion date, the CP shall expire, and all rights forfeited. However, upon good cause shown, the Commission will extend the completion date for a reasonable period of time. The Commission will recognize, among other things, developmental problems attributed to the experimental nature of the facility or fire, flood explosion, strike, sabotage, domestic violence, enemy action, an act of the elements and other acts beyond the control of the permit holder, as a basis for extending the completion date.

§ 53.4945 Transfer of construction permits.

A CP may be transferred under § 53.6070.

§ 53.4948 Termination of construction permits.

When a permit holder has determined to permanently cease construction, the holder must, within 30 days, submit a written certification to the NRC.

§ 53.4960 Operating licenses.

Sections 53.4960 through 53.5005 set out the requirements and procedures applicable to Commission issuance of an OL for a nuclear power facility.

§ 53.4966 Contents of applications for operating licenses; general information.

An application for an OL must include the information required by § 53.4709 and the following information:

(a) Except for an electric utility applicant, information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, in accordance with the regulations in this chapter, the activities for which the license is sought. As applicable, the following should be provided:

(1) The applicant must submit information that demonstrates the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license. The applicant must submit estimates for total annual operating costs for each of the first 5 years of operation of the facility. The applicant must also indicate the source(s) of funds to cover these costs.

(2) Each application for an OL submitted by a newly-formed entity organized for the primary purpose of operating the facility must also include information showing —

(i) The legal and financial relationships the entity has or proposes to have with its stockholders or owners;

(ii) The stockholders' or owners' financial ability to demonstrate compliance with any contractual obligation to the entity which they have incurred or proposed to incur; and

(iii) Any other information considered necessary by the Commission to enable it to determine the applicant's financial qualification.

(3) The Commission may request an established entity or newly-formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding a licensee's ability to continue the conduct of the activities authorized by the license and to decommission the facility.

(b) The application must include information in the form of a report, as described in subpart Q, indicating how reasonable assurance will be provided that funds will be available to decommission the facility.

§ 53.4969 Contents of applications for operating licenses; technical information.

(a) *Final Safety Analysis Report*. Each application for an OL must include an FSAR. The FSAR must include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the SSCs and of the facility as a whole, and must include the following:

(1) *Current information relating to site evaluation*. All current information, such as the results of environmental and meteorological monitoring programs, which has been developed since issuance of the CP, relating to site evaluation factors identified in subpart N of this part;

(2) *Facility description*. A final description and analysis of the SSCs of the facility in accordance with § 53.4730(a)(2);

(3) *Kinds and quantities of radioactive materials*. The information necessary to address the requirements in accordance with § 53.4730(a)(3);

(4) *Initiating events and accident analysis*. A final analysis and evaluation of the design and performance of SSCs with the objective stated in § 53.4730(a)(2) and (5) and taking into account any pertinent information developed since the submittal of the PSAR;

(5) *Research and development*. A description and evaluation of the results of the applicant's programs, including research and development, if any, to demonstrate that any safety questions identified at the CP stage have been resolved;

(6) *Facility operation*. The following information concerning facility operation:

(i) *Role of personnel*. The information necessary to address the requirements for personnel in § 53.4730(a)(9);

(ii) *Maintenance rule*. A description of the program, and its implementation, for monitoring the effectiveness of maintenance necessary to demonstrate compliance with the requirements of § 53.4730(a)(10);

(iii) *Emergency plans*. The information necessary to address the requirements for emergency plans in § 53.4730(a)(15);

(iv) *State, participating Tribal, and local government cooperation*. The information necessary to address the requirements for State, participating Tribal, and local government cooperation in § 53.4730(a)(16);

(v) *Quality assurance program*. The information necessary to address the requirements for the applicant's QAP in § 53.4730(a)(18);

(vi) *Organizational structure*. The information necessary to address the requirements for organizational structure in § 53.4730(a)(19);

(vii) *Managerial and administrative controls*. The information necessary to address the requirements for managerial and administrative controls in § 53.4730(a)(20);

(viii) *Preoperational testing and initial startup*. The information necessary to address the requirements for preoperational testing and initial startup in § 53.4730(a)(21);

(ix) *Normal operations and maintenance*. The information necessary to address the requirements for normal operations and maintenance in § 53.4730(a)(22)(i);

(x) *Plans for coping with emergencies*. The information necessary to address the requirements for plans for coping with emergencies in § 53.4730(a)(22)(ii);

(xi) *Technical specifications*. Proposed technical specifications prepared in accordance with the requirements of § 53.4730(a)(23);

(xii) *Fitness-for-duty program*. The information necessary to address the requirements for FFD programs in § 53.4730(a)(24);

(xiii) *Training program*. The information necessary to address the requirements for training programs in accordance with § 53.4730(a)(27);

(xiv) *Physical security plan*. The information necessary to address the requirements for a physical security plan in § 53.4730(a)(28);

(xv) *Safeguards, security, and related training and qualifications*. The information necessary to address the requirements for a safeguards contingency plan, plan for training and qualification of security personnel, cyber security plan, and implementation of these plans in § 53.4730(a)(29);

(xvi) *Radiation protection program*. A description of the radiation protection program in accordance with § 53.4730(a)(31);

(xvii) *Integrity assessment program*. A description of an Integrity Assessment Program that addresses the elements described in § 53.4400; and

(xviii) *Risk-informed SSC classification*. For applicants that seek to use risk-informed treatment of SSCs in accordance with § 53.4731, the information required by § 50.4731(b)(2) of this chapter;

(7) *Additional technical information*. The information required by —

(i) Section 53.4730(a)(4) – design bases and principal design criteria;

(ii) Section 53.4730(a)(6) – fire protection;

(iii) For applications under Framework B of this part that do not satisfy the criteria in § 53.4730(a)(34)(ii)(A) and (B), the requirements of § 53.4730(a)(7) – combustible gas control;

(iv) Section 53.4730(a)(8) – environmental qualification of electric equipment important to safety;

(v) Section 53.4730(a)(11) – dose to members of the public;

(vi) Section 53.4730(a)(12) – post-accident radiation monitoring and protection;

(vii) Section 53.4730(a)(14) – earthquake engineering criteria;

(viii) Section 53.4730(a)(17) – safety feature testing, analyses, operating experience, and prototypes;

(ix) Section 53.4730(a)(25) – multi-unit sites;

(x) Section 53.4730(a)(26) – technical qualifications;

(xi) Section 53.4730(a)(33) – minimization of contamination;

(xii) Section 53.4730(a)(34) – description of risk evaluation;

(xiii) For applicants that do not reference a standard design certification or standard design approval, § 53.4730(a)(35) – aircraft impact assessment; and

(xiv) Section 53.4730(a)(36) – containment requirements; and

(8) *Water-cooled reactor applicants*. The information required by –

(i) Section 53.4730(a)(37)(i) – emergency core cooling systems;

(ii) Section 53.4730(a)(37)(ii) – codes and standards;

(iii) Section 53.4730(a)(37)(iii) – pressurized thermal shock and fracture toughness requirements;

(iv) Section 53.4730(a)(37)(iv) – anticipated transients without scram;

(v) Section 53.4730(a)(37)(v) – station blackout;

(vi) Section 53.4730(a)(37)(vi) – reactor vessel material surveillance;

(vii) Section 53.4730(a)(37)(vii) – resolution of generic issues; and

(viii) Section 53.4730(a)(37)(viii) – requirements from light-water-reactor operating experience.

(b) [Reserved]

§ 53.4972 Contents of applications for operating licenses; other application content.

(a) In addition to the FSAR, the application must also include the following:

(1) *Environmental report.* An environmental report in accordance with § 51.53(b) of this chapter; and

(2) *Mitigation of beyond-design-basis events.* For applications for a commercial nuclear plant OL under Framework B of this part that does not demonstrate compliance with the criteria in § 53.4730(a)(34)(ii)(A) and (B), the applicant's plans for implementing the requirements of § 53.4420, including a schedule for achieving full compliance with these requirements and a description of the equipment upon which the strategies and guidelines required by § 53.4420(b)(1) rely, including the planned locations of the equipment and how the equipment demonstrates compliance with the requirements of § 53.4420(c).

(b) [Reserved]

§ 53.4975 Review of applications.

(a) *Standards for review of applications.* Applications filed under Framework B of this part will be reviewed according to the standards set out in 10 CFR parts 20, 26, 51, 53, 73, and 140. Upon receipt of an application, the NRC will –

(1) Give notice in writing to the regulatory agency or State as may have jurisdiction over the rates and services incident to the proposed activity;

(2) Publish notice of the application in trade or news publications as appropriate to give reasonable notice to municipalities, private utilities, public bodies, and cooperatives which might have a potential interest in the facility; and

(3) Publish notice of the application once each week for four consecutive weeks in the *Federal Register*.

(b) *Administrative review of applications; hearings.* A proceeding on an OL is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). All hearings on OLs are governed by the procedures contained in 10 CFR part 2.

§ 53.4981 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application that concern safety and must apply the standards referenced in § 53.4975(a).

§ 53.4984 Exemptions, departures, and variances.

(a) Applicants for an OL under this subpart, or any amendment to an OL, may include in the application a request for an exemption from one or more of the Commission's regulations. The Commission may grant an exemption request if it determines that the exemption complies with § 53.080.

(b) An applicant for an OL who has filed an application referencing a NRC approval, permit, license, or certification issued under Framework B of this part may include in the application a request for departures, variances, or exemptions related to the subject referenced NRC approval, permit, license, or certification. In determining whether to grant the departure, variance, or exemption, the Commission must apply the

same technically relevant criteria as were applicable to the application for the original or renewed approval, license, or certification.

§ 53.4987 Issuance of operating licenses.

(a)(1) After receiving the report submitted by the ACRS, the Commission may issue an OL if the Commission finds that—

(i) Construction of the facility has been substantially completed, in conformity with the CP and the application as amended, the provisions of the ActEA, and the rules and regulations of the Commission;

(ii) Any required notifications to other agencies or bodies have been duly made;

(iii) The facility will operate in conformity with the application as amended, the provisions of the ActEA, and the rules and regulations of the Commission;

(iv) There is reasonable assurance that—

(A) that the activities authorized by the OL can be conducted without endangering the health and safety of the public; and

(B) such activities will be conducted in compliance with the regulations in this chapter.

(v) The applicant is technically and financially qualified to engage in the activities authorized, however, no finding of financial qualification is necessary for an electric utility applicant for an OL;

(vi) Issuance of the license will not be inimical to the common defense and security or to the health and safety of the public;

(vii) The applicable provisions of 10 CFR part 140 have been satisfied; and

(viii) The findings required by subpart A of 10 CFR part 51 have been made.

(2) [Reserved]

(b) Fuel loading may not begin until the OL is issued.

(c) The OL may include appropriate provisions with respect to any uncompleted items of construction and such limitations or conditions as are required to assure that operation during the period of the completion of such items will not endanger public health and safety.

(d) The Commission will issue an OL in such form and containing such conditions and limitations, including technical specifications, as it deems necessary and appropriate.

§ 53.4990 Backfitting of operating licenses.

After issuance of an OL, the Commission may not modify, add, or delete any term or condition of the OL, except in accordance with the provisions of § 53.6090.

§ 53.4996 Duration of operating license.

The Commission will issue an OL under Framework B of this part for the term requested by the applicant, not to exceed 40 years from the date of issuance, or for the estimated useful life of the facility if the Commission determines that the estimated useful life is less than the term requested.

§ 53.4999 Transfer of an operating license.

An OL may be transferred in accordance with § 53.6070.

§ 53.5002 Application for renewal.

The filing of an application for a renewed license must be in accordance with § 53.6095.

§ 53.5005 Continuation of an operating license.

Each OL for a facility that has permanently ceased operations continues in effect beyond the expiration date to authorize ownership and possession of the facility until the Commission notifies the licensee in writing that the license is terminated. During this period of continued effectiveness, the licensee must—

(a) Take actions necessary to decommission and decontaminate the facility and continue to maintain the facility, including, where applicable, the storage, control and maintenance of the spent fuel, in a safe condition; and

(b) Conduct activities in accordance with all other restrictions applicable to the facility in accordance with the NRC's regulations and the provisions of the OL for the facility.

§ 53.5010 Combined licenses.

Sections 53.5010 through 53.5061 set out the requirements and procedures applicable to Commission issuance of COLs for commercial nuclear plants under Framework B of this part.

§ 53.5013 Contents of applications for combined licenses; general information.

An application for a COL must include the information required by § 53.4709 and the following information:

(a) Except for an electric utility applicant, the application must include information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, in accordance with the regulations in this chapter, the activities for which the permit or license is sought. As applicable, the following should be provided:

(1) The applicant must submit information that demonstrates that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs. The applicant must submit estimates of the total construction costs of the facility and related fuel cycle costs and must indicate the source(s) of funds to cover these costs.

(2) The applicant must submit information that demonstrates the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license. The applicant must submit

estimates for total annual operating costs for each of the first 5 years of operation of the facility. The applicant must also indicate the source(s) of funds to cover these costs.

(3) Each application for a COL submitted by a newly-formed entity organized for the primary purpose of constructing and operating a facility must also include information showing:

(i) The legal and financial relationships the entity has or proposes to have with its stockholders or owners;

(ii) The stockholders' or owners' financial ability to demonstrate compliance with any contractual obligation to the entity which they have incurred or proposed to incur; and

(iii) Any other information considered necessary by the Commission to enable it to determine the applicant's financial qualification.

(4) The Commission may request an established entity or newly formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding a licensee's ability to continue the conduct of the activities authorized by the license and to decommission the facility.

(b) The application must include information in the form of a report, as described in subpart Q, indicating how reasonable assurance will be provided that funds will be available to decommission the facility.

§ 53.5016 Contents of applications for combined licenses; technical information.

(a) *Final Safety Analysis Report*. The application must contain an FSAR that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the SSCs of the facility as a whole. The FSAR must include the following information, at a level of information sufficient to enable the Commission to

reach a final conclusion on all safety matters that must be resolved by the Commission before issuance of a COL:

(1) The information related to site characteristics necessary to address requirements in § 53.4730(a)(1);

(2) The information for the facility necessary to address requirements in § 53.4730(a)(2);

(3) The following information concerning facility operation:

(i) *Role of personnel*. The information necessary to address the requirements associated with personnel in § 53.4730(a)(9);

(ii) *Integrity assessment program*. A description of an integrity assessment program that addresses the elements described in § 53.4400;

(iii) *Emergency plans*. The information necessary to address the requirements for emergency plans in § 53.4730(a)(15);

(iv) *State, participating Tribal, and local government cooperation*. The information necessary to address the requirements for State, participating Tribal, and local government cooperation in § 53.4730(a)(16);

(v) *Quality assurance program*. The information necessary to address the requirements for the applicant's QAP in § 53.4730(a)(18);

(vi) *Organizational structure*. The information necessary to address the requirements for organizational structure in § 53.4730(a)(19);

(vii) *Managerial and administrative controls*. The information necessary to address the requirements for managerial and administrative controls in § 53.4730(a)(20);

(viii) *Preoperational testing and initial startup*. The information necessary to address the requirements for preoperational testing and initial startup in § 53.4730(a)(21);

(ix) *Normal operations and maintenance*. The information necessary to address the requirements for normal operations and maintenance in § 53.4730(a)(22)(i);

(x) *Plans for coping with emergencies*. The information necessary to address the requirements for plans for coping with emergencies in § 53.4730(a)(22)(ii);

(xi) *Technical specifications*. Proposed technical specifications prepared in accordance with the requirements of § 53.4730(a)(23);

(xii) *Fitness-for-duty program*. The information necessary to address the requirements for FFD programs in § 53.4730(a)(24);

(xiii) *Training program*. The information necessary to address the requirements for training programs in § 53.4730(a)(27);

(xiv) *Physical security plan*. The information necessary to address the requirements for a physical security plan in § 53.4730(a)(28);

(xv) *Safeguards, security, and related training and qualifications*. The information necessary to address the requirements for a safeguards contingency plan, plan for training and qualification of security personnel, cyber security plan, and implementation of these plans in § 53.4730(a)(29);

(xvi) *Radiation protection program*. Radiation protection program under § 53.4730(a)(31);

(xvii) *Maintenance rule*. A description of the program, and its implementation, for monitoring the effectiveness of maintenance necessary to demonstrate compliance with the requirements of § 53.4730(a)(10); and

(xviii) *Risk-informed SSC classification*. For applicants that seek to use risk-informed treatment of SSCs under § 53.4731, the information required by § 50.4731(b)(2) of this chapter;

(4) The information required by —

(i) Section 53.4730(a)(3) – kinds and quantities of radioactive materials;

(ii) Section 53.4730(a)(4) – design bases and principal design criteria;

(iii) Section 53.4730(a)(5) – initiating events and accident analysis;

(iv) Section 53.4730(a)(6) – fire protection;

(v) For applications under Framework B of this part that do not satisfy the criteria in § 53.4730(a)(34)(ii)(A) and (B), the requirements in § 53.4730(a)(7) – combustible gas control;

(vi) Section 53.4730(a)(8) – environmental qualification of electric equipment important to safety;

(vii) Section 53.4730(a)(11) – dose to members of the public;

(viii) Section 53.4730(a)(12) – post-accident radiation monitoring and protection;

(ix) Section 53.4730(a)(14) – earthquake engineering criteria;

(x) Section 53.4730(a)(17) – safety feature testing, analyses, operating experience, and prototypes;

(xi) Section 53.4730(a)(25) – multi-unit sites;

(xii) Section 53.4730(a)(26) – technical qualifications;

(xiii) Section 53.4730(a)(30) – operating experience;

(xiv) Section 53.4730(a)(32) – criticality accident requirements;

(xv) Section 53.4730(a)(33) – minimization of contamination;

(xvi) Section 53.4730(a)(34) – description of risk evaluation;

(xvii) For applicants that do not reference a standard design certification, standard design approval, or ML, § 53.4730(a)(35) – aircraft impact assessment; and

(xviii) Section 53.4730(a)(36) – containment requirements; and

(5) For water-cooled reactor applicants, the information required by—

(i) Section 53.4730(a)(37)(i) – emergency core cooling systems;

~~(ii) Section 53.4730(a)(37)(ii) – codes and standards;~~

~~(iii) Section 53.4730(a)(37)(iii) – pressurized thermal shock and fracture toughness requirements;~~

~~(iv) Section 53.4730(a)(37)(iv) – anticipated transients without scram;~~

~~(v) Section 53.4730(a)(37)(v) – station blackout;~~

~~(vi) Section 53.4730(a)(37)(vi) – reactor vessel material surveillance;~~

~~(vii) Section 53.4730(a)(37)(vii) – resolution of generic issues; and~~

~~(viii) Section 53.4730(a)(37)(viii) – Requirements from light-water-reactor operating experience.~~

~~(b) If the COL application references an early site permit, then the following requirements apply:~~

~~(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the early site permit provided that the FSAR either include or incorporate by reference the early site permit Site Safety Analysis Report and contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit.~~

~~(2) If the FSAR does not demonstrate that design of the facility falls within the site characteristics and design parameters, the application must include a request for a variance that complies with the requirements of §§ 53.4798(d) and 53.5037.~~

~~(3) The FSAR must demonstrate that all terms and conditions that have been included in the early site permit will be satisfied by the date of issuance of the COL. Any terms or conditions of the early site permit that could not be met by the time of issuance of the COL, must be set forth as terms or conditions of the COL.~~

~~(4) If the early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the FSAR must include any new or additional information that updates and corrects the information that was provided under § 53.4756(b)(2) and discuss whether the new or additional information materially changes the bases for compliance with the applicable requirements. The application must identify changes to the emergency plans or major features of emergency plans that have been incorporated into the proposed facility emergency plans and that constitute or would constitute a change in an emergency plan that results in reducing the licensee's capability to perform an emergency planning function in the event of a radiological emergency.~~

~~(5) If complete and integrated emergency plans are approved as part of the early site permit, new certifications demonstrating compliance with the requirements of paragraph (a)(3)(iii) of this section are not required.~~

~~(c) If the COL application references a standard design approval, then the following requirements apply:~~

~~(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the design approval, provided, however, that the FSAR must either include or incorporate by reference the standard design approval FSAR and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the characteristics of the site fall within the site parameters specified in the design approval. In addition, the plant-specific risk evaluation information must use the risk evaluation information for the design approval and must be updated to account for site specific design information and any design changes or departures.~~

~~(2) The FSAR must demonstrate that the interface requirements established for the design have been met.~~

(3) The FSAR must demonstrate that all terms and conditions that have been included in the design approval will be satisfied by the date of issuance of the COL.

(d) If the COL application references a standard design certification, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the standard design certification, provided, however, that the FSAR must either include or incorporate by reference the standard design certification FSAR and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the standard design certification. In addition, the plant specific risk evaluation information must use the risk evaluation information for the standard design certification and must be updated to account for site-specific design information and any design changes or departures.

(2) The FSAR must demonstrate that the interface requirements established for the design under § 53.4839(a)(4) have been met.

(3) The FSAR must demonstrate that all requirements and restrictions set forth in the referenced standard design certification rule must be satisfied by the date of issuance of the COL. Any requirements and restrictions set forth in the referenced standard design certification rule that could not be satisfied by the time of issuance of the COL, must be set forth as terms or conditions of the COL.

(e) If the COL application references the use of one or more manufactured nuclear power reactors licensed under § 53.4870, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the ML, provided, however, that the FSAR must either include or incorporate by reference the ML FSAR and must contain, in addition to the

~~information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the ML. In addition, the plant-specific risk evaluation information must use the risk evaluation information for the manufactured reactor and must be updated to account for site-specific design information and any design changes or departures.~~

~~(2) The FSAR must demonstrate that the interface requirements established for the design have been met.~~

~~(3) The FSAR must demonstrate that all terms and conditions that have been included in the ML will be satisfied by the date of issuance of the COL. Any terms or conditions of the ML that could not be met by the time of issuance of the COL must be set forth as terms or conditions of the COL.~~

~~(f) Each applicant for a COL under this part must protect safeguards information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.~~

~~§ 53.5019 Contents of applications for combined licenses; other application content.~~

~~(a) In addition to the FSAR, the application must also include the following:~~

~~(1) *Environmental report*.~~

~~(i) An environmental report either in accordance with § 51.50(c) of this chapter if an LWA under § 53.4740 is not requested in conjunction with the COL application, or in accordance with §§ 51.49 and 51.50(c) of this chapter if an LWA is requested in conjunction with the COL application; or~~

~~(ii) If the applicant wishes to request that an LWA under § 53.4740 be issued before issuance of the COL, the information otherwise required by § 53.4740, in accordance with either § 2.101(a)(1) through (a)(4), or § 2.101(a)(9) of this chapter;~~

(2) *ITAAC.* The proposed inspections, tests, and analyses, including those applicable to emergency planning, that the licensee must perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will be operated in conformity with the COL, the provisions of the Act<u>EA</u>, and the Commission's rules and regulations.

(i) If the application references an early site permit with ITAAC, the early site permit ITAAC must apply to those aspects of the COL which are approved in the early site permit.

(ii) If the application references a standard design certification, the ITAAC contained in the certified design must apply to those portions of the facility design which are approved in the standard design certification.

(iii) If the application references an ML, the ITAAC contained in the ML must apply to those portions of the facility design which are approved in the ML.

(iv) If the application references an early site permit with ITAAC, standard design certification, an ML, or a combination thereof, the application may include a notification that a required inspection, test, or analysis in the ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The *Federal Register* notification required by § 53.5022 must indicate that the application includes this notification.

(3) *Mitigation of beyond-design-basis events.* For applications under Framework B of this part that do not demonstrate compliance with the criteria in § 53.4730(a)(34)(ii)(A) and (B), the applicant's plans for implementing the requirements of § 53.4420, including a schedule for achieving full compliance with these requirements and a description of the equipment upon which the strategies and guidelines required by

§ 53.4420(b)(1) rely, including the planned locations of the equipment and how the equipment demonstrates compliance with the requirements of § 53.4420(c).

(b) [Reserved]

§ 53.5022 Review of applications.

(a) *Standards for review of applications.* Applications filed under Framework B of this part will be reviewed according to the standards set out in 10 CFR parts 20, 51, 53, 73, and 140.

(b) *Administrative review of applications; hearings.* A proceeding on a COL is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). If an applicant requests a Commission finding on certain ITAAC with the issuance of the COL, then those ITAAC will be identified in the notice of hearing. All hearings on COLs are governed by the procedures contained in 10 CFR part 2.

§ 53.5025 Finality of referenced NRC approvals.

If the application for a COL under Framework B of this part references an early site permit, standard design certification rule, standard design approval, or ML, issued under Framework B of this part, the scope and nature of matters resolved for the application and any COL issued are governed by the relevant provisions addressing finality, including §§ 53.4798, 53.4863, 53.4821, and 53.4888.

§ 53.5031 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application that concern safety and must apply the standards referenced in § 53.5022(a), in accordance with the finality provisions in § 53.5025.

§ 53.5034 Authorization to conduct limited work authorization activities.

(a) If the application of a COL under Framework B of this part does not reference an early site permit which authorizes the holder to perform the activities under § 53.4740(b), the applicant may not perform those activities without obtaining the separate authorization required by § 53.4740(a). Authorization may be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by § 53.4740(b)(1)(ii) and (b)(1)(iv), and the Director, Office of Nuclear Reactor Regulation makes the determination required by § 53.4740(b)(1)(iii).

(b) If, after an applicant has performed the activities permitted by paragraph (a) of this section, the application for the COL is withdrawn or denied, then the applicant must implement the approved site redress plan.

§ 53.5037 Exemptions, departures, and variances.

(a) Applicants for a COL, or any amendment to a COL, may include in the application a request for an exemption from one or more of the Commission's regulations.

(1) If the request is for an exemption from any part of a referenced standard design certification rule, the Commission may grant the request if it determines that the exemption complies with any exemption provisions of the referenced standard design certification rule, or with § 53.4863 if there are no applicable exemption provisions in the referenced standard design certification rule.

(2) For all other requests for exemptions, the Commission may grant a request if it determines that the exemption complies with § 53.080.

(b) An applicant for a COL who has filed an application referencing an early site permit issued under § 53.4768 may include in the application a request for a variance from one or more site characteristics, design parameters, or terms and conditions of the

permit, or from the Site Safety Analysis Report. In determining whether to grant the variance, the Commission must apply the same technically relevant criteria as were applicable to the application for the original or renewed site permit. Once a COL referencing an early site permit is issued, variances from the early site permit will not be granted for that CP or COL.

(c) An applicant for a COL who has filed an application referencing a nuclear power reactor manufactured under an ML issued under § 53.4870 may include in the application a request for a departure from one or more design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The Commission may grant a request only if it determines that the departure will comply with the requirements of § 53.080, and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure.

(d) Issuance of a variance under paragraph (b) of this section or a departure under paragraph (c) of this section is subject to litigation during the COL proceeding in the same manner as other issues material to that proceeding.

§ 53.5040 Issuance of combined licenses.

(a)(1) After conducting a hearing in accordance with § 53.5022(b) and receiving the report submitted by the ACRS, the Commission may issue a COL if the Commission finds that—

(i) The applicable standards and requirements of the Act<u>EA</u> and the Commission's regulations have been met;

(ii) Any required notifications to other agencies or bodies have been duly made;

(iii) There is reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of the Act<u>EA</u>, and the Commission's regulations;

~~(iv) The applicant is technically and financially qualified to engage in the activities authorized, however, no finding of financial qualification is necessary for an electric utility applicant for a COL;~~

~~(v) Issuance of the license will not be inimical to the common defense and security or to the health and safety of the public; and~~

~~(vi) The findings required by subpart A of 10 CFR part 51 have been made.~~

~~(2) The Commission may also find, at the time it issues the COL, that certain acceptance criteria in one or more of the ITAAC in a referenced early site permit, standard design certification, or manufacturing license have been met. This finding will finally resolve that those acceptance criteria have been met, those acceptance criteria will be deemed to be excluded from the COL, and findings under § 53.5052(g) with respect to those acceptance criteria are unnecessary.~~

~~(b) The Commission must identify within the COL the inspections, tests, and analyses, including those applicable to emergency planning, that the licensee must perform, and the acceptance criteria that, if met, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act~~EA, and the Commission's rules and regulations.

~~(c) A COL must contain the terms and conditions, including technical specifications, as the Commission deems necessary and appropriate.~~

~~§ 53.5043 Finality of combined licenses.~~

~~(a) After issuance of a COL, the Commission may not modify, add, or delete any term or condition of the COL, the design of the facility, the ITAAC contained in the license that are not derived from a referenced standard design certification or ML, except in accordance with the provisions of § 53.5052 or § 53.6090.~~

~~(b) If the COL does not reference a standard design certification or a reactor manufactured under § 53.4870, then a licensee may make changes in the facility as described in the FSAR (as updated), make changes in the procedures as described in the FSAR (as updated), and conduct tests or experiments not described in the FSAR (as updated) under the applicable change processes in subpart S of this part.~~

~~(c) If the COL references a certified design, then—~~

~~(1) Changes to or departures from information within the scope of the referenced standard design certification rule are subject to the applicable change processes in that rule; and~~

~~(2) Changes that are not within the scope of the referenced standard design certification rule are subject to the applicable change processes in subpart S, unless they also involve changes to or noncompliance with information within the scope of the referenced standard design certification rule. In these cases, the applicable provisions of this section and the standard design certification rule apply.~~

~~(d) If the COL references a reactor manufactured under an ML under Framework B of this part, then—~~

~~(1) Changes to or departures from information within the scope of the manufactured reactor's design are subject to the change processes in § 53.4888; and~~

~~(2) Changes that are not within the scope of the manufactured reactor's design are subject to the applicable change processes in subpart S.~~

~~(e) The Commission may issue and make immediately effective any amendment to a COL upon a determination by the Commission that the amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person. The amendment may be issued and made immediately effective in advance of the holding and completion of any required hearing.~~

The amendment will be processed in accordance with the procedures specified in § 53.6015.

(f) Any modification to, addition to, or deletion from the terms and conditions of a COL, including any modification to, addition to, or deletion from the inspections, tests, and analyses, or related acceptance criteria contained in the license is a proposed amendment to the license. There must be an opportunity for a hearing on the amendment.

§ 53.5049 Inspection during construction.

(a) *Licensee schedule for inspections, tests, or analyses*. The licensee must submit to the NRC, no later than 1 year after issuance of the COL or at the start of construction as defined at § 53.020, whichever is later, its schedule for completing the inspections, tests, or analyses in the ITAAC. The licensee must submit updates to the ITAAC schedules every 6 months thereafter and, within 1 year of its scheduled date for initial loading of fuel, the licensee must submit updates to the ITAAC schedule every 30 days until the final notification is provided to the NRC under paragraph (c)(1) of this section.

(b) *Licensee and applicant conduct of activities subject to ITAAC*. With respect to activities subject to an ITAAC, an applicant for a COL may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any one of the prescribed acceptance criteria are met.

(c) *Licensee notifications*.

(1) *ITAAC closure notification*. The licensee must notify the NRC that prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria are met. The notification must contain sufficient information to

demonstrate that the prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria are met.

(2) *ITAAC post-closure notifications*. Following the licensee's ITAAC closure notifications under paragraph (c)(1) of this section until the Commission makes the finding under § 53.5052(g), the licensee must notify the NRC, in a timely manner, of new information that materially alters the basis for determining that either inspections, tests, and analyses were performed as required, or that acceptance criteria are met. The notification must contain sufficient information to demonstrate that, notwithstanding the new information, the prescribed inspections, tests, and analyses have been performed as required, and the prescribed acceptance criteria are met.

(3) *Uncompleted ITAAC notification*. If the licensee has not provided, by the date 225 days before the scheduled date for initial loading of fuel, the notification required by paragraph (c)(1) of this section for all ITAAC, then the licensee must notify the NRC that the prescribed inspections, tests, and analyses for all uncompleted ITAAC will be performed and that the prescribed acceptance criteria will be met prior to operation. The notification must be provided no later than the date 225 days before the scheduled date for initial loading of fuel, and must provide sufficient information to demonstrate that the prescribed inspections, tests, and analyses will be performed and the prescribed acceptance criteria for the uncompleted ITAAC will be met, including, but not limited to, a description of the specific procedures and analytical methods to be used for performing the prescribed inspections, tests, and analyses and determining that the prescribed acceptance criteria are met.

(4) *All ITAAC complete notification*. The licensee must notify the NRC that all ITAAC are complete.

(d) *Licensee determination of noncompliance with ITAAC*.

(1) In the event that an activity is subject to an ITAAC derived from a referenced standard design certification and the licensee has not demonstrated that the prescribed acceptance criteria are met, the licensee may take corrective actions to successfully complete that ITAAC or request an exemption from the standard design certification ITAAC, as applicable. A request for an exemption must also be accompanied by a request for a license amendment under subpart S.

(2) In the event that an activity is subject to an ITAAC not derived from a referenced standard design certification and the licensee has not demonstrated that the prescribed acceptance criteria are met, the licensee may take corrective actions to successfully complete that ITAAC or request a license amendment under subpart S.

(e) *NRC inspection, publication of notices, and availability of licensee notifications.* The NRC must ensure that the prescribed inspections, tests, and analyses in the ITAAC are performed.

(1) At appropriate intervals until the last date for submission of requests for hearing under § 53.5052, the NRC must publish notices in the *Federal Register* of the NRC staff's determination of the successful completion of inspections, tests, and analyses.

(2) The NRC must make publicly available the licensee notifications under paragraph (c) of this section. The NRC must, no later than the date of publication of the notice of intended operation required by § 53.5052(a), make publicly available those licensee notifications under paragraph (c) of this section that have been submitted to the NRC at least 7 days before that notice.

§ 53.5052 Operation under a combined license.

(a) The licensee must notify the NRC of its scheduled date for initial loading of fuel no later than 270 days before the scheduled date and must notify the NRC of

~~updates to its schedule every 30 days thereafter. Not less than 180 days before the date scheduled for initial loading of fuel into a plant by a licensee that has been issued a COL under Framework B of this part, the Commission must publish notice of intended operation in the *Federal Register*. The notice must provide that any person whose interest may be affected by operation of the plant may, within 60 days, request that the Commission hold a hearing on whether the facility as constructed complies, or on completion will comply, with the acceptance criteria in the COL, except that a hearing must not be granted for those ITAAC which the Commission found were met under § 53.5040(a)(2).~~

~~(b) A request for hearing under paragraph (a) of this section must show, prima facie,—~~

~~(1) That one or more of the acceptance criteria of the ITAAC in the COL have not been, or will not be, met; and~~

~~(2) The specific operational consequences of nonconformance that would be contrary to providing reasonable assurance of adequate protection of the public health and safety.~~

~~(c) The Commission, acting as the presiding officer, must determine whether to grant or deny the request for hearing in accordance with the applicable requirements of § 2.309 of this chapter. If the Commission grants the request, the Commission, acting as the presiding officer, must determine whether during a period of interim operation there will be reasonable assurance of adequate protection to the public health and safety. The Commission's determination must consider the petitioner's prima facie showing and any answers thereto. If the Commission determines there is such reasonable assurance, it must allow operation during an interim period under the COL.~~

(d) The Commission, in its discretion, must determine appropriate hearing procedures, whether informal or formal adjudicatory, for any hearing under paragraph (a) of this section, and must state its reasons therefore.

(e) The Commission must, to the maximum possible extent, render a decision on issues raised by the hearing request within 180 days of the publication of the notice provided by paragraph (a) of this section or by the anticipated date for initial loading of fuel into the reactor, whichever is later.

(f) A petition to modify the terms and conditions of the COL will be processed as a request for action in accordance with § 2.206 of this chapter. The petitioner must file the petition with the Secretary of the Commission. Before the licensed activity allegedly affected by the petition (fuel loading, low power testing, etc.) commences, the Commission must determine whether any immediate action is required. If the petition is granted, then an appropriate order will be issued. Fuel loading and operation under the COL will not be affected by the granting of the petition unless the order is made immediately effective.

(g) The licensee must not operate the facility until the Commission makes a finding that the acceptance criteria in the COL are met, except for those acceptance criteria that the Commission found were met under § 53.5040(a)(2). If the COL is for a modular design, each reactor unit may require a separate finding as construction proceeds.

(h) After the Commission has made the finding in paragraph (g) of this section, the ITAAC do not, by virtue of their inclusion in the COL, constitute regulatory requirements either for licensees or for renewal of the license; except for the specific ITAAC for which the Commission has granted a hearing under paragraph (a) of this section, all ITAAC expire upon final Commission action in the proceeding. However,

subsequent changes to the facility or procedures described in the FSAR (as updated) must comply with the requirements in § 53.5043(e) or (f), as applicable.

§ 53.5055 Duration of combined license.

A COL is issued for a specified period not to exceed 40 years from the date on which the Commission makes a finding that acceptance criteria are met under § 53.5052(g) or allowing operation during an interim period under the COL under § 53.5052(c).

§ 53.5056 Transfer of a combined license.

A COL may be transferred under § 53.6070.

§ 53.5058 Application for renewal.

The filing of an application for a renewed license must be in accordance with § 53.6095.

§ 53.5061 Continuation of combined license.

Each COL for a facility that has permanently ceased operations continues in effect beyond the expiration date to authorize ownership and possession of the facility until the Commission notifies the licensee in writing that the license is terminated. During this period of continued effectiveness, the licensee must —

(a) Take actions necessary to decommission and decontaminate the facility and continue to maintain the facility, including, where applicable, the storage, control and maintenance of the spent fuel, in a safe condition; and

(b) Conduct activities in accordance with all other restrictions applicable to the facility in accordance with the NRC's regulations and the provisions of the COL for the facility.

§ 53.5070 Standardization of commercial nuclear plant designs: licenses to construct and operate nuclear power reactors of identical design at multiple sites.

~~(a) Except as otherwise specified in this section, the provisions of this section apply to CP, OL, and COL applications under Framework B of this part.~~

~~(b) Each application for a CP, OL, or COL submitted pursuant to this section must be submitted as specified in § 53.4900, § 53.4960, or § 53.5010 and § 2.101 of this chapter. Each application should state that the applicant wishes to have the application considered under this section and should list each of the applications to be treated together under this section.~~

~~(c) Each application must include the information required by the applicable sections of this subpart, *provided however*, that the application must identify the common design, and, if applicable, reference a standard design certification or standard design approval under Framework B of this part, or the use of a reactor manufactured under Framework B of this part. The FSAR for each application must either incorporate by reference or include the final safety analysis of the common design, including, if applicable, the FSAR for the referenced standard design certification or the manufactured reactor.~~

~~(d) Each application submitted pursuant to this section must contain an environmental report as required by § 53.4912, § 53.4972, or § 53.5019, as applicable, and which complies with the applicable provisions of 10 CFR part 51, provided, however, that the application may incorporate by reference a single environmental report on the environmental impacts of the common design.~~

~~(e) Upon a determination that each application is acceptable for docketing under § 2.101 of this chapter, each application will be docketed and a notice of docketing for each application will be published in the *Federal Register*, in accordance with § 2.104 of this chapter, provided, however, that the notice must state that the application will be processed under the provisions of this section and subpart D of 10 CFR part 2. At the~~

discretion of the Commission, a single notice of docketing for multiple applications may be published in the *Federal Register*.

(f) The NRC must prepare draft and final environmental impact statements for each of the applications under 10 CFR part 51. Scoping under §§ 51.28 and 51.29 of this chapter for each of the license applications may be conducted simultaneously and joint scoping may be conducted with respect to the environmental issues relevant to the common design. If the applications reference a standard design certification, then the environmental impact statement for each of the applications must incorporate by reference the standard design certification environmental assessment. If the applications do not reference a standard design certification, then the NRC must prepare draft and final supplemental environmental impact statements which address severe accident mitigation design alternatives for the common design, which must be incorporated by reference into the environmental impact statement prepared for each application. Scoping under §§ 51.28 and 51.29 of this chapter for the supplemental environmental impact statement may be conducted simultaneously and may be part of the scoping for each of the applications.

(g) The ACRS must report on each of the applications as required by the applicable sections of this subpart. Each report must be limited to those safety matters for each application which are not relevant to the common design. In addition, the ACRS must separately report on the safety of the common design, provided, however, that the report need not address the safety of a referenced standard design certification or reactor manufactured under Framework B of this part.

(h) The Commission must designate a presiding officer to conduct the proceeding with respect to the health and safety, common defense and security, and environmental matters relating to the common design. The hearing will be governed by

the applicable provisions of subparts A, C, G, L, N, and O of 10 CFR part 2 relating to applications for CPs, OLs, and COLs. The presiding officer must issue a partial initial decision on the common design.

(i) If the design for the power reactor(s) proposed in a particular application is not identical to the others, that application may not be processed under this section and subpart D of 10 CFR part 2.

(j) As used in this section, the design of a nuclear power reactor included in a single referenced Safety Analysis Report means the design of those SSCs important to radiological health and safety and the common defense and security.

Subpart S — Maintaining and Revising Licensing Basis Information

§ 53.6000 Licensing basis information.

This subpart provides the requirements for each holder of a license for a commercial nuclear plant licensed under Framework B of this part to maintain licensing basis information as defined in § 53.020; evaluate changes to site characteristics, plant design features, and programmatic controls to determine needed approvals and revisions; and submit appropriate updates to the NRC.

§ 53.6002 Specific terms and conditions of licenses.

(a) Each license issued under Framework B of this part is subject to the provisions of the Act<u>EA</u> and to all rules, regulations, and orders of the Commission. The terms and conditions of the license must be subject to amendment, revision, or modification, by reason of amendments of the Act<u>EA</u> or by reason of rules, regulations, and orders issued in accordance with the terms of the Act<u>EA</u>.

(b) Each license issued under Framework B of this part must be subject to all conditions imposed as a matter of law by sections 401(a)(2) and 401(d) of the Federal Water Pollution Control Act, as amended (33 U.S.C.A. 1341(a)(2) and (d)).

(c) A holder of an OL or COL under Framework B of this part may take reasonable action that departs from a license condition or a technical specification (included in a license issued under Framework B of this part) in a national security emergency—

(1) When this action is immediately needed to implement national security objectives as designated by the national command authority through the Commission, and

(2) No action consistent with license conditions and technical specifications that can satisfy national security objectives is immediately apparent.

(3) A national security emergency is established by a law enacted by the Congress or by an order or directive issued by the President pursuant to statutes or the Constitution of the United States. The authority under this paragraph must be exercised in accordance with law, including section 57e. of the Act, and is in addition to the authority granted under § 53.740(h), which remains in effect unless otherwise directed by the Commission during a national security emergency.

(d)(1) If the NRC finds that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency (including findings based on requirements of 10 CFR part 50, appendix E, section IV.D.3) and if the deficiencies (including deficiencies based on requirements of 10 CFR part 50, appendix E, section IV.D.3) are not corrected within 4 months of that finding, the Commission will determine whether the facility must be shut down or cease operations until such deficiencies are remedied or whether other enforcement action is appropriate. In determining whether a shutdown, cessation of operations, or other enforcement action is appropriate, the Commission will take into account, among other factors, whether the licensee can demonstrate to the

Commission's satisfaction that the deficiencies in the plan are not significant for the plant in question, or that adequate interim compensating actions have been or will be taken promptly, or that that there are other compelling reasons for continued operation.

(2) If the planning standards for radiological emergency preparedness apply to offsite emergency response plans, then the NRC will base its finding on a review of the FEMA findings and determinations as to whether State, participating Tribal and local emergency plans are adequate and capable of being implemented, and on the NRC assessment as to whether the licensee's emergency plans are adequate and capable of being implemented. Nothing in this paragraph will be construed as limiting the authority of the Commission to take action under any other regulation or authority of the Commission or at any time other than that specified in this paragraph.

§ 53.6005 Changes to licensing basis information requiring prior NRC approval.

(a) Sections 53.6010 through 53.6020 provide the process for a licensee to request and the NRC to issue amendments to licenses, including any conditions contained therein, technical specifications or other attachments to a license, and any orders issued by the NRC modifying a license. Sections 53.6025 and 53.6030 govern proposed changes to a commercial nuclear plant referencing a certified design or ML.

(b) A licensee may propose changing licensing basis information established by NRC regulations by requesting an exemption in accordance with § 53.080.

§ 53.6010 Application for amendment of license.

Whenever a holder of a license under Framework B of this part desires to amend the license, an application for an amendment must be filed with the Commission, as specified in § 53.040, that fully describes the changes desired and, following as far as applicable, the form prescribed for original applications. Applications for amendments

must include analysis of whether the amendment includes no significant hazards consideration using the standards in § 53.6020.

§ 53.6015 Public notices; State consultation.

The Commission will use the following procedures for an application requesting an amendment to an OL or COL issued under Framework B of this part.

(a) Public notices.

(1)(i) The Commission may publish in the *Federal Register* under § 2.105 of this chapter an individual notice of proposed action for an amendment for which it makes a proposed determination that no significant hazards consideration is involved, or, at least once every 30 days, publish a periodic *Federal Register* notice of proposed actions, which identifies each amendment issued and each amendment proposed to be issued since the last such periodic notice, or it may publish both such notices.

(ii) For each amendment proposed to be issued, the notice will (A) contain the staff's proposed determination under the standards in § 53.6020, (B) provide a brief description of the amendment and of the facility involved, (C) solicit public comments on the proposed determination, and (D) provide for a 30-day comment period.

(iii) The comment period will begin on the day after the date of the publication of the first notice, and, normally, the amendment will not be granted until after this comment period expires.

(2) The Commission may inform the public about the final disposition of an amendment request for which it has made a proposed determination of no significant hazards consideration either by issuing an individual notice of issuance under § 2.106 of this chapter or by publishing such a notice in its periodic system of *Federal Register* notices. In either event, it will not make and will not publish a final determination of no

~~significant hazards consideration unless it receives a request for a hearing on that amendment request.~~

~~(3) Where the Commission makes a final determination that no significant hazards consideration is involved and that the amendment should be issued, the amendment will be effective on issuance, even if adverse public comments have been received and even if an interested person satisfying the provisions for intervention called for in § 2.309 of this chapter has filed a request for a hearing. The Commission need hold any required hearing only after it issues an amendment, unless it determines that a significant hazards consideration is involved, in which case the Commission will provide an opportunity for a prior hearing.~~

~~(4) Where the Commission finds that an emergency situation exists, in that failure to act in a timely way would result in derating or shutdown of a commercial nuclear reactor, or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, it may issue a license amendment involving no significant hazards consideration without prior notice and opportunity for a hearing or for public comment. In such a situation, the Commission will not publish a notice of proposed determination on no significant hazards consideration, but will publish a notice of issuance under § 2.106 of this chapter providing for opportunity for a hearing and for public comment after issuance. The Commission expects its licensees to apply for license amendments in timely fashion. It will decline to dispense with notice and comment on the determination of no significant hazards consideration if it determines that the licensee has abused the emergency provision by failing to make timely application for the amendment and thus itself creating the emergency. Whenever an emergency situation exists, a licensee requesting an amendment must explain why this emergency situation occurred and why it could not avoid this situation, and the~~

Commission will assess the licensee's reasons for failing to file an application sufficiently in advance of that event.

(5) Where the Commission finds that exigent circumstances exist, in that a licensee and the Commission must act quickly and that time does not permit the Commission to publish a *Federal Register* notice allowing 30 days for prior public comment, and it also determines that the amendment involves no significant hazards considerations, it—

(i)(A) Will either issue a *Federal Register* notice providing notice of an opportunity for hearing and allowing at least 2 weeks from the date of the notice for prior public comment; or

(B) Will use local media to provide reasonable notice to the public in the area surrounding a licensee's facility of the licensee's amendment and of its proposed determination as described in paragraph (a)(1) of this section, consulting with the licensee on the proposed media release and on the geographical area of its coverage;

(ii) Will provide for a reasonable opportunity for the public to comment, using its best efforts to make available to the public whatever means of communication it can for the public to respond quickly, and, in the case of telephone comments, have these comments recorded or transcribed, as necessary and appropriate;

(iii) When it has issued a local media release, may inform the licensee of the public's comments, as necessary and appropriate;

(iv) Will publish a notice of issuance under § 2.106 of this chapter;

(v) Will provide a hearing after issuance, if one has been requested by a person who satisfies the provisions for intervention specified in § 2.309 of this chapter; and

(vi) Will require the licensee to explain the exigency and why the licensee cannot avoid it and use its normal public notice and comment procedures in paragraph (a)(1) of

this section if it determines that the licensee has failed to use its best efforts to make a timely application for the amendment in order to create the exigency and to take advantage of this procedure.

(6) Where the Commission finds that significant hazards considerations are involved, it will issue a *Federal Register* notice providing an opportunity for a prior hearing even in an emergency situation, unless it finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

(b) *State consultation*.

(1) At the time a licensee requests an amendment, it must notify the State in which its facility is located of its request by providing that State with a copy of its application and its reasoned analysis about no significant hazards considerations and indicate on the application that it has done so.

(2) The Commission will advise the State of its proposed determination about no significant hazards consideration normally by sending it a copy of the *Federal Register* notice.

(3) The Commission will make the names of the Project Manager or other NRC personnel it designated to consult with the State available to the State official designated to consult about its proposed determination. The Commission will consider any comments of that State official. If it does not hear from the State in a timely manner, it will consider that the State has no interest in its determination; nonetheless, to ensure that the State is aware of the application, before it issues the amendment, it will make a good faith effort to communicate directly with that official. (Inability to consult with a responsible State official following good faith attempts will not prevent the Commission

from making effective a license amendment involving no significant hazards consideration .)

(4) The Commission will make a good faith attempt to consult with the State before it issues a license amendment involving no significant hazards consideration. If, however, it does not have time to use its normal consultation procedures because of an emergency situation, it will attempt to communicate directly with the appropriate State official. (Inability to consult with a responsible State official following good faith attempts will not prevent the Commission from making effective a license amendment involving no significant hazards consideration, if the Commission deems it necessary in an emergency situation.)

(5) After the Commission issues the requested amendment, it will send a copy of its determination to the State.

(c) *Caveats about State consultation.*

(1) The State consultation procedures in paragraph (b) of this section do not give the State a right —

(i) To veto the Commission's proposed or final determination;

(ii) To a hearing on the determination before the amendment becomes effective; or

(iii) To insist upon a postponement of the determination or upon issuance of the amendment.

(2) These procedures do not alter present provisions of law that reserve to the Commission exclusive responsibility for setting and enforcing radiological health and safety requirements for commercial nuclear plants.

§ 53.6020 Issuance of amendment.

(a) In determining whether an amendment to a license will be issued to the applicant, the Commission will be guided by the considerations which govern the issuance of initial licenses to the extent applicable and appropriate. If the application involves the material alteration of a licensed facility, a CP will be issued before the issuance of the amendment to the license, provided however, that if the application involves a material alteration to a manufactured reactor under Framework B of this part before its installation at a site, or a COL before the date that the Commission makes the finding under § 53.5052(g), no application for a CP is required. If the amendment involves a significant hazards consideration, the Commission will give notice of its proposed action—

(1) Under § 2.105 of this chapter before acting thereon; and

(2) As soon as practicable after the application has been docketed.

(b) The Commission will be particularly sensitive to a license amendment request that involves irreversible consequences (such as one that permits a significant increase in the amount of effluents or radiation emitted by a commercial nuclear plant).

(c) The Commission may make a final determination, under the procedures in § 53.6015, that a proposed amendment to an OL or a COL for a commercial nuclear plant under Framework B of this part involves no significant hazards consideration, if operation of the plant in accordance with the proposed amendment would not—

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or

(3) Involve a significant reduction in a margin of safety.

§ 53.6025 Revising certification information within a design certification rule.

(a) A holder of an OL or COL who references a design certification rule issued under Framework B of this part must request an exemption if proposing to change one or more elements of the certification information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 53.080 and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure.

(b) The request for an exemption must be included with the associated license amendment request, which must be requested and processed in accordance with §§ 53.6010, 53.6015, and 53.6020.

(c) Licensees must evaluate changes to the design as described in the FSAR not involving changes to the certification information using the criteria in § 53.6050.

§ 53.6030 Revising design information within a manufacturing license.

(a) The holder of an ML may not make changes to the design of the manufactured reactor authorized to be manufactured without obtaining an amendment pursuant to § 53.6010 and, as applicable, § 53.6020.

(b) The holder of a COL under Framework B of this part who references or uses a manufactured reactor under Framework B of this part must request approval for any proposed departure from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The application for such departures must be submitted and processed in accordance with §§ 53.6010, 53.6015, and 53.6020. In those cases where an ML references a design certification rule, the amendment application from the holder of the COL must also request an exemption from the design certification rule in accordance with § 53.6025 if one or more elements of the certification information are adversely affected by the proposed change. The holder of

the COL must evaluate changes to the commercial nuclear plant as described in the FSAR but outside of the scope of the referenced ML using the criteria in § 53.6050.

§ 53.6035 Amendments during construction.

(a) The holder of a CP or LWA under Framework B of this part may request an amendment to the CP or LWA in order to gain Commission approval of the safety of selected design features or specifications, including proposed departures from a design certification rule or ML. Amendments to CPs or LWAs under Framework B of this part must be requested and processed in accordance with §§ 53.6010 and 53.6020.

(b) The holder of a COL under Framework B of this part for which the NRC has not yet made a finding in accordance with § 53.5052(g) must request amendments required by § 53.6025 or § 53.6050 no later than 45 days from the date the licensee begins the construction of the SSCs to implement the change or departure requiring NRC approval. The licensee proceeds with such changes at its own risk recognizing that there is a possibility that the amendment will not be granted.

§ 53.6040 Updating licensing basis information and determining the need for NRC approval.

(a) Sections 53.6045 through 53.6065 provide the process for a holder of an OL or COL to modify licensing basis information and to evaluate potential changes to its facilities, procedures, programs, and organizations to determine if NRC approval is required. These sections also apply to the holder of a license authorizing operation of a nuclear power reactor that has submitted the certification of permanent cessation of operations required under § 53.4670(a)(1) or a reactor licensee whose license has been amended to allow possession of nuclear fuel but not operation of the facility.

(b) Definitions for the purposes of §§ 53.6045 through 53.6065—

Change means a modification or addition to, or removal from, the commercial nuclear plant or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

Departure from a method of evaluation described in the UFSAR used in establishing the design bases or in the safety analyses means—

(1) Changing any of the elements of the method described in the UFSAR unless the results of the analysis are conservative or essentially the same; or

(2) Changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

Facility as described in the UFSAR means—

(1) The SSCs that are described in the UFSAR,

(2) The design and performance requirements for such SSCs described in the UFSAR, and

(3) The evaluations or methods of evaluation included in the UFSAR for such SSCs which demonstrate that their intended function(s) will be accomplished.

Final Safety Analysis Report (as updated) means the FSAR submitted in accordance with § 53.4969 or § 53.5016, as amended and supplemented, and as updated per the requirements in § 53.6045, as applicable.

Procedures as described in the Final Safety Analysis Report (as updated) means those procedures that contain information described in the UFSAR such as how SSCs are operated and controlled (including assumed operator actions and response times).

Tests or experiments not described in the Final Safety Analysis Report (as updated) means any activity where any structure, system, or component is utilized or controlled in a manner which is either—

(1) Outside the reference bounds of the design bases as described in the UFSAR or

(2) Inconsistent with the analyses or descriptions in the UFSAR.

§ 53.6045 Updating Final Safety Analysis Reports.

(a) Each holder of an OL or COL under Framework B of this part for which the Commission has made the finding under § 53.5052(g) must update the FSAR originally submitted as part of the application for the license every 24 months or more frequently to assure that the information included in the report contains the latest information developed. The submittal must include the effects on the content of the FSAR of —

(1) Changes made to the facility or procedures as described in the FSAR;

(2) Safety analyses and evaluations performed by the licensee either in support of approved license amendments or in support of conclusions that changes did not require a license amendment in accordance with § 53.6050;

(3) Analyses of new safety issues performed by or on behalf of the licensee at Commission request.

(b)(1) The licensee must submit revisions containing updated information to the Commission, as specified in § 53.040, identifying the location of revised or new information.

(2) The submittal must include —

(i) a certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittal, necessary to reflect information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made; and

(ii) an identification of changes made under the provisions of § 53.6050 but not previously submitted to the Commission.

~~(c) Each applicant for or holder of a COL under Framework B of this part for which the Commission has not made the finding under § 53.5052(g) must submit an update to the FSAR annually. COL applicants who have requested the NRC to suspend its review of the COL application and COL holders who have informed the NRC that they do not plan to pursue construction need not submit an annual update of the FSAR. If a COL applicant requests that the NRC resume its review, or a COL holder notifies the NRC that the COL holder plans to commence or resume construction, then the COL applicant or holder must submit to NRC an update to its FSAR within 90 days of the request or notification, as applicable, and annually thereafter.~~

~~(d) The UFSAR must be retained by the licensee until the Commission terminates their license.~~

~~(e) [Reserved]~~

~~(f) Each person licensed to manufacture a reactor under Framework B of this part must update the FSAR originally submitted as part of the application to reflect any modification to the design that is directed or approved by the Commission under § 53.4888 or § 53.6030, and any new analyses of the design performed by or on behalf of the licensee at the NRC's request. This submittal must contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee with respect to the modification approved under § 53.6030 or the analyses requested by the Commission under § 53.4888. The updated information must be appropriately located within the update to the FSAR.~~

~~§ 53.6050 Evaluating changes to facility as described in Final Safety Analysis Reports.~~

~~(a) A licensee may make changes in the facility as described in the UFSAR, make changes in the procedures as described in the UFSAR, and conduct tests or~~

~~experiments not described in the UFSAR without obtaining a license amendment pursuant to § 53.6010 only if—~~

~~(1) A change to the technical specifications incorporated in the license is not required, and~~

~~(2) The change, test, or experiment would not—~~

~~(i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the UFSAR;~~

~~(ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component important to safety previously evaluated in the UFSAR;~~

~~(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the UFSAR;~~

~~(iv) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the UFSAR;~~

~~(v) Create a possibility for an accident of a different type than any previously evaluated in the UFSAR;~~

~~(vi) Create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the UFSAR;~~

~~(vii) Result in a design basis limit for a fission product barrier as described in the UFSAR being exceeded or altered;~~

~~(viii) Result in a departure from a method of evaluation described in the UFSAR used in establishing the design bases or in the safety analyses.~~

~~(3) In implementing this paragraph, the UFSAR is considered to include FSAR changes resulting from evaluations performed pursuant to this section and analyses~~

performed pursuant to § 53.6010 since submittal of the last update of the FSAR pursuant to § 53.6045.

(4) The provisions in this section do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(b)(1) A licensee who references a design certification rule may make departures from the standard design, without prior Commission approval, unless the proposed departure involves a change to the design as described in the rule certifying the design, in which case the requirements of § 53.6025 are applicable.

(2) The licensee must maintain records of all departures from the certified design of the facility and these records must be maintained and available for audit until the date of termination of the license. The licensee must identify the location and nature of departures from licensing basis information within supporting documents for a certified design within the updates to the Final Safety Analysis Report required by § 53.6045.

(3) Licensees for which the NRC has docketed the certifications required under § 53.4670 are not required to retain records of departures from the design of the facility associated with SSCs that have been permanently removed from service using an NRC-approved change process.

(c)(1) The licensee must maintain records of changes in the facility and procedures made pursuant to paragraph (a) of this section. These records must include a written evaluation which provides the bases for the determination that the change does not require a license amendment pursuant to paragraph (a)(2) of this section.

(2) The licensee must submit, as specified in § 53.040, a report containing a brief description of any departures and changes, including a summary of the evaluation of each. A report must be submitted at intervals not to exceed 24 months. For COLs, the

report must be submitted at intervals not to exceed 6 months during the period from the date of application for a COL to the date the Commission makes its findings under § 53.5052(g).

(3) The records of changes in the facility must be maintained until the termination of an OL or COL issued under Framework B of this part, or the termination of a renewed license issued under § 53.6095—whichever is later. Records of changes in procedures must be maintained for a period of 5 years.

§ 53.6052 Maintenance of risk evaluations.

Applicants or licensees required to submit a risk evaluation under § 53.4730(a)(34) must meet the following requirements:

(a) No later than the scheduled date for initial loading of fuel, each holder of an operating or combined license for a commercial nuclear plant under Framework B of this part must develop a risk evaluation.

(b) Each licensee required to develop a risk evaluation under paragraph (a) of this section must maintain the risk evaluation to reflect the as-built, as-operated facility. The risk evaluation must be maintained at least every 5 years until the permanent cessation of operations under § 53.4670. If a PRA is performed under § 53.4730(a)(34)(i), the licensee must upgrade the PRA to cover initiating events and modes of operation contained in consensus standards on PRA that are endorsed by the NRC. The upgrade must be completed within 5 years of NRC endorsement of the standard.

(c) Each licensee required to develop a risk evaluation based on a PRA must, no later than the date on which the licensee submits an application for a renewed license, upgrade the PRA required by paragraph (a) of this section to cover all modes and all initiating events.

(d) Each licensee who developed an alternative evaluation for risk insights under § 53.4730(a)(34)(ii) must, no later than the date on which the licensee submits an application for a renewed license, confirm that the alternative evaluation for risk insights reflects the as-built, as-operated facility.

§ 53.6054 Control of aircraft impact assessments.

(a) For CPs subject to § 53.4730(a)(35)(i) of this section, if the permit holder changes the information required by § 53.4909(a)(7)(xii) to be included in the PSAR, then the permit holder must consider the effect of the changed feature or capability on the original assessment required by § 53.4730(a)(35)(i) and amend the information required by § 53.4909(a)(7)(xii) to be included in the PSAR to describe how the modified design features and functional capabilities continue to demonstrate compliance with the assessment requirements in § 53.4730(a)(35)(i)(A).

(b) For OLs subject to § 53.4730(a)(35)(i) of this section, if the licensee changes the information required by § 53.4969(a)(7)(xiv) to be included in the FSAR, then the licensee must consider the effect of the changed feature or capability on the original assessment required by § 53.4730(a)(35)(i) and amend the information required by § 53.4969(a)(7)(xiv) to be included in the FSAR to describe how the modified design features and functional capabilities continue to demonstrate compliance with the assessment requirements in § 53.4730(a)(35)(i)(A).

(c) For standard design certifications subject to § 53.4730(a)(35)(i), generic changes to the information required by § 53.4839(a)(8)(xvii) to be included in the FSAR are governed by the applicable requirements of § 53.4863.

(d)(1) For COLs subject to § 53.4730(a)(35)(i), if the licensee changes the information required by § 53.5016(a)(4)(xvii) to be included in the FSAR, then the licensee must consider the effect of the changed feature or capability on the original

~~assessment required by § 53.4730(a)(35)(i), and amend the information required by § 53.5016(a)(4)(xvii) to be included in the FSAR to describe how the modified design features and functional capabilities continue to demonstrate compliance with the assessment requirements in § 53.4730(a)(35)(i)(A).~~

~~(2) For COLs not subject to § 53.4730(a)(35)(i) but which reference a standard design certification subject to § 53.4730(a)(35)(i), proposed departures from the information required by § 53.4839(a)(8)(xvii) to be included in the FSAR for the referenced standard design certification are governed by the change control requirements in the applicable design certification rule and the provisions in § 53.6050(b).~~

~~(3) For COLs not subject to § 53.4730(a)(35)(i) but which reference a manufactured reactor subject to § 53.4730(a)(35)(i), proposed departures from the information required by § 53.4879(d)(14)(xii) to be included in the FSAR for the ML are governed by the applicable requirements in § 53.6030.~~

~~(e)(1) For MLs subject to § 53.4730(a)(35)(i), generic changes to the information required by § 53.4879(d)(14)(xii) to be included in the FSAR are governed by the applicable requirements of § 53.4888.~~

~~(2) For MLs not subject to § 53.4730(a)(35)(i) but which reference a standard design certification subject to § 53.4730(a)(35)(i), proposed departures from the information required by § 53.4839(a)(8)(xvii) to be included in the FSAR for the referenced standard design certification are governed by the change control requirements in the applicable design certification rule.~~

~~§ 53.6060 Updating program documents included in licensing basis information.~~

~~(a) Each holder under Framework B of this part of an OL or COL for which the Commission has made the finding under § 53.5052(g) must biennially or more frequently~~

~~update the program documents submitted as part of an application to obtain or maintain the license to assure that the information included in the documents contains the latest information developed. The submittals must include the effects on the content of the program documents of—~~

~~(1) changes made in the facility, procedures, licensee's organization, or site environs;~~

~~(2) safety analyses and evaluations performed by the applicant or licensee either in support of approved license amendments or in support of conclusions that changes did not require a license amendment in accordance with § 53.6050;~~

~~(3) analyses of new safety issues performed by or on behalf of the licensee at Commission request; and~~

~~(4) changes to the programs as a result of operating experience, corrective actions, or other reasons deemed appropriate to ensure the programs serve their underlying purpose to satisfy applicable NRC regulations in Framework B.~~

~~(b)(1) The licensee must submit revisions containing updated information to the Commission, as specified in § 53.040, identifying the location of revised or new information.~~

~~(2) The submittal must include (i) a certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittals, necessary to reflect information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made; and (ii) an identification of changes made under the provisions of § 53.6050 but not previously submitted to the Commission.~~

~~(c) The updated program documents must be retained by the licensee until the Commission terminates their license.~~

§ 53.6065 Evaluating changes to programs included in licensing basis information.

(a) A licensee may make changes to the facility, procedures, or organizations or to address changes to site environs as described in the program documents included in licensing basis information without obtaining prior NRC approval only if—

(1) A change to the technical specifications incorporated in the license is not required,

(2) An exemption from an NRC regulation is not required,

(3) The change conforms to program-specific requirements included in regulations in Framework B of this part, technical specifications, or the NRC-approved program document included and reviewed as part of a license application under subpart R or an amendment under this subpart.

(b) In implementing this paragraph, the program documents (as updated) include changes since submittal of the last updates of the program documents pursuant to § 53.6060.

(c) The provisions in this section do not apply to changes to the program documents when the applicable regulations establish more specific criteria for accomplishing such changes.

(d) To make changes to the facility, procedures, or organizations or to address changes to site environs as described in the program documents included in licensing basis information for individual programs, the following requirements must be satisfied:

(1) *Quality assurance program—operation.* (i) Each holder under Framework B of this part of an OL or COL, after the Commission makes the finding under § 53.5052(g), may make a change to a previously accepted QAP description included or referenced in the Safety Analysis Report without prior NRC approval, provided the change does not

reduce the commitments in the program description as accepted by the NRC. Changes to the QAP description that do not reduce the commitments must be submitted to the NRC in accordance with the requirements of § 53.6045. In addition to QAP changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered to be reductions in commitment:

(A) The use of a QA standard approved by the NRC which is more recent than the QA standard in the licensee's QAP at the time of the change;

(B) The use of a QA alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility;

(C) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

(D) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text;

(E) The elimination of QAP information that duplicates language in QA regulatory guides and QA standards to which the licensee is committed; and

(F) Organizational revisions that ensure that persons and organizations performing QA functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(ii) Changes to the QAP description that do reduce the commitments must be submitted to the NRC and receive NRC approval prior to implementation, as follows:

(A) Changes made to the QAP description as presented in the Safety Analysis Report or in a topical report must be submitted as specified in § 53.040.

(B) The submittal of a change to the Safety Analysis Report QAP description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of subpart U of this part and the Safety Analysis Report QAP description commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(C) A copy of the forwarding letter identifying the change must be maintained as a facility record for 3 years.

(D) Changes to the QAP description included or referenced in the Safety Analysis Report must be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

(2) *Quality assurance program—siting, construction, and manufacturing*. Each holder of an LWA, early site permit, CP, ML, or COL, before the Commission makes the finding under § 53.5052(g), under Framework B of this part may make a change to a previously accepted QAP description included or referenced in the Safety Analysis Report without prior NRC approval, provided the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the QAP description that do not reduce the commitments must be submitted to NRC within 90 days. Changes to the QAP description that reduce the commitments must be submitted to NRC and receive NRC approval before implementation, as follows:

(i) Changes to the Safety Analysis Report must be submitted for review as specified in § 53.040. Changes made to NRC-accepted QA topical report descriptions must be submitted as specified in § 53.040.

(ii) The submittal of a change to the Safety Analysis Report QAP description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of subpart U of this part and the Safety Analysis Report QAP description commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(iii) A copy of the forwarding letter identifying the changes must be maintained as a facility record for 3 years.

(iv) Changes to the QAP description included or referenced in the Safety Analysis Report must be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

(3) *Emergency preparedness program.*

(i)(A) The licensee shall provide for the development, revision, implementation, and maintenance of its emergency preparedness program. The licensee shall ensure that all program elements are reviewed by persons who have no direct responsibility for the implementation of the emergency preparedness program either—

(*1*) At intervals not to exceed 12 months or,

(2) As necessary, based on an assessment by the licensee against performance indicators, and as soon as reasonably practicable after a change occurs in personnel, procedures, equipment, or facilities that potentially could adversely affect emergency

preparedness, but no longer than 12 months after the change. In any case, all elements of the emergency preparedness program must be reviewed at least once every 24 months.

(B) The review must include an evaluation for adequacy of interfaces with State, participating Tribal and local governments and of licensee drills, exercises, capabilities, and procedures. The results of the review, along with recommendations for improvements, must be documented, reported to the licensee's corporate and plant management, and retained for a period of 5 years. The part of the review involving the evaluation for adequacy of interface with State, participating Tribal and local governments must be available to the appropriate State, participating Tribal and local governments.

(ii) The licensee may make changes to its emergency plan without NRC approval only if the licensee performs and retains an analysis demonstrating that the changes do not reduce the effectiveness of the plan and the plan, as changed, continues to demonstrate compliance with the requirements in § 53.4320. A change reduces the effectiveness of the plan if it results in reducing the licensee's capability to perform an emergency planning function required by § 53.4320 in the event of a radiological emergency.

(iii) The licensee must retain a record of each change to the emergency plan made without prior NRC approval for a period of 3 years from the date of the change and must submit, as specified in § 53.040, a report of each such change, including a summary of its analysis, within 30 days after the change is put in effect.

(iv) The changes to a licensee's emergency plan that reduce the effectiveness of the plan may not be implemented without prior approval by the NRC. A licensee desiring to make such a change must submit an application for an amendment to its license. In

addition to the filing requirements of §§ 53.6010, 53.6015, and 53.6020, the request must include all emergency plan pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the licensee's emergency plan, as revised, will continue to demonstrate compliance with the requirements of § 53.4320.

(v) The commercial nuclear plant licensee must retain the emergency plan and each change for which NRC approval was obtained, pursuant to paragraph (d)(3)(iv) of this section, as a record until the Commission terminates the license for the nuclear power reactor.

(4) *Security programs.*

(i) The licensee must prepare and maintain safeguards contingency plan procedures in accordance with appendix C of part 73 of this chapter for affecting the actions and decisions contained in the Responsibility Matrix of the safeguards contingency plan. The licensee may not make a change which would decrease the effectiveness of a physical security plan, or training and qualification plan, or cyber security plan submitted under subpart R or part 73 of this chapter, or of the first four categories of information (Background, Generic Planning Base, Licensee Planning Base, Responsibility Matrix) contained in a licensee safeguards contingency plan submitted under subpart R or part 73 of this chapter, as applicable, without prior approval of the Commission. A licensee desiring to make such a change must submit an application for amendment to the licensee's license under §§ 53.6010, 53.6015, and 53.6020.

(ii) The licensee may make changes to the plans referenced in paragraph (d)(4)(i) of this section without prior Commission approval if the changes do not decrease the safeguards effectiveness of the plan. The licensee must maintain records of changes to the plans made without prior Commission approval for a period of 3 years

from the date of the change, and must submit, as specified in § 53.040, a report containing a description of each change within 2 months after the change is made. Prior to the safeguards contingency plan being put into effect, the licensee must have—

(A) All safeguards capabilities specified in the safeguards contingency plan available and functional;

(B) Detailed procedures developed according to appendix C to part 73 of this chapter available at the licensee's site; and

(C) All appropriate personnel trained to respond to safeguards incidents as outlined in the plan and specified in the detailed procedures.

(iii) The licensee must provide for the development, revision, implementation, and maintenance of its safeguards contingency plan. The licensee must ensure that all program elements are reviewed by individuals independent of both security program management and personnel who have direct responsibility for implementation of the security program either—

(A) At intervals not to exceed 12 months; or

(B) As necessary, based on an assessment by the licensee against performance indicators, and as soon as reasonably practicable after a change occurs in personnel, procedures, equipment, or facilities that potentially could adversely affect security, but no longer than 12 months after the change. In any case, all elements of the safeguards contingency plan must be reviewed at least once every 24 months.

(iv) The review must include a review and audit of safeguards contingency procedures and practices, an audit of the security system testing and maintenance program, and a test of the safeguards systems along with commitments established for response by local law enforcement authorities. The results of the review and audit, along with recommendations for improvements, must be documented, reported to the

licensee's corporate and plant management, and kept available at the plant for inspection for a period of 3 years.

§ 53.6070 Transfer of licenses.

(a) No commercial nuclear plant license issued under Framework B of this part, or any right thereunder, shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission gives its consent in writing.

(b)(1) An application for transfer of a license must include—

(i) As much of the information described in §§ 53.4709, 53.4906, 53.4966, and 53.5013 with respect to the identity and technical and financial qualifications of the proposed transferee as would be required by those sections if the application were for an initial license. The Commission may require additional information such as data respecting proposed safeguards against hazards from radioactive materials and the applicant's qualifications to protect against such hazards.

(ii) A statement of the purposes for which the transfer of the license is requested, the nature of the transaction necessitating or making desirable the transfer of the license, and an agreement by the proposed transferee to limit access to Restricted Data or Classified National Security Information pursuant to § 53.4715. The Commission may require any person who submits an application for license pursuant to the provisions of this section to file a written consent from the existing licensee or a certified copy of an order or judgment of a court of competent jurisdiction attesting to the person's right (subject to the licensing requirements of the Act<u>EA</u> and these regulations) to possession of the facility or site involved.

(2) [Reserved]

~~(c) After appropriate notice to interested persons, including the existing licensee, and observance of such procedures as may be required by the Act~~EA or regulations or orders of the Commission, the Commission will approve an application for the transfer of a license, if the Commission determines—

~~(1) That the proposed transferee is qualified to be the holder of the license; and~~

~~(2) That transfer of the license is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.~~

~~§ 53.6075 Termination of license.~~

~~(a) When the holder of an OL or COL under Framework B of this part has determined to permanently cease operations the licensee must, within 30 days, submit a written certification to the NRC, consistent with the requirements of § 53.4670.~~

~~(b) Once fuel has been permanently removed from the reactor system, the licensee must submit a written certification to the NRC that meets the requirements of § 53.4670.~~

~~(c)(1) Upon docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor system, or when a final legally effective order to permanently cease operations has come into effect, the license no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor system.~~

~~(2) Activities associated with decommissioning will be carried out in accordance with the requirements and procedures in subpart Q.~~

~~(3) The Commission shall terminate the license if it determines that—~~

~~(i) The remaining dismantlement has been performed in accordance with the approved license termination plan required in subpart Q, and~~

(ii) The final radiation survey and associated documentation, including an assessment of dose contributions associated with parts released for use before approval of the license termination plan, demonstrate that the facility and site have met the criteria for decommissioning in 10 CFR part 20, subpart E.

(d) A holder of a CP or COL under Framework B of this part may request the termination of the license as well as licenses issued by the NRC under parts 30, 40, 70 of this chapter prior to plant operations. Such requests may support an immediate NRC approval of the site for unrestricted use.

§ 53.6080 Information requests.

Any licensee under Framework B of this part must at any time before expiration of the license, upon request of the Commission, submit, as specified in § 53.040 written statements, signed under oath or affirmation, to enable the Commission to determine whether or not the license should be modified, suspended, or revoked. Except for information sought to verify licensee compliance with the current licensing basis for that facility, the NRC must prepare the reason or reasons for each information request prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such justification provided for an evaluation performed by the NRC staff must be approved by the Executive Director for Operations or his or her designee prior to issuance of the request.

§ 53.6085 Revocation, suspension, modification of licenses and approvals for cause.

A license or standard design approval issued under Framework B of this part may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or in the supplemental or other statement of fact required of

the applicant; or because of conditions revealed by the application or statement of fact of any report, record, inspection, or other means which would warrant the Commission to refuse to grant a license or approval on an original application; or for failure to manufacture a reactor, or construct or operate a facility in accordance with the terms of the license, provided, however, that failure to make timely completion of the proposed construction or alteration of a facility under a CP under Framework B of this part shall be governed by the provisions of § 53.4942(b); or for violation of, or failure to observe, any of the terms and provisions of the act, regulations, license, approval, or order of the Commission.

§ 53.6090 Backfitting.

(a)(1) Backfitting means the modification of or addition to systems, structures, components, or design of a facility; or the design approval or ML for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after the date of the commercial nuclear plant license issued under Framework B of this part.

(2) Except as provided in paragraph (a)(4) of this section, the Commission shall require a systematic and documented analysis pursuant to paragraph (b) of this section for backfits which it seeks to impose.

(3) Except as provided in paragraph (a)(4) of this section, the Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (b) of this section, that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to

be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.

(4) The provisions of paragraphs (a)(2) and (a)(3) of this section are inapplicable and, therefore, backfit analysis is not required and the standards in paragraph (a)(3) of this section do not apply where the Commission or staff, as appropriate, finds and declares, with appropriated documented evaluation for its finding, either—

(i) That a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee; or

(ii) That regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security; or

(iii) That the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate.

(5) The Commission shall always require the backfitting of a facility if it determines that such regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security.

(6) The documented evaluation required by paragraph (a)(4) of this section shall include a statement of the objectives of and reasons for the modification and the basis for invoking the exception. If immediately effective regulatory action is required, then the documented evaluation may follow rather than precede the regulatory action.

(7) If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written licensee commitments, or there are

~~two or more ways to reach a level of protection which is adequate, then ordinarily the applicant or licensee is free to choose the way which best suits its purposes. However, should it be necessary or appropriate for the Commission to prescribe a specific way to comply with its requirements or to achieve adequate protection, then cost may be a factor in selecting the way, provided that the objective of compliance or adequate protection is met.~~

~~(b) In reaching the determination required by paragraph (a)(3) of this section, the Commission will consider how the backfit should be scheduled in light of other ongoing regulatory activities at the facility and, in addition, will consider information available concerning any of the following factors as may be appropriate and any other information relevant and material to the proposed backfit:~~

~~(1) The statement of the specific objectives that the proposed backfit is designed to achieve;~~

~~(2) The general description of the activity that would be required by the licensee or applicant in order to complete the backfit;~~

~~(3) The potential change in the risk to the public from the accidental off-site release of radioactive material;~~

~~(4) The potential impact on radiological exposure of facility employees;~~

~~(5) The installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay;~~

~~(6) The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements;~~

~~(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;~~

(8) The potential impact of differences in facility type, design or age on the relevancy and practicality of the proposed backfit;

(9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

(c) No licensing action will be withheld during the pendency of backfit analyses required by the Commission's rules.

(d) The Executive Director for Operations shall be responsible for implementation of this section, and all analyses required by this section shall be approved by the Executive Director for Operations or his designee.

§ 53.6095 Renewal.

Commented [A408]: Staff should incorporate application requirements as appropriate.

(a) Operating Licenses and combined licenses may be renewed by the Commission upon expiration of the period of the license.

(b) A renewed license will be issued for a fixed period of time, which is the sum of the additional amount of time beyond the expiration of the operating license or combined license (not to exceed 20 years) that is requested in a renewal application plus the remaining number of years on the operating license or combined license currently in effect. The term of any renewed license may not exceed 40 years.

(c) A renewed license will become effective immediately upon its issuance, thereby superseding the operating license or combined license previously in effect. If a renewed license is subsequently set aside upon further administrative or judicial appeal, the operating license or combined license previously in effect will be reinstated unless its term has expired and the renewal application was not filed in a timely manner.

(d) A renewed license may be subsequently renewed in accordance with all applicable requirements.

Subpart T — Reporting and Other Administrative Requirements

§ 53.6300 General information.

Each applicant and licensee under Framework B of this part must ensure that NRC inspectors have unfettered access to sites and facilities licensed or proposed to be licensed in § 53.6310, must maintain records and make reports to the NRC in accordance with requirements in §§ 53.6320 through 53.6350, must demonstrate compliance with financial qualification and reporting requirements in §§ 53.6360 through 53.6400, and must obtain and maintain required financial protections in case of an accident in §§ 53.6420 and 53.6430.

§ 53.6310 Unfettered access for inspections.

(a) Each applicant for or holder of an ML, OL, COL, CP, or early site permit must permit inspection, by duly authorized representatives of the Commission, of its records, premises, activities, and of licensed materials in possession or use, related to the license or CP or early site permit as may be necessary to effectuate the purposes of the Act<u>EA</u> and the ERA.

(b)(1) Each holder of an ML, OL, COL, or CP must, upon request by the Director, Office of Nuclear Reactor Regulation, provide rent-free office space for the exclusive use of the Commission inspection personnel. Heat, air conditioning, light, electrical outlets, and janitorial services must be furnished by each licensee and each holder of a CP. The office must be convenient to and have full access to the facility and must provide the inspectors both visual and acoustic privacy.

(2) For a site or facility with an assigned resident inspector, the space provided must be adequate to accommodate a full-time inspector, a part-time secretary, and transient NRC personnel and must be generally commensurate with other office facilities at the site. For sites or facilities assigned multiple resident inspectors, additional space may be requested. The office space that is provided must be subject to the approval of

the Director, Office of Nuclear Reactor Regulation. All furniture, supplies, and communication equipment will be furnished by the Commission.

(3) For a site or facility without an assigned resident inspector, temporary space to accommodate periodic or special inspections must be provided. The office space must be generally commensurate with other office accommodations at the site.

(4) The licensee or permit holder must afford any NRC resident inspector assigned to that site, or other NRC inspectors identified by the Regional Administrator as likely to inspect the facility, immediate unfettered access, equivalent to access provided regular plant employees, following proper identification and compliance with applicable access control measures for security, radiological protection, and personal safety.

(5) The licensee or permit holder must ensure that the arrival and presence of an NRC inspector, who has been properly authorized facility access as described in paragraph (b)(4) of this section, is not announced or otherwise communicated by its employees or contractors to other persons at the facility unless specifically requested by the NRC inspector.

§ 53.6320 Maintenance of records, making of reports.

(a) Each holder of an ML, OL, COL, CP, or early site permit must maintain all records and make all reports, in connection with the activity, as may be required by the conditions of the license or permit or by the regulations and orders of the Commission in effectuating the purposes of the Act<u>EA</u> and the ERA. Reports must be submitted in accordance with § 53.040.

(b) [Reserved]

(c) Records that are required by the regulations in Framework B of this part, by license condition, or by technical specifications must be retained for the period specified by the appropriate regulation, license condition, or technical specification. If a retention

~~period is not otherwise specified, these records must be retained until the Commission terminates the facility license or, in the case of an early site permit, until the permit expires.~~

~~(d)(1) Records which must be retained under Framework B of this part may be the original or a reproduced copy or a microform if the reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations. The record may also be stored in electronic media with the capability of producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with and loss of records.~~

~~(2) If there is a conflict between the Commission's regulations in Framework B of this part, license condition, or technical specification, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in Framework B of this part for such records must apply unless the Commission, pursuant to § 53.080 of this part, has granted a specific exemption from the record retention requirements in the regulations in Framework B of this part.~~

~~(e) Each licensee must notify the Commission as specified in § 53.040, of successfully completing power ascension testing or startup testing as applicable within 30 calendar days of completing the testing.~~

~~§ 53.6330 Immediate notification requirements for operating commercial nuclear plants.~~

(a) *General requirements.** (1) Each holder of an OL under Framework B of this part or a COL under Framework B of this part after the Commission makes the finding under § 53.5052(g), must notify the NRC Operations Center via the Emergency Notification System of—

(i) The declaration of any of the Emergency Classes specified in the licensee's approved Emergency Plan; or

(ii) Those non-emergency events specified in paragraph (b) of this section that occurred within 3 years of the date of discovery.

(2) If the Emergency Notification System is inoperative, the licensee must make the required notifications via commercial telephone service, other dedicated telephone system, or any other method which will ensure that a report is made as soon as practical to the NRC Headquarters Operations Center at the numbers specified in appendix A to part 73 of this chapter.

(3) The licensee must notify the NRC immediately after notification of the appropriate State or local agencies and not later than 1 hour after the time the licensee declares one of the Emergency Classes.

(4) The licensee must activate the data links with the NRC as specified in their emergency plans after declaring an Emergency Class for events of actual or potential substantial degradation of plant safety or security, probable risk to site personnel life, o, site equipment damage caused by hostile action. The data links may also be activated by the licensee during emergency drills or exercises if the licensee's computer system has the capability to transmit the exercise data.

(5) When making a report under paragraph (a)(1) of this section, the licensee must identify—

(i) The Emergency Class declared; or

(ii) Paragraph (b)(1), "One-hour reports," paragraph (b)(2), "Four-hour reports," or paragraph (b)(3), "Eight-hour reports," as the paragraph of this section requiring notification of the non-emergency event.

(b) *Non-emergency events.* (1) *One-hour reports.* If not reported as a declaration of an Emergency Class under paragraph (a) of this section, the licensee must notify the NRC as soon as practical and in all cases within 1 hour of the occurrence of any deviation from the plant's Technical Specifications authorized pursuant to § 53.740(h) of this part.

(2) *Four-hour reports.* If not reported under paragraphs (a) or (b)(1) of this section, the licensee must notify the NRC as soon as practical, and in all cases, within 4 hours of the occurrence of any of the following:

(i) The initiation of any commercial nuclear plant shutdown required by the plant's Technical Specifications.

(ii) Any event or condition that results in actuation of the RPS when the reactor is critical except when the actuation results from and is part of a pre-planned sequence during testing or reactor operation.

(iii) Any event or condition that results in an unplanned actuation of an SR standby cooling system or the unplanned sole reliance on an SR standby cooling system for those systems that are in constant operation.

(iv) Any event or condition that results in an unplanned movement of, change of state in, or chemical interaction involving a significant amount of radioactive material within the commercial nuclear plant.

(v) Any event or situation, related to the health and safety of the public or onsite personnel, or protection of the environment, for which a news release is planned or

notification to other government agencies has been or will be made. Such an event may include an onsite fatality or inadvertent release of radioactively contaminated materials.

(3) *Eight-hour reports.* If not reported under paragraphs (a), (b)(1) or (b)(2) of this section, the licensee must notify the NRC as soon as practical and in all cases within 8 hours of the occurrence of any of the following:

(i) Any event or condition that results in —

(A) The condition of the commercial nuclear plant, including its principal safety barriers, being seriously degraded; or

(B) The commercial nuclear plant being in an unanalyzed condition that significantly degrades plant safety.

(ii) Any event or condition that results in valid actuation of an SR system, except when the actuation results from and is part of a pre-planned sequence during testing or reactor operation.

(iii) Any event or condition that at the time of discovery could have prevented the fulfillment of the safety function of structures or systems that are needed to —

(A) Shut down the reactor and maintain it in a safe shutdown condition;

(B) Remove residual heat;

(C) Control the release of radioactive material; or

(D) Mitigate the consequences of an accident.

(iv) Events covered in paragraph (b)(3)(iii) of this section may include one or more procedural errors, equipment failures, and/or discovery of design, analysis, fabrication, construction, and/or procedural inadequacies. However, individual component failures need not be reported pursuant to paragraph (b)(3)(iii) of this section if redundant equipment in the same system was operable and available to perform the required safety function.

(v) Any event requiring the transport of a radioactively contaminated person to an offsite medical facility for treatment.

(vi) Any event that results in a major loss of emergency assessment capability, offsite response capability, or offsite communications capability (e.g., significant portion of control room indication, Emergency Notification System, or offsite notification system).

(c) *Follow-up Notification:* With respect to the notifications made under paragraphs (a) and (b) of this section, in addition to making the required initial notification, each licensee, must during the course of the event—

(1) Immediately Report: (i) any further degradation in the level of safety of the plant or other worsening plant conditions, including those that require the declaration of any of the Emergency Classes, if such a declaration has not been previously made, or

(ii) any change from one Emergency Class to another, or

(iii) a termination of the Emergency Class.

(2) Immediately Report: (i) the results of ensuing evaluations or assessments of plant conditions,

(ii) the effectiveness of response or protective measures taken, and

(iii) important information related to plant behavior that is not understood.

(3) Maintain an open, continuous communication channel with the NRC Operation Center upon request by the NRC.

*Other requirements for immediate notification of the NRC by licensed operating commercial nuclear plants are contained elsewhere in this chapter, in particular, §§ 20.1906, 20.2202, 72.216, 73.71, and 73.77 of this chapter.

§ 53.6340 Licensee event report system.

(a) *Reportable events.*

(1) Each commercial nuclear plant licensee holding an OL under Framework B of this part or a COL under Framework B of this part after the Commission makes the finding under § 53.5052(g), must submit an LER for any event of the type described in this section within 60 days after discovery of the event. In the case of an invalid actuation reported under § 53.6340(a)(2), other than automatic reactor shutdown when the reactor is critical, the licensee may, at its option, provide a telephone notification to the NRC Operations Center within 60 days after discovery of the event instead of submitting a written LER. Unless otherwise specified in this section, the licensee must report an event if it occurred within 3 years of the date of discovery regardless of the plant mode or power level, and regardless of the significance of the structure, system, or component that initiated the event.

(2) The licensee must report —

(i)(A) The completion of any commercial nuclear plant shutdown required by the plant's Technical Specifications.

(B) Any operation or condition which was prohibited by the plant's Technical Specifications except when —

(1) The Technical Specification is administrative in nature;

(2) The event consisted solely of a case of a late surveillance test where the oversight was corrected, the test was performed, and the equipment was found to be capable of performing its specified safety functions; or

(3) The Technical Specification was revised prior to discovery of the event such that the operation or condition was no longer prohibited at the time of the event.

(C) Any deviation from the plant's Technical Specifications authorized pursuant to § 53.740(h) of this part.

(ii) Any event or condition that resulted in —

(A) The condition of the commercial nuclear plant, including its principal safety barriers, being seriously degraded; or

(B) The commercial nuclear plant being in an unanalyzed condition that significantly degraded plant safety.

(iii) Any natural phenomena or other external condition that posed an actual threat to the safety of the commercial nuclear plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the commercial nuclear plant.

(iv) Any event or condition that resulted in manual or automatic actuation of an SR system, except when—

(A) The actuation resulted from and was part of a pre-planned sequence during testing; or

(B) The actuation was invalid and—

(*1*) Occurred while the system was properly removed from service; or

(2) Occurred after the safety function had been already completed.

(v) Any event or condition that could have prevented the fulfillment of the safety function of structures or systems that are needed to—

(A) Shut down the reactor and maintain it in a safe shutdown condition;

(B) Remove residual heat;

(C) Control the release of radioactive material; or

(D) Mitigate the consequences of an accident.

(vi) Events covered in paragraph (a)(2)(v) of this section may include one or more procedural errors, equipment failures, and/or discovery of design, fabrication, construction, and/or procedural inadequacies. However, individual component failures

need not be reported pursuant to paragraph (a)(2)(v) of this section if any other equipment was operable and available to perform the required safety function.

(vii) Any event where a single cause or condition caused at least one independent train or channel to become inoperable in multiple systems or two independent trains or channels to become inoperable in a single system designed to—

(A) Shut down the reactor and maintain it in a safe shutdown condition;

(B) Remove residual heat;

(C) Control the release of radioactive material; or

(D) Mitigate the consequences of an accident.

(viii)(A) Any airborne radioactive release that, when averaged over a time period of 1 hour, resulted in airborne radionuclide concentrations in an unrestricted area that exceeds 20 times the applicable concentration limits specified in appendix B to part 20, table 2, column 1.

(B) Any liquid effluent release that, when averaged over a time period of 1 hour, exceeds 20 times the applicable concentrations specified in appendix B to part 20, table 2, column 2, at the point of entry into the receiving waters (i.e., unrestricted area) for all radionuclides except tritium and dissolved noble gases.

(ix)(A) Any event or condition that as a result of a single cause could have prevented the fulfillment of a safety function for two or more trains or channels in different systems that are needed to—

(*1*) Shut down the reactor and maintain it in a safe shutdown condition;

(2) Remove residual heat;

(*3*) Control the release of radioactive material; or

(*4*) Mitigate the consequences of an accident.

(B) Events covered in paragraph (a)(2)(ix)(A) of this section may include cases of procedural error, equipment failure, and/or discovery of a design, analysis, fabrication, construction, and/or procedural inadequacy. However, licensees are not required to report an event pursuant to paragraph (a)(2)(ix)(A) of this section if the event results from—

(*1*) A shared dependency among trains or channels that is a natural or expected consequence of the approved plant design; or

(2) Normal and expected wear or degradation.

(x) Any event that posed an actual threat to the safety of the commercial nuclear plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the plant, including fires, toxic gas releases, or radioactive releases.

(b) *Contents*. The LER must contain—

(1) A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.

(2)(i) A clear, specific narrative description of what occurred so that knowledgeable readers conversant with the design of commercial nuclear plants, but not familiar with the details of a particular plant, can understand the complete event.

(ii) The narrative description must include the following specific information as appropriate for the particular event:

(A) Plant operating conditions before the event.

(B) Status of structures, components, or systems that were inoperable at the start of the event and that contributed to the event.

(C) Dates and approximate time of the occurrences.

(D) The cause of each component or system failure or personnel error, if known.

(E) The failure mode, mechanism, and effect of each failed component, if known.

(F) [Reserved]

(G) For failures of components with multiple functions, include a list of systems or secondary functions that were also affected.

(H) For failure that rendered a train of a safety system inoperable, an estimate of the elapsed time from the discovery of the failure until the train was returned to service.

(I) The method of discovery of each component or system failure or procedural error.

(J) For each human performance related root cause, the licensee must discuss the cause(s) and circumstances.

(K) Automatically and manually initiated safety system responses.

(L) The manufacturer and model number (or other identification) of each component that failed during the event.

(3) An assessment of the safety consequences and implications of the event. This assessment must include —

(i) The availability of systems or components that could have performed the same function as the components and systems that failed during the event, and

(ii) For events that occurred when the reactor was shut down, the availability of systems or components that are needed to shut down the reactor and maintain safe shutdown conditions, remove residual heat, control the release of radioactive material, or mitigate the consequences of an accident.

(4) A description of any corrective actions planned as a result of the event, including those to reduce the probability of similar events occurring in the future.

(5) Reference to any previous similar events at the same plant that are known to the licensee.

(6) The name and contact information of a person within the licensee's organization who is knowledgeable about the event and can provide additional information concerning the event and the plant's characteristics.

(c) *Supplemental Information*: The Commission may require the licensee to submit specific additional information beyond that required by paragraph (b) of this section if the Commission finds that supplemental material is necessary for complete understanding of an unusually complex or significant event. These requests for supplemental information will be made in writing and the licensee must submit, as specified in § 53.040, the requested information as a supplement to the initial LER.

(d) *Submission of Reports*: LERs must be prepared on Form NRC 366 and submitted to the NRC, as specified in § 53.040.

(e) *Report Legibility*: The reports and copies that licensees are required to submit to the Commission under the provisions of this section must be of sufficient quality to permit legible reproduction and micrographic processing.

§ 53.6345 Reports of radiation exposure to members of the public.

(a) Each holder of an OL, and each holder of a COL after the Commission has made the finding under § 53.5052(g), must submit a report to the Commission annually that specifies the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents during the previous 12 months. In addition, the report shall include an estimate of the dose received by the maximally exposed member of the public in an unrestricted area from effluents and direct radiation from contained sources during the previous 12 months and include any other information as may be required by the Commission to estimate maximum potential annual radiation doses to

~~the public. The report must be submitted as specified in § 53.040, and the time between submission of the reports must be no longer than 12 months. If the TEDE to members of the public in unrestricted areas during the reporting period is greater than the established ALARA design objectives or 10 mrem/year TEDE, the report must specify the causes for exceeding the ALARA design objective and describe any corrective actions. On the basis of these reports and any additional information the Commission may obtain from the licensee or others, the Commission may require the licensee to take action as the Commission deems appropriate.~~

~~(b) If during any calendar quarter the radiation exposure to a member of the public in the unrestricted areas, calculated on the same basis as the respective ALARA design objective exposure, exceeds one-half of the annual ALARA design objective exposure, the licensee must submit a report as specified in 53.040. The report shall specify the causes for exceeding one-half the annual ALARA design objective exposure in a quarter and describe corrective actions that the licensee will take to maintain radiation exposure to levels within the ALARA design objectives for the remainder of the year. The report shall be submitted within 30 days from the end of the quarter when one-half of the annual ALARA design objective exposure was exceeded.~~

~~§ 53.6350 Facility information and verification.~~

~~(a) In response to a written request by the Commission, each applicant for a CP or license and each recipient of a CP or a license must submit facility information, as described in § 75.10 of this chapter, on IAEA Design Information Questionnaire forms and site information on DOC/NRC Form AP-A and associated forms;~~

~~(b) As required by the Additional Protocol, must submit location information described in § 75.11 of this chapter on DOC/NRC Form AP-1 and associated forms; and~~

(c) Must permit verification thereof by the IAEA and take other action as necessary to implement the US/IAEA Safeguards Agreement, as described in part 75 of this chapter.

§ 53.6360 Financial requirements.

Sections 53.6370 through 53.6400 set out the requirements and procedures related to financial qualifications and related reporting requirements.

§ 53.6370 Financial qualifications.

Except for an electric utility applicant for a license to operate a commercial nuclear plant, an applicant for a CP, OL, or COL under Framework B of this part must possess or have reasonable assurance of obtaining the funds necessary for the activities for which the permit or license is sought.

§ 53.6380 Annual financial reports.

With respect to any commercial nuclear plant of a type described in § 53.020, each licensee and each holder of a CP must submit its annual financial report, including the certified financial statements, to the Commission, as specified in § 53.040, upon issuance of the report. However, licensees and holders of a CP who submit a Form 10-Q with the Securities and Exchange Commission or a Form 1 with FERC need not submit the annual financial report or the certified financial statement under this paragraph.

§ 53.6390 Licensee's change of status; financial qualifications.

(a) An electric utility licensee holding an OL or COL (including a renewed license) for a commercial nuclear plant, no later than seventy-five (75) days prior to ceasing to be an electric utility in any manner not involving a license transfer under § 53.4999 or § 53.5056, must provide the NRC with the financial qualifications information that would be required for obtaining an initial OL or COL under Framework B of this part. The financial

qualifications information must address the first full 5 years of operation after the date the licensee ceases to be an electric utility.

(b)(1) Any holder of a license issued under Framework B of this part must notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code by or against—

(i) The licensee;

(ii) An entity (as 11 U.S.C. 101(14) defines that term) controlling the licensee or listing the license or licensee as property of the estate; or

(iii) An affiliate (as 11 U.S.C. 101(2) defines that term) of the licensee.

(2) This notification must indicate—

(i) The bankruptcy court in which the petition for bankruptcy was filed; and

(ii) The date of the filing of the petition.

§ 53.6400 Creditor regulations.

(a) Pursuant to section 184 of the ActEA, the Commission consents, without individual application, to the creation of any mortgage, pledge, or other lien upon any facility not owned by the United States which is the subject of a license or upon any leasehold or other interest in such facility; provided—

(1) That the rights of any creditor so secured may be exercised only in compliance with and subject to the same requirements and restrictions as would apply to the licensee pursuant to the provisions of the license, the ActEA, and regulations issued by the Commission pursuant to the ActEA; and

(2) That no creditor so secured may take possession of the facility pursuant to the provisions of this section prior to either the issuance of a license from the Commission authorizing such possession or the transfer of the license.

(b) Any creditor so secured may apply for transfer of the license covering such facility by filing an application for transfer of the license pursuant to § 53.6070. The Commission will act upon such application pursuant to subpart S of this part.

(c) Nothing contained in this regulation must be deemed to affect the means of acquiring, or the priority of, any tax lien or other lien provided by law.

(d) As used in this section —

License includes any license under Framework B of this part, which may be issued by the Commission with regard to a facility;

Creditor includes, without implied limitation, the trustee under any mortgage, pledge or lien on a facility made to secure any creditor, any trustee or receiver of the facility appointed by a court of competent jurisdiction in any action brought for the benefit of any creditor secured by such mortgage, pledge or lien, any purchaser of such facility at the sale thereof upon foreclosure of such mortgage, pledge, or lien or upon exercise of any power of sale contained therein, or any assignee of any such purchaser.

Facility includes, but is not limited to, a site which is the subject of an early site permit under Framework B of this part, and a reactor manufactured under an ML under Framework B of this part.

§ 53.6410 Financial protection.

Sections 53.6420 and 53.6430 set out the requirements and procedures related to licensees obtaining and maintaining insurance to cover stabilization and decontamination activities in the event of an accident and financial protection in accordance with part 140, "Financial Protection Requirements and Indemnity Agreements," of this chapter.

§ 53.6420 Insurance required to stabilize and decontaminate plant following an accident.

~~Each commercial nuclear plant licensee under Framework B of this part must take reasonable steps to obtain insurance available at reasonable costs and on reasonable terms from private sources or to demonstrate that it possesses an equivalent amount of protection covering the licensee's obligation, in the event of an accident at the licensee's commercial nuclear reactor, to stabilize and decontaminate the plant and the plant site at which such an accident may occur, provided that—~~

~~(a) The insurance required by this section must have a minimum coverage limit for each commercial nuclear plant site of $1.06 billion, an amount based on plant-specific estimates of costs to stabilize and decontaminate a plant, or whatever amount of insurance is generally available from private sources, whichever is less. The required insurance must clearly state that, as and to the extent provided in paragraph (d)(1) of this section, any proceeds must be payable first for stabilization of the plant and next for decontamination of the plant and the plant site. If a licensee's coverage falls below the required minimum, the licensee must within 60 days take all reasonable steps to restore its coverage to the required minimum. The required insurance may, at the option of the licensee, be included within policies that also provide coverage for other risks, including, but not limited to, the risk of direct physical damage.~~

~~(b)(1) With respect to policies issued or annually renewed, the proceeds of such required insurance must be dedicated, as and to the extent provided in this paragraph, to reimbursement or payment on behalf of the insured of reasonable expenses incurred or estimated to be incurred by the licensee in taking action to fulfill the licensee's obligation, in the event of an accident at the licensee's plant, to ensure that the plant is in, or is returned to, and maintained in, a safe and stable condition and that radioactive contamination is removed or controlled such that personnel exposures are consistent with the occupational exposure limits in 10 CFR part 20. These actions must be~~

consistent with any other obligation the licensee may have under this chapter and must be subject to paragraph (d) of this section. As used in this section, an "accident" means an event that involves the release of radioactive material from its intended place of confinement within the commercial nuclear plant such that there is a present danger of release off site in amounts that would pose a threat to the public health and safety.

(2) The stabilization and decontamination requirements set forth in paragraph (d) of this section must apply uniformly to all insurance policies required under this section.

(c) The licensee must report to the NRC on April 1 of each year the current levels of this insurance or financial security it maintains and the sources of this insurance or financial security.

(d)(1) In the event of an accident at the licensee's plant, whenever the estimated costs of stabilizing the licensed plant and of decontaminating the plant and the plant site exceed one tenth of the minimum insurance under paragraph (a), the proceeds of the insurance required by this section must be dedicated to and used, first, to ensure that the licensed plant is in, or is returned to, and can be maintained in, a safe and stable condition so as to prevent any significant risk to the public health and safety and, second, to decontaminate the plant and the plant site in accordance with the licensee's cleanup plan as approved by order of the Director, Office of Nuclear Reactor Regulation. This priority on insurance proceeds must remain in effect for 60 days or, upon order of the Director, for such longer periods, in increments not to exceed 60 days except as provided for activities under the cleanup plan required in paragraphs (d)(3) and (d)(4) of this section, as the Director may find necessary to protect the public health and safety. Actions needed to bring the plant to and maintain the plant in a safe and stable condition may include one or more of the following, as appropriate:

(i) Shutdown of the reactor(s) and other processes at the plant;

(ii) Establishment and maintenance of long-term cooling with stable decay heat removal;

(iii) Maintenance of sub-criticality;

(iv) Control of radioactive releases; and

(v) Securing of structures, systems, or components to minimize radiation exposure to onsite personnel or to the offsite public or to facilitate later decontamination or both.

(2) The licensee must inform the Director, Office of Nuclear Reactor Regulation in writing when the plant is and can be maintained in a safe and stable condition so as to prevent any significant risk to the public health and safety. Within 30 days after the licensee informs the Director that the plant is in this condition, or at such earlier time as the licensee may elect or the Director may for good cause direct, the licensee must prepare and submit a cleanup plan for the Director's approval. The cleanup plan must identify and contain an estimate of the cost of each cleanup operation that will be required to decontaminate the reactor sufficiently to permit the licensee either to resume operation of the reactor or to apply to the Commission under subpart Q for authority to decommission the reactor and to surrender the license voluntarily. Cleanup operations may include one or more of the following, as appropriate:

(i) Processing any contaminated materials generated by the accident and by decontamination operations to remove radioactive materials;

(ii) Decontamination of surfaces inside the plant buildings to levels consistent with the Commission's occupational exposure limits in 10 CFR part 20, and decontamination or disposal of equipment;

(iii) Decontamination or removal and disposal of internal parts, damaged fuel from the reactor coolant or fuel systems, or related process or waste systems; and

~~(iv) Cleanup of the reactor coolant or fuel systems or related process or waste systems.~~

~~(3) Following review of the licensee's cleanup plan, the Director will order the licensee to complete all operations that the Director finds are necessary to decontaminate the reactor sufficiently to permit the licensee either to resume operation of the reactor or to apply to the Commission under subpart Q for authority to decommission the reactor and to surrender the license voluntarily. The Director approves or disapproves, in whole or in part for stated reasons, the licensee's estimate of cleanup costs for such operations. Such order may not be effective for more than 1-year, at which time it may be renewed. Each subsequent renewal order, if imposed, may be effective for not more than 6 months.~~

~~(4) Of the balance of the proceeds of the required insurance not already expended to place the plant in a safe and stable condition pursuant to paragraph (b)(1) of this section, an amount sufficient to cover the expenses of completion of those decontamination operations that are the subject of the Director's order must be dedicated to such use, provided that, upon certification to the Director of the amounts expended previously and from time to time for stabilization and decontamination and upon further certification to the Director as to the sufficiency of the dedicated amount remaining, policies of insurance may provide for payment to the licensee or other loss payees of amounts not so dedicated, and the licensee may proceed to use in parallel (and not in preference thereto) any insurance proceeds not so dedicated for other purposes.~~

~~§ 53.6430 Financial protection requirements.~~

~~Commercial nuclear plant licensees must satisfy the applicable provisions of part 140, “Financial Protection Requirements and Indemnity Agreements,” of this chapter.~~

Subpart U — Quality Assurance Criteria for Commercial Nuclear Plants

§ 53.6600 General provisions.

(a) Commercial nuclear plants and manufactured reactors include SSCs that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This subpart establishes QA requirements for the design, manufacture, construction, and operation of those SSCs classified as SR under Framework B of this part. The pertinent requirements of this subpart apply to all activities affecting the SR functions of those SSCs; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

(b) As used in this subpart, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. QA includes quality control, which comprises those QA actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

§ 53.6605 Organization.

The applicant[17] must establish and execute the QAP. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the QAP, or any part thereof, but must retain responsibility for the QAP. The authority and duties of persons and organizations performing activities affecting the SR functions of SSCs must be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the QA functions. The QA functions are those of assuring that an appropriate QAP is established and effectively executed; and verifying, such as by checking, auditing, and

inspecting, that activities affecting the SR functions have been correctly performed. The persons and organizations performing QA functions must have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. The persons and organizations performing QA functions must report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided. Because of the many of the variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the QAP may take various forms, provided that the persons and organizations assigned the QA functions have the required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the QAP at any location where activities subject to this subpart are being performed, must have direct access to the levels of management necessary to perform this function.

[17] While the term "applicant" is used in these criteria, the requirements are applicable after such a person has received a license to construct and operate a commercial nuclear plant or manufacturing facility or has received an early site permit, design approval, design certification, or ML, as applicable. These criteria will also be used for guidance in evaluating the adequacy of QAPs in use by holders of CPs, OLs, early site permits, design approvals, COLs, and MLs.

§ 53.6610 Quality assurance program.

The applicant must establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a QAP which complies with the requirements of this subpart. The program must be documented by written policies, procedures, or instructions and must be carried out throughout the plant life in accordance with those policies, procedures, or instructions. The applicant must identify the SSCs to be covered by the QAP and the major organizations participating in the program, together with the designated functions of these organizations. The QAP must provide control over

activities affecting the quality of the identified SSCs, to an extent consistent with their importance to safety. Activities affecting quality must be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied. The program must take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test. The program must provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. The applicant must regularly review the status and adequacy of the QAP. Management of other organizations participating in the QAP must regularly review the status and adequacy of that part of the QAP which they are executing.

§ 53.6615 Design control.

(a) Measures must be established to assure that applicable regulatory requirements and the design basis, as specified in the license application, for those SSCs to which this subpart applies are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures must also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the SR functions of the SSCs.

(b) Measures must be established for the identification and control of design interfaces and for the coordination among participating design organizations. These measures must include the establishment of procedures among participating design

organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

(c) The design control measures must provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program.

(d) The verifying or checking process must be performed by individuals or groups other than those who performed the original design but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it must include suitable qualifications testing of a prototype unit under the most adverse design conditions. Design control measures must be applied to items such as the following: reactor physics, stress, thermal hydraulic, and accident analyses; compatibility of materials; accessibility for ISI, maintenance, and repair; and delineation of acceptance criteria for inspections and tests.

(e) Design changes, including field changes, must be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.

§ 53.6620 Procurement document control.

Measures must be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality, are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents must require

contractors or subcontractors to provide a QAP consistent with the pertinent provisions of this subpart.

§ 53.6625 Instructions, procedures, and drawings.

Activities affecting quality must be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and must be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

§ 53.6630 Document control.

Measures must be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents must be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.

§ 53.6635 Control of purchased material, equipment, and services.

Measures must be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and

~~equipment conform to the procurement requirements must be available at the commercial nuclear plant site or manufacturing facility prior to installation or use of such material and equipment. This documentary evidence must be retained at the commercial nuclear plant site or manufacturing facility and must be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment. The effectiveness of the control of quality by contractors and subcontractors must be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.~~

~~§ 53.6640 Identification and control of materials, parts, and components.~~

~~Measures must be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures must assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective material, parts, and components.~~

~~§ 53.6645 Control of special processes.~~

~~Measures must be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.~~

~~§ 53.6650 Inspection.~~

~~A program for inspection of activities affecting quality must be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Such~~

~~inspection must be performed by individuals other than those who performed the activity being inspected. Examinations, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the applicant's designated representative and beyond which work must not proceed without the consent of its designated representative are required, the specific hold points must be indicated in appropriate documents.~~

~~§ 53.6655 Test control.~~

~~A test program must be established to assure that all testing required to demonstrate that SSCs will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. The test program must include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during commercial nuclear plant and manufacturing facility operation, of SSCs. Test procedures must include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results must be documented and evaluated to assure that test requirements have been satisfied.~~

~~§ 53.6660 Control of measuring and test equipment.~~

~~Measures must be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specific periods to maintain accuracy within~~

~~necessary limits.~~

~~§ 53.6665 Handling, storage, and shipping.~~

~~Measures must be established to control the handling, storage, shipping, cleaning, and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, must be specified and provided.~~

~~§ 53.6670 Inspection, test, and operating status.~~

~~Measures must be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the commercial nuclear plant. These measures must provide for the identification of items which have satisfactorily passed required inspections and tests where necessary to preclude inadvertent bypassing of such inspections and tests. Measures must also be established for indicating the operating status of SSCs of the commercial nuclear plant, such as by tagging valves and switches, to prevent inadvertent operation.~~

~~§ 53.6675 Nonconforming materials, parts, or components.~~

~~Measures must be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.~~

~~§ 53.6680 Corrective action.~~

~~Measures must be established to assure that conditions adverse to quality, such~~

as failures, malfunctions, deficiencies, deviations, defective material, and equipment and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures must assure that the cause of the condition is determined and corrective action is taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

§ 53.6685 Quality assurance records.

Sufficient records must be maintained to furnish evidence of activities affecting quality. The records must include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and material analyses. The records must also include closely related data such as qualifications of personnel, procedures, and equipment. Inspection and test records must, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records must be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant must establish requirements concerning record retention, such as duration, location, and assigned responsibility.

§ 53.6690 Audits.

A comprehensive system of planned and periodic audits must be carried out to verify compliance with all aspects of the QAP and to determine the effectiveness of the program. The audits must be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including reaudit of deficient areas, must be taken where indicated.

~~Subparts V and W [Reserved]~~

Subpart X — Enforcement

§ 53.9000 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued ~~pursuant to~~under those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued ~~pursuant to~~under the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

§ 53.9010 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 53 are issued under one or more of sections 161b,

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Commented [A410]: Modified to use an em dash here for consistency with the usage elsewhere in this regulatory text.

161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in 10 CFR part 53 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 53.000, 53.015, 53.020, ~~53.53.024, 53.028,~~ 53.040, 53.080, 53.090, 53.100, 53.110, 53.120, 53.600, 53.725, 53.726, ~~53.727,~~ 53.735, 53.760, ~~53.775, 53.790, 53.795,~~ 53.820, ~~53.910,~~ 53.1000, 53.1050, 53.1100, 53.1103, 53.1106, 53.1109, 53.1112, 53.1115, 53.1118, ~~53.1120,~~ 53.1121, 53.1124, 53.1140, 53.1143, 53.1144, 53.1146, 53.1149, 53.1155, 53.1158, 53.1164, 53.1170, 53.1173, 53.1176, 53.1179, 53.1188, 53.1200, 53.1203, 53.1206, 53.1209, 53.1210, 53.1212, 53.1215, 53.1218, 53.1221, 53.1230, 53.1236, 53.1239, 53.1241, 53.1242, 53.1245, 53.1248, 53.1251, ~~53.1254, 52.1257, 52.1260,~~ 53.1263, 53.1270, 53.1273, 53.1276, 53.1279, 53.1282, 53.1285, 53.1286, 53.1287, 53.1288, 53.1291, 53.1293, 53.1295, 53.1300, 53.1306, 53.1309, 53.1312, 53.1315, 53.1318, 53.1324, 53.1330, 53.1333, 53.1336, 53.1348, 53.1360, 53.1366, 53.1369, 53.1372, 53.1375, 53.1381, 53.1384, 53.1387, 53.1390, 53.1396, ~~53.1401,~~ 53.1405, 53.1410, 53.1416, 53.1419, 53.1422, 53.1425, 53.1431, 53.1437, 53.1440, 53.1443, 53.1452, 53.1455, 53.1456, 53.1458, 53.1461, 53.1470, 53.1500, 53.1510, 53.1515, 53.1520, 53.1525, 53.1530, 53.1535, 53.1540, 53.1560, 53.1585, 53.1590, 53.1595, 53.1600, 53.1660, 53.1670, 53.1700, ~~53.1710, 53.1730, 53.1800, 53.4100, 53.4220, 53.4390, 53.4600, 53.4650, 53.4700, 53.4703, 53.4706, 53.4709, 53.4712, 53.4715, 53.4718, 53.4720, 53.4721, 53.4724, 53.4750, 53.4753, 53.4754, 53.4756, 53.4759, 53.4765, 53.4768, 53.4774, 53.4780, 53.4783, 53.4786, 53.4789, 53.4798, 53.4800, 53.4803, 53.4806, 53.4809, 53.4812, 53.4815, 53.4818, 53.4821, 53.4830, 53.4833, 53.4836, 53.4839, 53.4841, 53.4842, 53.4845, 53.4848, 53.4851, 53.4854, 53.4857, 53.4860, 53.4863, 53.4870, 53.4873, 53.4876, 53.4879, 53.4882, 53.4885, 53.4886, 53.4887, 53.4888, 53.4891, 53.4893, 53.4895, 53.4900, 53.4906, 53.4909, 53.4912, 53.4915,~~

~~53.4918, 53.4924, 53.4930, 53.4933, 53.4936, 53.4948, 53.4960, 53.4966, 53.4975, 53.4981, 53.4984, 53.4987, 53.4990, 53.4996, 53.5002, 53.5005, 53.5010, 53.5013, 53.5016, 53.5019, 53.5022, 53.5025, 53.5031, 53.5037, 53.5040, 53.5043, 53.5052, 53.5055, 53.5056, 53.5058, 53.5061, 53.5070, 53.6000, 53.6010, 53.6015, 53.6020, 53.6025, 53.6030, 53.6035, 53.6040, 53.6060, 53.6085, 53.6090, 53.6095, 53.6300, 53.6360, 53.6370, 53.6400, 53.6410, 53.6430, 53.6600,~~ 53.9000, and 53.9010.

PART 55 – OPERATORS' LICENSES

129. The authority citation for part 55 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 107, 161, 181, 182, 183, 186, 187, 223, 234 (42 U.S.C. 2137, 2201, 2231, 2232, 2233, 2236, 2237, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); 44 U.S.C. 3504 note.

§ 55.1 [Amended]

130. In § 55.1, in paragraph (a) add " part 53," after "part 52,".

131. In § 55.2 revise paragraphs (b) and (c) and add new paragraph (d) to read as follows:

§ 55.2 Scope

* * * * *

(b) Any individual designated by a facility licensee licensed under parts 50, 52, or 54 of this chapter to be responsible for directing the licensed activities of a licensed operator.

(c) Any facility licensee licensed under parts 50, 52, or 54 of this chapter.

(d) Any individual who manipulates the controls of any interaction-dependent mitigation facility licensed under part 53 of this chapter, any individual designated by a

facility licensee licensed under part 53 of this chapter to be responsible for directing the licensed activities of a licensed operator, and any facility license under part 53 of this chapter except that:

(1) The requirements of § 53.735 apply in lieu of the requirements of subpart B of this part, and

(2) The requirements of § 53.730(g) and § 53.780 apply in lieu of the requirements of subpart E, § 55.53(h), and § 55.59 of this part, and

(3) The requirements of subpart X in part 53 of this chapter apply in lieu of the requirements of subpart H of this part.

132. In § 55.5, revise paragraphs (b)(1) and (2) to read as follows:

§ 55.5 Communications

* * * * *

(b)(1) Except for test and research reactor facilities, the Director, Office of Nuclear Reactor Regulation, has delegated to the Regional Administrators of Regions I, II, III, and IV authority and responsibility under the regulations in this part for the issuance and renewal of licenses for operators and senior operators of nuclear power reactors licensed under parts 50, 52, or 54 of this chapter and for the issuance and renewal of licenses for operators and senior operators of interaction-dependent mitigation facilities licensed under part 53 of this chapter and located in these regions.

(2) Any application for a license or license renewal filed under the regulations in this part involving a nuclear power reactor licensed under parts 50, 52 or 54 of this chapter or interaction-dependent mitigation facilities licensed under part 53 of this

chapter and any related inquiry, communication, information, or report must be submitted to the Regional Administrator by an appropriate method listed in paragraph (a) of this section. The Regional Administrator or the Administrator's designee will transmit to the Director, Office of Nuclear Reactor Regulation, any matter that is not within the scope of the Regional Administrator's delegated authority.

* * * * *

PART 70 – DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

13~~7~~. The authority citation for 10 CFR part 70 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57(d), 108, 122, 161, 182, 183, 184, 186, 187, 193, 223, 234, 274, 1701 (42 U.S.C. 2071, 2073, 2077(d), 2138, 2152, 2201, 2232, 2233, 2234, 2236, 2237, 2243, 2273, 2282, 2021, 2297f); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

§ 70.20a [Amended]

13~~8~~. In § 70.20a(b), add "52, 53," after "50,".

§ 70.22 [Amended]

13~~9~~. In § 70.22, wherever it may appear, remove "part 50" and add in its place "parts 50, 52, or 53."

136. In § 70.24, revise paragraph (d) to read as follows:

§ 70.24 Criticality accident requirements.

* * * * *

(d)(1) The requirements in paragraphs (a) through (c) of this section do not apply to a holder of a construction permit or operating license for a nuclear power reactor issued under part 50 or part 53 of this chapter or a combined license issued under part 52 or part 53 of this chapter, if the holder complies with the requirements of paragraph (b) of 10 CFR 50.68 or paragraph (m)(2) of 10 CFR 53.440.

(2) An exemption from § 70.24 held by a licensee who thereafter elects to comply with requirements of paragraph (b) of 10 CFR 50.68 or paragraph (m)(2) of 10 CFR 53.440 does not exempt that licensee from complying with any of the requirements in § 50.68 or § 53.440(m) but shall be ineffective so long as the licensee elects to comply with § 50.68(b) or § 53.440(m)(2), as applicable.

§ 70.32 [Amended]

137~~40~~. In § 70.32:

a. In paragraph (c)(1) remove "part 50" and add in its place "parts 50, 52, or 53"; and

b. in paragraph (d), remove "or § 70.34" and add in its place "§ 704.34~~,~~ or § 53.1510~~, or § 53.6010.~~".

138~~41~~. In § 70.50, revise paragraph (d) to read as follows:

§ 70.50 Reporting requirements.

* * * * *

(d) The provisions of § 70.50 do not apply to licensees subject to § 50.72~~,~~ or § 53.1630 of this chapter~~, or § 53.6330~~. They do apply to those ~~10 CFR part 50 or part 53~~ licensees under parts 50, 52, and 53 of this chapter possessing material licensed under ~~10 CFR~~this part ~~70~~ that are not subject to the notification requirements in § 50.72~~,~~ or § 53.1630~~, or § 53.6330~~ of this chapter.

PART 72 – LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

139~~42~~. The authority citation for 10 CFR part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093,

2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

§ 72.3 [Amended]

14~~03~~. In § 72.3, in the definition for Independent spent fuel storage installation or ISFSI remove "part 50" and add in its place "parts 50, 52, or 53~~.~~".

14~~14~~. In § 72.30, revise paragraph (e)(5) to read as follows:

§ 72.30 Financial assurance and recordkeeping for decommissioning.

* * * * *

(e) * * *

(5) In the case of licensees who are issued a power reactor license under parts 50, 52, or 53 of this chapter or ISFSI licensees who are an electric utility, as defined in parts 50 or 53 of this chapter, with a specific license issued under this part, the methods of § 50.75(b), (e), and (h)~~,~~ or §§ 53.1010, 53.1040, 53.1045(b), and 53.1060 ~~or §§ 53.4610, 53.4640, 53.4645(b), and 53.4660~~ as applicable. In the event that funds remaining to be placed into the licensee's ISFSI decommissioning external sinking fund are no longer approved for recovery in rates by a competent rate making authority, the licensee must make changes to provide financial assurance using one or more of the methods stated in paragraphs (1) through (4) of this section.

* * * * *

§ 72.32 [Amended]

14~~25~~. In § 72.32(c)(2), add "or § 53.020" after "10 CFR part 100."

§ 72.40 [Amended]

14~~36~~. In § 72.40(c), remove "part 50" and add in its place "parts 50 or 53."

§ 72.75 [Amended]

14~~47~~. In § 72.75(i)(1)(ii), wherever it may appear, remove “part 50” and add in its place “parts 50, 52, or 53~~.~~”.

§ 72.184 [Amended]

14~~58~~. In § 72.184(a), remove “part 50” and add in its place “parts 50, 52, or 53.”

§ 72.210 [Amended]

14~~69~~. In § 72.210, remove “part 50 or 10 CFR part 52” and add in its place “parts 50, 52, or 53.”

§ 72.212 [Amended]

14750. In § 72.212(b)(8), add “~~,~~or § 53.1550~~, or § 53.6050~~” after “§ 50.59(c).”

14~~85~~1. In § 72.218, revise paragraphs (a) and (b) to read as follows:

§ 72.218 Termination of licenses.

(a) The notification regarding the program for the management of spent fuel at the reactor required by § 50.54(bb)~~,~~ or § 53.1060~~, or § 53.4660~~ of this chapter must include a plan for removal of the spent fuel stored under this general license from the reactor site. The plan must show how the spent fuel will be managed before starting to decommission systems and components needed for moving, unloading, and shipping this spent fuel.

(b) An application for termination of a reactor operating license issued under 10 CFR part 50 and submitted under § 50.82 of this chapter, or a combined license issued under 10 CFR part 52 and submitted under § 52.110 of this chapter, or a reactor operating or combined license under 10 CFR part 53 and submitted under § 53.1070 ~~or § 53.4670~~ must contain a description of how the spent fuel stored under this general license will be removed from the reactor site.

* * * * *

PART 73 – PHYSICAL PROTECTION OF PLANTS AND MATERIALS

14952. The authority citation for 10 CFR part 73 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 147, 149, 161, 170D, 170E, 170H, 170I, 223, 229, 234, 1701 (42 U.S.C. 2073, 2167, 2169, 2201, 2210d, 2210e, 2210h, 2210i, 2273, 2278a, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

Section 73.37(b)(2) also issued under sec. 301, Pub. L. 96-295, 94 Stat. 789 (42 U.S.C. 5841 note).

§ 73.1 [Amended]

1503. In § § 73.1(b)(1)(i), add ", or 53" after "50, 52".

§ 73.2 [Amended]

1514. In § 73.2(a), add ", or 53" after "50, 52".

§ 73.8 [Amended]

1525. In § 73.8(b), add "73.77, 73.100, 73.110, 73.120," in numerical order.

§ 73.50 [Amended]

1536. In § 73.50 introductory text, remove "parts 50 or 52" and add in its place "parts 50, 52, or 53".

1547. In § 73.55, revise paragraphs (a)(4) and (6), (i)(4)(iii), (l)(1) and (7)(ii), (p)(1)(i), (r)(2) and (4)(iii) to read as follows:

§ 73.55 Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage.

(a) * * *

(4) Applicants for an operating license under the provisions of part 50 or part 53 of this chapter or holders of a combined license under the provisions of part 52 or part 53 of this chapter, mustshall implement the requirements of this section before fuel is allowed onsite (protected area).

* * *

(6) Applicants for an operating license under the provisions of part 50 or part 53 of this chapter, or holders of a combined license under the provisions of part 52 or part 53 of this chapter that do not reference a standard design certification or reference a standard design certification issued after May 26, 2009, mustshall meet the requirement of § 73.55(i)(4)(iii).

* * * * *

* * * * *

(i) * * *

(4) * * *

(iii) Applicants for an operating license under the provisions of part 50 of this chapter, or holders of a combined license under the provisions of part 52 of this chapter, or licensees under part 53 of this chapter that elect to demonstrate compliance with § 73.55, consistent with § 53.860(a)(2) or § 53.4330(a)(2), mustshall construct, locate, protect, and equip both the central and secondary alarm stations to the standards for the central alarm station contained in this section. Both alarm stations mustshall be equal and redundant, such that all functions needed to satisfy the requirements of this section can be performed in both alarm stations.

* * * * *

(l) * * *

(1) Commercial nuclear power reactors licensed under 10 CFR parts 50, 52, or 53 and authorized to use special nuclear material in the form of MOX fuel assemblies containing up to 20 weight percent PuO_2 shallmust, in addition to demonstrating compliance with the requirements of this section, protect un-irradiated MOX fuel assemblies against theft or diversion as described in this paragraph.

* * * * *

(7) * * *

(ii) Additional measures for the physical protection of un-irradiated MOX fuel assemblies containing greater than 20 weight percent PuO_2 mustshall be determined by the Commission on a case-by-case basis and documented during initial review of the license application or through license amendment in accordance with under § 50.90, or § 53.1510, or § 53.6010 of this chapter.

* * * * *

(p) * * *

(1) * * *

(i) UnderIn accordance with §§ 50.54(x) and 50.54(y), or § 53.740(h) of this chapter, the licensee may suspend any security measures under this section in an emergency when this action is immediately needed to protect the public health and safety and no action consistent with license conditions and technical specifications that can provide adequate or equivalent protection is immediately apparent. This suspension of security measures must be approved as a minimum by a licensed senior operator or generally licensed operator, or, for a facility for which the certifications required under §§ 50.82(a)(1), 52.110(a), or 53.1070(a) have been submitted, by a licensed senior operator, generally licensed operator, or certified fuel handler before taking this action.

* * * * *

(r) * * *

(2) The licensee mustshall submit proposed alternative measure(s) to the Commission for review and approval underin accordance with §§ 50.4 and 50.90, or § 53.040, and § 53.1510 or § 53.6010 of this chapter before implementation.

* * * * *

(4) * * *

(iii) Based on comparison of the costs of the alternative measures to the costs of demonstrating compliance with the Commission's requirements using the essential elements of § 50.109~~,~~ or § 53.1590~~, or § 53.6090~~ of this chapter, the costs of fully demonstrating compliance with the Commission's requirements are not justified by the protection that would be provided.

15~~8~~. In § 73.56, revise paragraph (a)(3) to read as follows:

§ 73.56 Personnel access authorization requirements for nuclear power plants.

(a) * * *

(3) Each applicant for an operating license under the provisions of part 50 of this chapter, each holder of a combined license under the provisions of part 52 of this chapter, and applicants for an operating license or holders of a combined license under part 53 of this chapter that do not meet the ~~requirements~~ criterion of § 53.860(a)(2)~~ or § 53.4330(a)(2)~~ of this chapter, must~~shall~~ implement the requirements of this section before fuel is allowed on site (protected area).

* * * * *

15~~9~~. In § 73.57, revise paragraph (a)(3) to read as follows:

§ 73.57 Requirements for criminal history records checks of individuals granted unescorted access to a nuclear power facility, a non-power reactor, or access to Safeguards Information.

(a) * * *

(3) Before receiving its operating license under 10 CFR parts 50 or 53 ~~or before the Commission makes its finding under § 52.103(g), § 53.1452(g), or § 53.5052(g)~~ of this chapter, each applicant for a license to operate a nuclear power reactor ~~(including an applicant for a combined license)~~ or a non-power reactor may submit fingerprints for those individuals who will require unescorted access to the nuclear power facility or non-

power reactor facility. Before the Commission makes its finding under §§ 52.103(g) or 53.1452(g) of this chapter, each holder of a combined license may submit fingerprints for those individuals who will require unescorted access to the nuclear power facility.

* * * * *

§ 73.58 [Amended]

157~~60~~. In § 73.58, remove "part 50 or 52" and add in its place "parts 50, 52, or 53".

§ 73.67 [Amended]

158~~61~~. In § 73.67, in paragraphs (d) introductory text and (f) introductory text, remove "part 50," and add in its place "parts 50, 52, or 53, provided that the special nuclear material is located within a protected area and protected under~~in accordance with~~ § 73.55 or § 73.100,".

~~162. In § 73.71, revise paragraphs (d) and (e) to read as follows:~~

~~**§ 73.71 Reporting of safeguards events.**~~

* * * * *

~~(d) Each licensee shall submit to the Commission the 60-day written reports required under the provisions of this section that are of a quality that will permit legible reproduction and processing. If the facility is subject to § 50.73, § 53.1640, or § 53.6340 of this chapter, the licensee shall prepare the written report on NRC Form 366. If the facility is not subject to § 50.73, § 53.1640, or § 53.6340 of this chapter, the licensee shall not use this form but shall prepare the written report in letter format. The report must include sufficient information for NRC analysis and evaluation.~~

~~(e) Duplicate reports are not required for events that are also reportable in accordance with §§ 50.72 and 50.73, §§ 53.1630 and 53.1640, or §§ 53.6330 and 53.6340 of this chapter.~~

15963. In § 73.77, revise paragraphs (a), (b), (c)(6), and (7) to read as follows:

§ 73.77 Cyber security event notifications.

* * * * *

(a) Each licensee subject to the provisions of § 73.54 or § 73.110 must~~shall~~ notify the NRC Headquarters Operations Center via the Emergency Notification System (ENS), under~~in accordance with~~ paragraph (c) of this section:

(1) Within one hour after discovery of a cyber attack that adversely impacted:

(i) Safety-related or important-to-safety functions, security functions, or emergency preparedness functions (including offsite communications); or that compromised support systems and equipment resulting in adverse impacts to safety, security, or emergency preparedness functions within the scope of § 73.54; or,

(ii) Functions performed by digital assets that would prevent a postulated fission product release resulting in offsite doses exceeding the values in § 53.210 of this chapter, or functions performed by digital assets used by the licensee for implementing the physical security requirements in § 53.860(a) ~~or § 53.4330(a)~~ of this chapter.

(2) Within 4 hours:

(i) After discovery of a cyber attack that could have caused an adverse impact to:

(A) Safety-related or important-to-safety functions, security functions, or emergency preparedness functions (including offsite communications); or that could have compromised support systems and equipment, which if compromised, could have adversely impacted safety, security, or emergency preparedness functions within the scope of § 73.54; or,

(B) Functions performed by digital assets that would prevent a postulated fission product release resulting in offsite doses exceeding the values in § 53.210 of this

chapter, or functions performed by digital assets used by the licensee for implementing the physical security requirements in § 53.860(a) ~~or § 53.4330(a)~~ of this chapter.

(ii) After discovery of a suspected or actual cyber attack initiated by personnel with physical or electronic access to digital computer and communication systems and networks within the scope of § 73.54 or § 73.110.

(iii) After notification of a local, State, or other Federal agency (e.g., law enforcement, FBI, etc.) of an event related to the licensee's implementation of their cyber security program for digital computer and communication systems and networks within the scope of § 73.54 or § 73.110 that does not otherwise require a notification under paragraph (a) of this section.

(3) Within 8 hours after receipt or collection of information regarding observed behavior, activities, or statements that may indicate intelligence gathering or pre-operational planning related to a cyber attack against digital computer and communication systems and networks within the scope of § 73.54 or § 73.110.

(b) *Twenty-four hour recordable events.*

(1) The licensee shall use the site corrective action program to record vulnerabilities, weaknesses, failures and deficiencies in their § 73.54 or § 73.110 cyber security program within 24 hours of their discovery.

* * * * *

(c) * * *

(6) *Declaration of emergencies*. Notifications made to the NRC for the declaration of an emergency class shall be performed in accordance with § 50.72~~,~~ or § 53.1630~~, or § 53.6330~~ of this chapter, as applicable.

(7) *Elimination of duplication*. Separate notifications and reports are not required for events that are also reportable under~~in accordance with~~ §§ 50.72 and 50.73~~,~~ or

§§ 53.1630 and 53.1640~~, or §§ 53.6330 and 53.6340~~ of this chapter. However, these notifications should also indicate the applicable § 73.77 reporting criteria.

* * * * *

Security Requirements at Commercial Nuclear Plants

16~~0~~4. Add undesignated center heading, "Security Requirements at Commercial Nuclear Plants" after § 73.81~~, and § 73.100 through 73.120, under the heading set forth above~~.

16~~1~~5. Add § 73.100 to read as follows:

§ 73.100 Technology-inclusive requirements for physical protection of licensed activities at commercial nuclear plants against radiological sabotage

(a) *Introduction*.

(1) Each holder of a license~~e that is licensed~~ to operate a commercial nuclear plant under ~~10 CFR~~ part 53 of this chapter that ~~and~~ elects to implement the requirements of this section must do so through its physical security plan, training and qualification plan, safeguards contingency plan, and cyber security plan, referred to collectively hereafter as ''security plans," before initial fuel load into the reactor.

(2) The security plans must identify, describe, and account for site-specific conditions that affect the licensee's capability to satisfy the requirements of this section.

(b) *General performance objective and requirements*.

(1) The licensee must establish, implement, and maintain a physical protection program and a security organization, which will have as their objective to provide reasonable assurance that activities involving special nuclear material are not inimical to the common defense and security and do not constitute an unreasonable risk to the public health and safety.

(2) To satisfy the general performance objective of paragraph (b)(1) of this

section, the physical protection program must protect against the design-basis threat of radiological sabotage as stated in § 73.1. Specifically, the licensee must—

(i) Ensure that the physical protection program capabilities to protect against the design-basis threat of radiological sabotage are maintained at all times; and

(ii) Provide defense in depth in achieving performance requirements through the integration of engineered systems, administrative controls, and management measures.

(3) The physical protection program must be designed and implemented to achieve and maintain the reliability and availability of structures, systems, and components required for demonstrating compliance with the following performance requirements at all times:

(i) Intrusion detection. The licensee must be capable of detecting attempted and actual unauthorized access to interior and exterior areas containing structures, systems, and components needed to implement safety and security functions.

(ii) Intrusion assessment. The licensee must be capable of timely assessment to~~for~~ determining the cause of a detected intrusion.

(iii) Security communication. The licensee must be capable of continuous security communications. Communication systems must account for design-basis threats that can interrupt or interfere with continuity or integrity of communications.

(iv) Security response. The physical protection program must be designed to provide timely security response to interdict and neutralize adversary attacks up to and including the design-basis threat of radiological sabotage. The physical protection program must be designed to provide layers of security response, with each layer assuring that a single failure does not result in the loss of capability to neutralize the design-basis threat adversary. Structures, systems, and components relied on for delay functions must be designed to ~~provide~~ allow for timely security responses to adversary

attacks with adequate defense in depth.

(A) The security response may rely on the use of onsite responders, law enforcement or other offsite armed responders, or a combination thereof, to fulfill the interdiction and neutralization functions required by paragraph (b)(3)(iv) of this section. A licensee relying entirely or partially on law enforcement or other offsite armed responders must—

(*1*) maintain the capability to detect, assess, interdict, and neutralize threats as required by paragraphs (b)(3)(i), (b)(3)(ii), and (b)(3)(iv) of this section;

(*2*) provide adequate delay to enable law enforcement or other offsite armed responders to fulfill the interdiction and neutralization functions for threats up to and including the design-basis threat of radiological sabotage;

(*3*) provide necessary information about the facility and make available periodic training to law enforcement or other offsite armed responders who will fulfill the interdiction and neutralization functions for threats up to and including the design-basis threat of radiological sabotage;

(*4*) fully describe in the safeguards contingency plan the role that law enforcement or other offsite armed responders will play in the licensee's protective strategy. The description must provide sufficient detail to enable the NRC to determine that the licensee's physical protection program provides reasonable~~high~~ assurance of adequate protection against threats up to and including the design-basis threat of radiological sabotage; and

(*5*) identify criteria and measures to compensate for the degradation or absence of law enforcement or other offsite armed responders and propose suitable compensatory measures that meet the requirements of paragraph (h)(3) of this section to address this degradation.

(B) For licensees relying entirely or partially on law enforcement responders to fulfill the interdiction and neutralization functions required by paragraph (b)(3)(iv) of this section, the training and qualification requirements related to armed response personnel in paragraphs (c) and (e) of this section do not apply to law enforcement responders. The licensee shall continue to satisfy the performance evaluation requirements in paragraph (g) of this section for all armed response personnel, including law enforcement.

(v) Protecting against land and waterborne vehicle bomb assaults. The licensee must be capable of protecting the plant against the design-basis threat vehicle bomb assault. The methods that are relied on to protect against a design-basis threat land vehicle and waterborne vehicle bomb assault must be designed to protect the reactor building and structures containing safety- or security-related systems, and components from explosive effects.

(vi) Access control portals. The licensee must be capable of detecting and denying unauthorized access to persons and pass-through of contraband materials (e.g., weapons, incendiaries, explosives) to protected areas.

(4) The licensee must meet the requirements related to target sets in § 73.55(f).

(5) The licensee must identify and analyze site-specific conditions, including target sets, that may affect the physical protection program needed to implement the requirements of this section. The licensee must account for these conditions in demonstrating compliance with the requirements of this section.

(6) The licensee must establish, implement, and maintain a performance evaluation program to assess the effectiveness of the licensee’s implementation of the physical protection program to protect against the design-basis threat of radiological sabotage.

(7) The licensee must establish, implement, and maintain an access authorization program underin accordance with § 73.56 and must describe the program in the physical security plan.

(8) The licensee must establish, implement, and maintain a cyber security program underin accordance with § 73.54 or § 73.110 and must describe the program in the cyber security plan.

(9) The licensee must establish, implement, and maintain an insider mitigation program and must describe the program in the physical security plan.

(i) The insider mitigation program must monitor the initial and continuing trustworthiness and reliability of individuals granted or retaining unescorted access or unescorted access authorization to a protected or vital area, and implement defense-in-depth methodologies to minimize the potential for an insider (active, passive, or both) to adversely affect, either directly or indirectly, the licensee's capability to protect against radiological sabotage.

(ii) The insider mitigation program must integrate elements of—

(A) The access authorization program underdescribed in § 73.56;

(B) The fitness-for-duty program underdescribed in 10 CFR part 26;

(C) The cyber security program underdescribed in § 73.54 or § 73.110; and

(D) The physical protection program underdescribed in this section.

(10) The licensee must have the capability to track, trend, correct, and prevent recurrence of failures and deficiencies in the implementation of the requirements of this section.

(11) Implementation of security plans and associated procedures must be coordinated with other onsite plans and procedures to preclude conflict during both normal and emergency conditions and ensure the adequate management of the safety

and security interface.

(c) *Security organization*. The licensee must establish and maintain a security organization that is staffed, trained, qualified, and equipped to implement the physical protection program under~~in accordance with~~ the requirements of this section.

(1) The licensee must establish a management system for maintaining and implementing security policies and procedures to implement the requirements of this section and the security plans.

(2) Implementing procedures must document the conduct of security operations, security design and configuration controls, maintenance, training and qualification, and contingency responses.

(3) The licensee must—

(i) Establish a process for the approval of designs, policies, processes, and procedures and changes by the individual with overall responsibility for the physical protection program; and

(ii) Ensure that revisions and changes to the physical protection program and implementing policies, processes, and procedures satisfy the requirements of this section.

(4) The licensee must retain, under paragraph (j) of this section~~in accordance with § 73.70~~, all analyses, assessments, calculations, and descriptions of the technical basis for demonstrating compliance with the performance requirements of § 73.100(b). The licensee must protect these records in accordance with the requirements for protecting safeguards information in §§ 73.21 and 73.22.

(5) The licensee may not permit any individual to implement any part of the physical protection program unless the individual has been trained, equipped, and qualified to perform their assigned duties and responsibilities in accordance with the

training and qualification plan.

(d) *Search requirements*. The licensee must establish and implement searches of individuals, vehicles, and materials to detect and prevent the introduction into the protected area of firearms, explosives, incendiary devices, or other items and material which could be used to commit radiological sabotage.

(e) *Training and qualification program*. The licensee must establish and maintain a training and qualification program that ensures personnel who are responsible for the physical protection of the facility against radiological sabotage are able to effectively perform their assigned security-related job duties for implementing the requirements of this section and must describe the program in the training and qualification plan.

(f) *Security reviews*. The licensee must establish and implement security reviews to assess the effectiveness of the implementation of the physical protection program. Security reviews must be performed by individuals independent of those personnel responsible for program management and any individual who has direct responsibility for implementing the onsite physical protection program.

(1) The licensee must review each element of the physical protection program at a frequency commensurate with the importance or significance to safety of plant operations to ensure timely identification and documentation of vulnerabilities, improvements, and corrective actions. The objective of these reviews must be maintaining effective implementation of the engineered and administrative controls required to achieve the physical protection program functions and the management system required to implement programs and requirements in this section.

(2) The licensee must establish and perform self-assessments to ensure the effective implementation of the physical protection program functions of detection, assessment, communication, delay, and interdiction and neutralization to protect against

the design-basis threat of radiological sabotage. The licensee must perform design verification and assessments of the capabilities of active and passive engineering systems relied on to protect against the design-basis threat.

(3) Reviews of the security program must include, but are not limited to, an audit of the effectiveness of the physical protection program, security plans, implementing procedures, cyber security programs, safety/security interface activities, the testing, maintenance, and calibration program, and response commitments by local, State, and Federal law enforcement authorities.

(4) The results and recommendations of the onsite physical protection program reviews, management's findings regarding program effectiveness, and any actions taken as a result of recommendations from prior program reviews, must be documented in a report and must be maintained in an auditable form and available for inspection.

(g) *Performance evaluation*. Licensee performance evaluations must include methods appropriate and necessary to assess, test, and challenge the integration of the physical protection program's functions to protect against the design-basis threat, including measures to protect against cyber attack and engineered systems designed to protect against the design-basis threat standalone ground vehicle bomb attack.

(1) The licensee must establish the frequencies for performance evaluations commensurate with the security significance of the physical protection program.

(2) The licensee must document processes and procedures for implementing the performance evaluations. The licensee must maintain records, including results, findings, and corrective actions identified during the performance evaluations.

(h) *Maintenance, testing, and calibration and corrective actions*.

(1) The licensee must ensure that security structures, systems, and components, including supporting systems, are inspected, tested, and calibrated for operability and

performance at intervals necessary and sufficient to meet the requirements of this section.

(2) The licensee must implement corrective actions to ensure resolution of identified vulnerabilities and deficiencies to meet the requirements of this section.

(3) The licensee must establish and implement timely compensatory measures for degraded or inoperable security structures, systems, and components to meet the requirements of this section. Compensatory measures must provide a level of protection that is equivalent to the protection that was provided prior to the degradation or inoperability of the security structures, systems, or components.

(4) The licensee must document processes and procedures and maintain records for implementing the corrective actions, compensatory measures, and maintenance, inspection, testing, and calibration of security structures, systems, and components.

(i) *Suspension of security measures*.

(1) The licensee may suspend implementation of affected requirements of this section in accordance with § 53.740(h) of this chapter under the following conditions:

(i) In an emergency, when action is immediately needed to protect the public health and safety; and

(ii) During severe weather, when the suspension of affected security measures is immediately needed to protect the personal health and safety of personnel.

(2) Suspended security measures must be reinstated as soon as conditions permit.

(3) The suspension of security measures must be reported and documented in accordance with the provisions of subpart T to this part~~§ 73.71~~.

(j) *Records*.

(1) The Commission may inspect, copy, retain, and remove all reports, records,

and documents required to be kept by Commission regulations, orders, or license conditions, whether the reports, records, and documents are kept by the licensee or a contractor.

(2) The licensee must maintain all records required to be kept by Commission regulations, orders, or license conditions, until the Commission terminates the license for which the records were developed, and must maintain superseded portions of these records for at least 3 years after the record is superseded, unless otherwise specified by the Commission.

(3) If a contracted security force is used to implement the onsite physical protection program, the licensee's written agreement with the contractor must be retained by the licensee as a record for the duration of the contract.

(4) Review and audit reports must be available for inspection, for a period of 3 years.

16~~2~~6. Add § 73.110 to read as follows:

§ 73.110 Technology-inclusive requirements for protection of digital computer and communication systems and networks

(a) Each holder of a licens~~e that is licensed~~ to operate a commercial nuclear plant under ~~10 CFR~~ part 53 of this chapter that~~and~~ elects to implement the requirements of this section must establish, implement, and maintain a cyber security program that is commensurate with the potential consequences resulting from cyberattacks, up to and including the design-basis threat as described in § 73.1. The cyber security program must provide reasonable assurance that digital computer and communication systems and networks are adequately protected against cyberattacks that are capable of causing the following consequences:

(1) Adversely impacting the functions performed by digital assets that would

prevent a postulated fission product release resulting in offsite doses exceeding the values in § 53.210 of this chapter.

(2) Adversely impacting the functions performed by digital assets used by the licensee for implementing the physical security requirements in § 53.860(a) ~~or § 53.4330(a)~~ of this chapter.

(b) To protect digital computer and communication systems and networks associated with the functions described in paragraphs (a)(1) and (2), the licensee must—

(1) Analyze the potential consequences resulting from cyber attacks on digital computer and communication systems and networks and identify those assets that must be protected to demonstrate compliance with paragraph (a) of this section; and

(2) Implement the cyber security program in accordance with paragraph (d) of this section.

(c) The licensee must comply with the requirements in § 73.54(a)(2) for the systems and networks identified in paragraph (b)(1) of this section in a manner that is commensurate with the potential consequences resulting from cyberattacks.

(d) The cyber security program must be designed in a manner that is commensurate with the potential consequences resulting from cyber attacks through the following steps:

(1) Implement security controls to protect the assets identified under paragraph (b)(1) of this section from cyber attacks, commensurate with their safety and security significance;

(2) Apply and maintain defense-in-depth protective strategies to ensure the capability to detect, delay, respond to, and recover from cyberattacks capable of causing the consequences identified in paragraph (a) of this section;

(3) Mitigate the adverse effects of cyber attacks capable of causing the consequences identified in paragraph (a) of this section; and

(4) Ensure that the functions of protected assets identified under paragraph (b)(1) of this section are not adversely impacted due to cyber attacks.

(e) The licensee must implement the following requirements in a manner that is commensurate with the potential consequences resulting from cyber attacks:

(1) As part of the cyber security program, the licensee must comply with the requirements in § 73.54(d)(1), (2), and (4), and must ensure that modifications to assets, identified under paragraph (b)(1) of this section are evaluated before implementation to ensure that the cyber security performance objectives identified in paragraph (a) of this section are maintained.

(2) The licensee must establish, implement, and maintain a cyber security plan that implements the cyber security program requirements of this section.

(i) The cyber security plan must describe how the requirements of this section will be implemented and must account for the site-specific conditions that affect implementation.

(ii) The cyber security plan must include measures for incident response and recovery for cyber attacks. The cyber security plan must include the analysis identified under paragraph (b)(1) of this section and describe how the licensee will—

(A) Apply and maintain defense-in-depth protective strategies as required in paragraph (d)(2) of this section;

(B) Maintain the capability for timely detection and response to cyber attacks;

(C) Mitigate the consequences of cyber attacks;

(D) Correct exploited vulnerabilities; and

(E) Restore affected systems, networks, and/or equipment affected by cyber

attacks.

(3) The licensee must develop and maintain written policies and implementing procedures to implement the cyber security plan. Policies, implementing procedures, and other supporting technical information used by the licensee need not be submitted for Commission review and approval as part of the cyber security plan but are subject to inspection by NRC staff on a periodic basis.

(4) The licensee must establish and implement cyber security reviews to assess the effectiveness of the implementation of the cyber security program.

(i) The licensee must review each element of the cyber security program at a frequency commensurate with the importance or significance to safety of plant operations to ensure timely identification and documentation of vulnerabilities, improvements, and corrective actions.

(ii) Cyber security reviews must be performed by individuals independent of those personnel responsible for program management and any individual who has direct responsibility for implementing the cyber security program.

(iii) The licensee must establish and perform self-assessments to ensure the effective implementation of the cyber security program.

(iv) The results and recommendations of the cyber security program reviews, management's findings regarding program effectiveness, and any actions taken as a result of recommendations from prior program reviews, must be documented in a report and must be maintained in an auditable form and available for inspection.

(5) The licensee must retain all records and supporting technical documentation required to demonstrate compliance with the requirements of this section as a record until the Commission terminates the license for which the records were developed and must maintain superseded portions of these records for at least three (3) years after the

record is superseded, unless otherwise specified by the Commission.

16~~3~~7. Add § 73.120 to read as follows:

§ 73.120 Access authorization program for commercial nuclear plants.

(a) *Introduction and scope*. Each applicant for an operating license or a holder of a combined license under 10 CFR part 53 must establish, maintain, and implement an access authorization program before initial fuel load into the reactor. The requirements in this section apply to licensees satisfying the criterion in § 53.860(a)(2)~~(i) or § 53.4330(a)(2)(i)~~ of this chapter.

(b) *Applicability*.

(1) The following individuals must be subject to an access authorization program under this section:

(i) Any individual to whom a licensee intends to grant unescorted access to a commercial nuclear plant protected area, vital area, material access area, or controlled access area where licensed material is used or stored;

(ii) Any individual whose duties and responsibilities permit the individual to take actions by electronic means, either on site or remotely, that could adversely impact the licensee's or applicant’s operational safety, security, or emergency preparedness;

(iii) Any individual who has responsibilities for implementing a licensee's or applicant's protective strategy, including armed security force officers, alarm station operators, and tactical response team leaders but not including Federal, State, or local law enforcement personnel; and

(iv) The licensee or applicant access authorization program reviewing official or contractor or vendor access authorization program reviewers.

(2) The licensee or applicant may subject other individuals, including employees of a contractor or a vendor who are designated in access authorization program

procedures, to an access authorization program that demonstrates compliance with the requirements of this section.

(c) *General performance objectives and requirements*. Each licensee's or applicant’s access authorization program under this section must demonstrate that the individuals who are specified in paragraph (b) of this section are trustworthy and reliable, such that they do not constitute an unreasonable risk to public health and safety or the common defense and security. The licensee’s access authorization program must maintain the capabilities for demonstrating compliance with the following performance requirements:

(1) *Background investigation*. (i)(A) Licensees and applicants must ensure that any individual seeking initial unescorted access or to maintain unescorted access is subject to a background investigation.

(B) Background investigations must include the program elements contained under § 37.25 of this chapter and must also include a credit history evaluation.

(ii) Background investigations must include fingerprinting and an FBI identification and criminal history records check in accordance with § 37.27 of this chapter.

(iii) Licensees must have the informed and signed consent of the subject individual to initiate a background investigation. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. A signed consent must be obtained prior to any reinvestigation. The subject individual may withdraw his or her consent at any time. Licensees must inform the individual that—

(A) If an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the

individual withdrew his or her consent; and

(B) The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

(2) *Behavioral observation*. Licensees, applicants, contractors, and vendors must ensure the access authorization program includes provisions that the individuals specified in paragraph (b) of this section are subject to behavioral observation.

(i) Each person subject to behavioral observation must communicate to the licensee or applicant observed behaviors or activities of individuals that may constitute an unreasonable risk to the health and safety of the public and common defense and security.

(ii) Behavioral observation must include visual observation, in person or remotely by video, to detect and promptly report to plant supervision any concerns arising from behavioral observation, including, but not limited to, concerns related to any questionable behavior patterns or activities of others.

(3) *Self-reporting of legal actions*. Licensees or applicants must inform personnel who are granted and who maintain unescorted access of their responsibilities to self-report to plant supervision legal actions taken by a law enforcement authority or court of law against the individual that could result in incarceration or a court order or that requires a court appearance, including but not limited to an arrest, an indictment, the filing of charges, or a conviction, but excluding minor civil actions or misdemeanors such as parking violations or speeding tickets, for any individual who has applied for unescorted access or who maintains unescorted access.

(4) *Unescorted access*. Licensees or applicants must grant unescorted access only after the licensee has verified an individual is trustworthy and reliable. A list of persons currently approved for unescorted access to a protected area, vital area,

material access area, or controlled access area must be maintained at all times. Unescorted access determinations must be reviewed annually by the reviewing official. Licensees and applicants must complete an FBI criminal history record check update for each individual maintaining unescorted access, within 10 years of the last review.

(5) *Termination of unescorted access.* Licensees and applicants must promptly terminate unescorted access when this access is no longer required or a reviewing official determines an individual is no longer trustworthy and reliable in accordance with this section.

(6) *Determination basis for access*. (i) The licensee's or applicant's reviewing official must determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access based on an evaluation of all of the information collected to demonstrate compliance with the requirements of this section.

(ii) Licensees and applicants must provide individuals subject to this section, prior to any final adverse determination, the right to complete, correct, and explain information obtained as a result of the licensee's background investigation pursuant to § 37.23(g) of this chapter.

(iii) The licensee's or applicant's reviewing officials are the only individuals authorized to make unescorted access determination decisions. Each licensee or applicant must name one or more individuals to be reviewing officials pursuant to the requirements of § 37.23(b)(2) of this chapter.

(7) *Review procedures*. Review procedures must be established in accordance with § 37.23(f) of this chapter, to include provisions for the notification in writing of individuals who are denied unescorted access or who are unfavorably terminated.

(8) *Protection of information*. Licensees, applicants, contractors, or vendors must establish and maintain a system of files and procedures in accordance with § 37.31 of this chapter, to ensure personal information is not disclosed to unauthorized persons.

(9) *Access authorization reviews and corrective action*. Licensees and applicants must develop, implement, and maintain procedures for conduct of access authorization reviews and corrective actions in accordance with § 37.33 of this chapter to ensure the continuing effectiveness of the access authorization program and to ensure that the access authorization program and program elements are in compliance with the requirements of this section. Each licensee and applicant must be responsible for the continuing effectiveness of the access authorization program, including access authorization program elements that are provided by the contractors or vendors, and the access authorization programs of any of the contractors or vendors that are accepted by the licensee or applicant.

(10) *Records.* Licensees, applicants, and contractors or vendors must document the processes and procedures for maintaining records used or created to establish an individual's trustworthiness and reliability or to document access determinations. Licensees, applicants, and contractor or vendors must—

(i) Retain documentation regarding the trustworthiness and reliability of individual employees for 3 years from the date the individual no longer requires unescorted access;

(ii) Retain a copy of the current access authorization program procedures as a record for 3 years after the procedure is no longer needed. If any portion of the procedure is superseded, retain the superseded material for 3 years after the record is superseded; and

(iii) Retain the list of persons approved for unescorted access for 3 years after

the list is superseded or replaced. Records maintained in any database(s) must be available for NRC review.

§ 73.1200 [Amended]

164. In § 73.1200, in paragraphs (o)(5)(i) and (o)(6)(i) add " § 53.1630 of this chapter," after "appendix E to part 50 of this chapter," wherever it appears and in paragraphs (r) and (s) add "53.1630, " after "50.72, " wherever it appears.

§ 73.1205 [Amended]

165. In § 73.1205, add " or § 53.1640" after "§ 50.73" wherever it appears.

166~~8~~. In appendix B to part 73, revise Definitions introductory text to read as follows:

Appendix B to Part 73 – General Criteria for Security Personnel

* * * * *

Definitions

Terms defined in parts 50, 53, 70, and 73 of this chapter have the same meaning when used in this appendix.

* * * * *

PART 74 – MATERIAL CONTROL AND ACCOUNTING OF SPECIAL NUCLEAR MATERIAL

167~~9~~. The authority citation for 10 CFR part 74 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 57, 161, 182, 223, 234, 1701 (42 U.S.C. 2073, 2077, 2201, 2232, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

§ 74.13 [Amended]

168. In § 74.13(a), remove "as defined in §§ 50.21 and 50.22" and add in its place "under §§ 50.21, 50.22 or part 53".

§ 74.31 [Amended]

16970. In § 74.31(a), add ", 52, 53," after "part 50.".

§ 74.41 [Amended]

1701. In § 74.41(a), remove "part 50" and add in its place "parts 50, 52, or 53.".

§ 74.51 [Amended]

1712. In § 74.51(a), remove "part 50" and add in its place "parts 50, 52, or 53.".

PART 75 – SAFEGUARDS ON NUCLEAR MATERIAL – IMPLEMENTATION OF SAFEGUARDS AGREEMENTS BETWEEN THE UNITED STATES AND THE INTERNATIONAL ATOMIC ENERGY AGENCY

1723. The authority citation for 10 CFR part 75 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 63, 103, 104, 122, 161, 223, 234, 1701 (42 U.S.C. 2073, 2093, 2133, 2134, 2152, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

1734. In § 75.4, revise the introductory text and the definition for "Facility" to read as follows:

§ 75.4 Definitions.

* * * * *

Unless otherwise defined in this section, the terms defined in §§ 40.4, 50.2, 53.020, and 70.4 of this chapter have the same meaning when used in this part.

* * * * *

Facility means:

(1) * * *

(6) Any plant or location where the possession of more than 1 effective kilogram of nuclear material is licensed pursuant to Parts 40, 50, 52, 53, 60, 61, 63, 70, 72, 76, or 150 of this chapter or an Agreement State license.

* * * * *

PART 95 – FACILITY SECURITY CLEARANCE AND SAFEGUARDING OF NATIONAL SECURITY INFORMATION AND RESTRICTED DATA

17~~4~~5. The authority citation for 10 CFR part 95 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 145, 161, 223, 234 (42 U.S.C. 2165, 2201, 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 44 U.S.C. 3504 note; E.O. 10865, as amended, 25 FR 1583, 3 CFR, 1959–1963 Comp., p. 398; E.O. 12829, 58 FR 3479, 3 CFR, 1993 Comp., p. 570; E.O. 12968, 60 FR 40245, 3 CFR, 1995 Comp., p. 391; E.O. 13526, 75 FR 707, 3 CFR, 2009 Comp., p. 298.

§ 95.5 [Amended]

17~~5~~6. In § 95.5, in the definition for "*License,*" add "53," after "52."

§ 95.39 [Amended]

17~~6~~7. In § 95.39(a), remove "part 52" and add in its place "parts 52 or 53."

PART 140 – FINANCIAL PROTECTION REQUIREMENTS AND INDEMNITY AGREEMENTS

17~~7~~8. The authority citation for 10 CFR part 140 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 161, 170, 223, 234 (42 U.S.C. 2201, 2210, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

17~~8~~9. In § 140.2, revise paragraphs (a)(1) and (2) to read as follows:

§ 140.2 Scope.

(a) * * *

(1) To each person who is an applicant for or holder of a license issued under 10 CFR parts 50, 52, 53, or 54 to operate a nuclear reactor, and

(2) With respect to an extraordinary nuclear occurrence, to each person who is an applicant for or holder of a license to operate a production facility or a utilization facility (including an operating license issued under parts 50 or 53 of this chapter and a combined license under parts 52 or 53 of this chapter), and to other persons indemnified with respect to the involved facilities.

* * * * *

17980. Revise § 140.10 to read as follows:

§ 140.10 Scope.

This subpart applies to each person who is an applicant for or holder of a license issued under 10 CFR parts 50, 53 or 54 to operate a nuclear reactor, or is the applicant for or holder of a combined license issued under parts 52, 53, or 54 of this chapter, except licenses held by persons found by the Commission to be Federal agencies or nonprofit educational institutions licensed to conduct educational activities. This subpart also applies to persons licensed to possess and use plutonium in a plutonium processing and fuel fabrication plant.

1804. In § 140.11, revise paragraph (b) to read as follows:

§ 140.11 Amounts of financial protection for certain reactors.

* * * * *

(b) In any case where a person is authorized under parts 50, 52, 53, or 54 of this chapter to operate two or more nuclear reactors at the same location, the total primary financial protection required of the licensee for all such reactors is the highest amount which would otherwise be required for any one of those reactors; provided, that such primary financial protection covers all reactors at the location.

1812. In § 140.12, revise paragraph (c) to read as follows:

§ 140.12 Amount of financial protection required for other reactors.

* * * * *

(c) In any case where a person is authorized under parts 50, 52, 53, or 54 of this chapter to operate two or more nuclear reactors at the same location, the total financial protection required of the licensee for all such reactors is the highest amount which

would otherwise be required for any one of those reactors; provided, that such financial protection covers all reactors at the location.

* * * * *

18~~23~~. Revise § 140.13 to read as follows:

§ 140.13 Amount of financial protection required of certain holders of construction permits and combined licenses under 10 CFR part~~s~~ 52 and 53.

Each holder of a part 50 or 53 construction permit, or a holder of a combined license under parts 52 or 53 of this chapter before the date that the Commission had made the finding under § 52.103(g)~~,~~ or § 53.1452(g)~~, or § 53.5052(g)~~ of this chapter, who also holds a license under part 70 of this chapter authorizing ownership, possession and storage only of special nuclear material at the site of the nuclear reactor for use as fuel in operation of the nuclear reactor after issuance of either an operating license under 10 CFR parts 50 or 53, or a combined license under 10 CFR parts 52 or 53, shall, during the period before issuance of a license authorizing operation under 10 CFR parts 50 or 53, or the period before the Commission makes the finding under § 52.103(g)~~,~~ or § 53.1452(g)~~, or § 53.5052(g)~~ of this chapter, as applicable, have and maintain financial protection in the amount of $1,000,000. Proof of financial protection shall be filed with the Commission in the manner specified in § 140.15 of this chapter before issuance of the license under part 70 of this chapter.

18~~34~~. In § 140.20, revise paragraphs (a)(1)(i) and (ii) to read as follows:

§ 140.20 Indemnity agreements and liens.

(a) * * *

(1)(i) The effective date of the license (issued under~~pursuant to~~ parts 50 or 53 of this chapter) authorizing the licensee to operate the nuclear reactor involved; or

(ii) The date that the Commission makes the finding under § 52.103(g)~~,~~ or § 53.1452(g)~~, or § 53.5052(g)~~ of this chapter; or

* * * * *

PART 150 – EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

18~~45~~. The authority citation for 10 CFR part 150 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 53, 81, 83, 84, 122, 161, 181, 223, 234, 274 (42 U.S.C. 2014, 2201, 2231, 2273, 2282, 2021); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

18~~56~~. In § 150.15, revise paragraphs (a)(7)(iii) and (a)(8) to read as follows:

§ 150.15 Persons not exempt.

(a) * * *

(7) * * *

(iii) Greater than Class C waste, as defined in part 72 of this chapter, in an ISFSI or an MRS licensed under part 72 of this chapter; the GTCC waste must originate in, or be used by, a facility licensed under parts 50, 52, or 53 of this chapter.

(8) Greater than Class C waste, as defined in part 72 of this chapter, that originates in, or is used by, a facility licensed under parts 50, 52, or 53 of this chapter and is licensed under part 30 and/or part 70 of this chapter.

* * * * *

PART 170 – FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

18~~67~~. The authority citation for 10 CFR part 170 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w) (42 U.S.C. 2014, 2201(w)); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2215; 31 U.S.C. 901, 902, 9701; 44 U.S.C. 3504 note.

18~~7~~8. In § 170.3, revise the definitions for "*Manufacturing License,"* "*Part 55 Reviews,"* "*Power reactor,"* and "*Special projects"* to read as follows:

§ 170.3 Definitions.

* * * * *

Manufacturing license means a license underpursuant to subpart F of part 52, of this chapter or subpart~~s~~ H ~~or R~~ of part 53 of this chapter to manufacture a nuclear power reactor(s) to be operated at sites not identified in the license application.

* * * * *

Part 55 Reviews as used in this part means those services provided by the Commission to administer requalification and replacement examinations and tests for reactor operators licensed underpursuant to 10 CFR part 55 or part 53 of the Commission's regulations and employed by part~~s~~ 50, 52, or 53 licensees. These services also include related items such as the preparation, review, and grading of the examinations and tests.

* * * * *

Power reactor means a nuclear reactor designed to produce electrical or heat energy licensed by the Commission under the authority of section 103 or subsection 104b of the Act, and underpursuant to the provisions of § 50.21(b), § 50.22, or part 53 of this chapter.

* * * * *

Special projects means specific services provided by the Commission for which fees are not otherwise specified in this chapter. This includes, but is not limited to, contested hearings on licensing actions directly related to U.S. Government national security initiatives (as determined by the NRC), topical report reviews, early site reviews, waste solidification activities, activities related to the tracking and monitoring of shipment

of classified matter, services provided to certify licensee, vendor, or other private industry personnel as instructors for 10 CFR parts 55 or 53 reactor operators, reviews of financial assurance submittals that do not require a license amendment, reviews of responses to Confirmatory Action Letters, reviews of uranium recovery licensees' land-use survey reports, and reviews of updated ~~§ 50.71, § 53.1545, or § 53.6045 of this chapter~~ Final Safety Analysis Reports submitted under § 50.71 or § 53.6045 of this chapter. The term ~~S~~special projects does not include activities otherwise exempt from fees under this part. It also does not include those contested hearings for which a fee exemption is granted in § 170.11(a)(2), including those related to individual plant security modifications.

* * * * *

§ 170.12 [Amended]

18~~89~~. In § 170.12(d)(1)(v), remove "10 CFR 50.71" and add in its place "10 CFR 50.71~~,~~ or 53.1545~~, or 53.6045.~~".

§ 170.21 [Amended]

189~~0~~. In § 170.21, footnote 1, add "10 CFR 53.080," after "10 CFR 50.12," inside the parenthetical.

§ 170.41 [Amended]

190~~1~~. In § 170.41, add "52, 53," after "40, 50,".

PART 171 – ANNUAL FEES FOR REACTOR LICENSES AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY THE NRC

191~~2~~. The authority citation for 10 CFR part 171 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w), 223, 234 (42 U.S.C. 2014, 2201(w), 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2215; 44 U.S.C. 3504 note.

19~~2~~3. Revise § 171.3 to read as follows:

§ 171.3 Scope.

The regulations in this part apply to any person holding an operating license for a test reactor or research reactor issued under part 50 of this chapter, and to any person holding an operating license for a power reactor licensed under 10 CFR parts 50 or 53, or a combined license issued under 10 CFR parts 52 or 53, that has provided notification to the NRC that the licensee has successfully completed power ascension testing. The regulations in this part also apply to any person holding a materials license as defined in this part, a Certificate of Compliance, a sealed source or device registration, a quality assurance program~~QAP~~ approval, and to a Government agency as defined in this part. Notwithstanding the other provisions in this section, the regulations in this part do not apply to uranium recovery and fuel facility licensees until after the Commission verifies through inspection that the facility has been constructed in accordance with the requirements of the license.

19~~3~~4. In § 171.5, revise the definitions for “Operating license,” and “Power reactor” to read as follows:

§ 171.5 Definitions.

* * * * *

Operating license means having a license issued ~~pursuant to~~under § 50.57~~,~~ or § 53.1387~~, or § 53.4987~~ of this chapter. It does not include licenses that only authorize possession of special nuclear material after the Commission has received a request from the licensee to amend its licensee to permanently withdraw its authority to operate or the Commission has permanently revoked such authority.

* * * * *

Power reactor means a nuclear reactor designed to produce electrical or heat energy and licensed by the Commission under the authority of section 103 or subsection 104b of the Atomic Energy Act of 1954, as amended, and underpursuant to the provisions of § 50.21(b) or 50.22, or part 53 of this chapter.

* * * * *

1945. In § 171.15, revise paragraphs (a), (b)(2)(iii), (c)(1), and (d)(1) to read as follows:

§ 171.15 Annual fees: Non-power production or utilization licenses, reactor licenses, and independent spent fuel storage licenses.

(a) Each person holding an operating license for one or more non-power production or utilization facilities under 10 CFR part 50 that has provided notification to the NRC of the successful completion of startup testing; each person holding an operating license for a power reactor licensed under 10 CFR part 50 or a combined license under 10 CFR part 52, or an operating license or combined license for a commercial nuclear plant under 10 CFR part 53, that has provided notification to the NRC of the successful completion of power ascension testing; each person holding a 10 CFR part 50, or 52, or 53 power reactor license, or a 10 CFR part 53 commercial nuclear plant license that is in decommissioning or possession only status, except those that have no spent fuel onsite; and each person holding a 10 CFR part 72 license who does not hold a 10 CFR parts 50, 52, or 53 license and provides notification underin accordance with § 72.80(g), shall pay the annual fee for each license held during the Federal fiscal year in which the fee is due. This paragraph (a) does not apply to test or research reactors exempted under § 171.11(b).

(b) * * *

(2) * * *

(iii) Generic activities required largely for NRC to regulate power reactors (e.g., updating parts 50, 52, or 53 of this chapter, operating the Incident Response Center, new reactor regulatory infrastructure). The base annual fee for operating power reactors does not include generic activities specifically related to reactor decommissioning.

(c)(1) The FY 2022 annual fee for each power reactor holding a 10 CFR part 50 operating license or combined license issued under 10 CFR parts 52 or 53 that is in a decommissioning or possession-only status and has spent fuel onsite, and for each independent spent fuel storage 10 CFR part 72 licensee who does not hold a 10 CFR parts 50 or 53 operating license, or a 10 CFR parts 52 or 53 combined license, is $227,000.

* * * * *

(d)(1) Each person holding an operating license for an SMR issued under 10 CFR parts 50 or 53, or a combined license issued under 10 CFR parts 52 or 53, that has provided notification to the NRC of the successful completion of power ascension~~startup~~ testing, shall pay the annual fee for all licenses held for an SMR site. The annual fee will be determined using the cumulative licensed thermal power rating of all SMR units and the bundled unit concept, during the fiscal year in which the fee is due. For a given site, the use of the bundled unit concept is independent of the number of SMR plants, the number of SMR licenses issued, or the sequencing of the SMR licenses that have been issued.

* * * * *

Commented [A411]: Edited to match the scoping criteria of 171.3 for SMR annual fees.

§ 171.17 [Amended]

19~~5~~6. In § 171.17, in paragraph (a) introductory text remove “or 10 CFR part 52” and add in its place, “10 CFR part 52, or 10 CFR part 53”; in paragraphs (a)(1)(ii) and (a)(2) remove “or 52,” wherever it may appear and add in its place, “52, or 53”.

Dated: <Month XX, 20XX>.

For the Nuclear Regulatory Commission.

<**INSERT:** Name,>

<**INSERT:** Title of signing official.>

Attachment 4 to Commissioner Caputo's Comments on SECY-23-0021, "Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31)"

Table of Typographic Errors and Inconsistencies in the Current Regulations

Affected Section	Comment
50.10	Paragraph 50.10(e)(1)(iii) should be modified to replace the period after the word “met” with a comma and the period after the word “authorized” with a comma and the word “and” along with corresponding changes to capitalization. These modifications would reflect that this paragraph contains a continuous list of items required for issuance of a limited work authorization.
50.33	Paragraph 50.33(j) should be edited to use the term “classified National Security Information” instead of the undefined term “other defense information.” The former term is defined in § 95.5. The latter term dates back to an Atomic Energy Commission (AEC) amendment of this section on January 19, 1956 (21 FR 355, 357) and was not changed with the promulgation of 10 CFR Part 95 (45 FR 14476; March 5, 1980) after the establishment of the NRC and the 1975 reissuance of the former AEC regulations.
50.36b	Paragraph 50.36b(b) should be edited to replace the phrase “for which the certification of permanent cessation of operations required under § 50.82(a)(1) or § 52.110(a) of this chapter” with “that no longer authorizes operation of the reactor under § 50.82(a)(1) or § 52.110(a) of this chapter” to reflect the potential for removal of the authority to operate the reactor when a final, legally effective order to permanently cease operations comes into effect under §§ 50.82(a)(1) or 52.110(a).
50.36b	The language in §§ 50.36b(a) and (b) should be reconciled so that there is a comma after the phrases “attachment to the permit or license” in § 50.36b(a) and "attachment to the license" in § 50.36b(b); this comma is missing in § 50.36b(b). Alternatively, the comma in § 50.36b(a) after the phrase “attachment to the permit or license” may be deleted to reconcile the two paragraphs.
50.37	The language in this paragraph should be edited to parallel that in § 52.54(c). Specifically, the word "or" should be added between "have access to" and "any facility" to correct a drafting error in this paragraph. The preamble for the 2007 rulemaking that modified the parallel language in 10 CFR Part 52 provides a discussion on the intended language for this paragraph (73 FR 49352).
50.43	In § 50.43(e), there are typographic errors where (1) a period follows the year 1997 rather than a comma and (2) the word "Or" is inadvertently capitalized due to the errant period. These errors have resulted in incomplete sentences.
50.55	Paragraph 50.55(e)(2)(i) should be edited to reflect the correct scope of license holders that are subject to this regulation. The existing requirements in this paragraph conflict with the scope of applicability in the prefatory paragraph in this section (i.e., the regulations are only applicable to holders of a construction permit, combined license, or a manufacturing license and not all licensees subject to the regulations in 10 CFR part 50).

Affected Section	Comment
50.55	Paragraph 50.55(e)(3)(iii) should be modified to include “or manufactured reactor” after the phrase “if the construction or manufacture of a facility or activity,” in this paragraph because the § 21.3 definition of "basic component" does not appear to be broad enough to cover a manufactured reactor due to that being a structure, system, or component, or part of an a structure, system, or component.
50.55	Paragraph 50.55(e)(4)(ii) should be modified to include “or manufactured reactor” after the phrase “or any defect found in the final design of a facility” in this paragraph because the § 21.3 definition of "basic component" does not appear to be broad enough to cover a manufactured reactor due to that being a structure, system, or component, or part of an a structure, system, or component.
50.55	Paragraph 50.55(e)(9)(iv) should be modified or deleted (reserved) to reflect that suppliers of basic components must follow applicable requirements in 10 CFR part 21. Record retention for suppliers of basic components is governed by § 21.51 and differs from the periods set forth in § 50.55(e)(9)(iv).
50.55	The initial notification requirements in § 50.55(e)(5)(i) should be updated to reflect that emails are also a permissible initial notification method in addition to facsimile and phone notification options. This would reflect that the existing requirements were likely developed during a time period where different means of communication were dominant.
50.30	Paragraph 50.30(d) should be modified to remove references to “an amendment to an application for a license to construct and operate a production or utilization facility” as this appears to be an outdated license application type (i.e., a forerunner to the current combined license).
50.59	Paragraph 50.59(c)(1)(i) should be edited to replace the phrase “A change” with “An amendment” to avoid using the defined term “change.”
50.75	Paragraph 50.75(e) should be modified to include “applicant or” in all appropriate places where currently only “licensee” is referenced. This change would address the fact that applicants or licensees would be subject to the requirements under this paragraph. Currently, only § 50.75(e)(1)(iii)(C) contains the inclusive “applicant or licensee.”
50.82	The semicolon is misplaced after the word "and" rather than after the word "arise" in § 50.82(a)(8)(i).
50.82	Paragraph 50.82(a)(6) should be edited to correct the reference to the term “decommissioning activities” since this term is not defined, contrary to the current wording suggesting that the term is defined in § 50.2.
50.82	Paragraph 50.82(a)(1)(iii) should be edited to replace the phrase "the effective date of this rule" with the date of the rule that inserted that provision in the regulations to correct the regulation and provide clarity to readers.
50.100	The reference in § 50.100 to § 50.42(a) should be modified to instead reference § 50.42. The provisions of § 50.42(a) were moved to § 50.42 by 73 FR 44620 and the reference to § 50.42(a) is no longer valid.
50.109	Paragraph 50.109(a)(4) should be modified to eliminate a typographical error at the end of this provision. Specifically, the phrase “with appropriated documented” should be replaced with “with appropriate documented”.

Affected Section	Comment
51.53	In § 51.53, a reference to “§ 52.110” should be added after “§ 50.82” to reflect that 10 CFR part 52 also includes license termination provisions.
52.26	In § 52.26(b), the words “early site” should be inserted after the phrase “timely application for renewal of the” to specify that the term "permit" refers back to the early site permit and not to the construction permit for which an application was submitted.
52.31	Paragraph 52.31(a) should be modified to read as follows: “The Commission shall grant the renewal only if it determines that:”. As drafted, this paragraph mandates the renewal by the Commission if the subparagraphs are met but does not prohibit the renewal if they are not met. The word "only" is inserted after the word "renewal" in order to make this a criterion for renewal.
52.31	Paragraph 52.31(b) should be modified to replace the phrase “for failure to comply with” with “under” to reflect that the provisions in § 52.31(a) are applicable to the Commission and not the applicant for renewal of an early site permit. Failure to comply with those provisions would only result when the Commission does not grant renewal despite the provisions of the subparagraphs having been met.
52.39	Paragraph 52.39(c)(2) should be modified to remove two instances of the word “should” after “early site permit” and “that permit” to improve the clarity of this paragraph.
52.39	In § 52.39(e), the phrase “changes to the early site permit, including the site safety analysis report,” should be modified to read as “changes to the early site permit or the site safety analysis report” to clarify the relationship between the early site permit and the Site Safety Analysis Report. As currently written, the language incorrectly implies that the Site Safety Analysis Report is part of the early site permit.
52.91	Paragraph 52.91(b) should be edited to replace the phrase “paragraph (a) of this section” with “a limited work authorization issued under § 50.10 of this chapter” to reflect that the sole activities permitted under paragraph (a) of this section are the submittal of an application for a limited work authorization under § 50.10. The activities are described in § 50.10.
52.103	Paragraph 52.103(b)(2) should be edited to remove the word "that" after the word "nonconformance." The word “that” which is already included before the em dash in § 52.103(b) eliminates the need for the superfluous “that” in § 52.103(b)(2).
52.110	The semicolon is misplaced after the word "and" rather than after the word "arise" in § 52.110(h)(1)(ii). This paragraph should be edited to modify the placement of the semicolon.
52.110	Paragraph 52.110(f) should be edited to correct the reference to the term “decommissioning activities” since this term is not defined, contrary to the current wording suggesting that the term is defined in § 52.1.
52.158	The semicolon between "manufacturing license" and "the provisions of the Act" in § 52.158(a)(1)(i) should be replaced with a comma.
52.177	The word “license” should be used instead of “permit” in § 52.177(d) to reflect that a manufacturing license is considered a license in accordance with the definitions in § 52.1.