2nd Iteration - Consolidated Part 53 Preliminary Proposed Rule Language

May 2022

This preliminary proposed rule language is the 2nd iteration of the consolidated version of the preliminary proposed rule language that the NRC staff has publicly released to date in support of the Part 53 rulemaking, with the exception of Part 5X. The 2nd iteration of Part 5X, now referred to as Framework B, will be released separately. This consolidated version contains additional revisions, as indicated in red, underscored text, compared to the previously released 1st iteration in February 2022. This version is based on additional reviews by NRC staff and consideration of stakeholder input. The NRC staff expects to adopt further changes in addition to those reflected in this consolidated version of the preliminary proposed rule language. Therefore, the absence in this document of changes made in response to a particular comment submittal by any stakeholder should not be construed to mean that the comment is no longer under consideration by the NRC staff. Rather, this consolidated preliminary proposed rule language is being released to support interactions with stakeholders and the Advisory Committee on Reactor Safeguards (ACRS). This language has not been subject to complete NRC management or legal review, and its contents should not be interpreted as official agency positions. The NRC staff plans to continue working on the proposed rule language provided in this document and continues to welcome public participation in the Part 53 rulemaking activities.

This iteration presents the consolidated Part 53 preliminary proposed rule language for Framework A, which is the set of preliminary proposed regulatory requirements in Subparts B through K. Subpart F has not been revised in this iteration. However, a second iteration of Subpart F will be publicly released in the near future. Also included in this document are proposed changes to Subpart A, "General Provisions," and Parts 26 and 73. The preliminary proposed rule language is a work-in-progress; the rule text will continue to be revised by the NRC staff to address formatting, consistency in terminology, and other editorial details.

While the NRC will consider all comments received in further developing the preliminary proposed rule language, it will not provide written responses to those comments. Once the proposed rule is issued in the *Federal Register*, the public will have an opportunity to provide comments, and the agency will respond in writing to all public comments on the proposed rule when issuing a final rule.

Please note that in Part 26 language, blue text indicates preliminary proposed rule text and black text is existing rule text. For the remainder of the document (Part 53 and Part 73) preliminary rule text is provided in black with revisions, as indicated in red, underscored text

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Sec.

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Sec.

List of Subjects

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 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 52

Administrative practice and procedure, Antitrust, Combined license, Early site permit, Emergency planning, Fees, Incorporation by reference, Inspection, Issue finality, Limited work authorization, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Penalties, Reporting and recordkeeping requirements, Standard design, Standard design certification.

10 CFR Part 53

TBD.

10 CFR Part 73

TBD.

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 26, 50, 52, and 73 and adding to 10 CFR chapter I a new part 53:

[In Part 26 language, blue text indicates preliminary proposed rule text and black text is existing rule text. – For the remainder of the document (Part 53 and Part 73) preliminary rule text is provided in black with revisions, as indicated in red, underscored text]

PART 26 – FITNESS FOR DUTY PROGRAMS

1. 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.

2. Section 26.3 is revised to include new paragraph (f):

§ 26.3 Scope.

(f) ~~Before~~ No later than the start of construction activities, licensees and other entities that have applied for or have been issued a license under Part 53~~, "Licensing and Regulation of Advanced Nuclear Reactors,"~~ of this chapter, other than a manufacturing license, shall implement the requirements in subpart M of this part or all the requirements of this part except subparts K and M. ~~Licensees and other entities who have received~~Holders of a manufacturing license under Part 53 must implement the requirements in subpart M or all the requirements of this part, except subparts K and M, before the earlier of commencing activities that assemble a manufactured reactor or loading of nuclear fuel in a manufactured reactor ~~vessel module~~.

3. Section 26.4, paragraphs (a), (b), (c), (e), (f), (g), and (h) are revised:

§ 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 nuclear power reactor protected areas by the licensees and other entities in § 26.3(f) and perform or direct the performance of the following duties shall be subject to an FFD program that meets the requirements in subpart M, unless the licensee or other entity subjects these individuals to an FFD program that meets all of the requirements of this part except for those requirements in subparts K and M~~.~~:

...

(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 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, and who do not perform or direct the performance of the duties described in § 26.4(a), shall be subject to the requirements in subpart M of this part, unless the licensee or other entity implements an FFD program that meets 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. For licensees or other entities in § 26.3(f), all persons who are assigned by the licensee to participate remotely and make decisions or direct actions regarding plant safety and security, and all persons who are assigned by the licensee to participate remotely in emergency response activities or physically report to the TSC or EOF (or an equivalent facility), shall be subject to an FFD program that meets all of the requirements described in subpart M of this part, unless the licensee or other entity implements an FFD program that meets 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 ~~the~~ have the following types of access, perform construction activities as defined in § 26.5, or perform the following activities shall be subject to an FFD program as described in subpart M of this part or an FFD program that meets 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;

(5) Supervises or manages the construction of safety- or security-related SSCs ~~or the construction of SSCs that a risk-informed evaluation process has shown to be significant to public health and safety~~; or

…

(f) Any individual who is constructing or directing the construction of safety- or security-related SSCs ~~activities as defined in § 26.5~~ 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, ~~and~~ 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, ~~and~~ K, and M

of this part, and, at the licensee's or other entity's discretion, subpart C of this part. All personnel ~~described, who~~whose duties require them to have the following types of access ~~and~~or perform ~~those duties and responsibilities described in this paragraph~~the following activities at facilities licensed under Part 53~~,~~ shall be subject to the requirements in subpart M or 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.

…

(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, ~~and~~ E through H, and~~, if applicable~~ M~~,~~ of this part.

3. In Section 26.5, revise definitions for Contractor/vendor (C/V), Constructing or construction activities, Other entity, Questionable validity, Reviewing official, Safety-related structures, systems, and components (SSCs), Security-related SSCs, and include definitions for Certified Operator, Change, and Reduction in FFD program effectiveness:

§ 26.5 Definitions.

Biological marker means, for a Part 53 licensee implementing subpart M, an endogenous substance that is used to validate that the biological specimen collected for testing was produced by the donor.

Certified Operator means an individual certified under the provisions of §§ 53.800 through 53.830 of this chapter to manipulate a control of a facility. ~~Certified operators are not licensed by the Commission.~~

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 mean, 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.

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.

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, *Questionable validity* means the results of validity screening or initial validity tests that a biological specimen obtained from an individual pursuant to subpart M may be adulterated, substituted, dilute, or invalid.

Reduction in FFD program effectiveness means, for a Part 53 licensee implementing subpart M, a change or series of changes to an element of the FFD program that reduces or eliminates the licensee's ability to meet or maintain site-

specific FFD program performance when compared to historical site-specific performance, the licensee's fleet-level program performance, or ~~generic~~ 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) mean, for licensees and other entities described in § 26.3(a) ~~- (d) and for the purposes of this part~~ (c) and (d) for C/Vs for Part 50 or Part 52 licensees and other entities, 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 licensees and other entities described in § 26.3(d) for C/Vs for Part 53 licensees and other entities and (f), safety-related has the meaning provided in § 53.020.

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.

4. Revise Section 26.21 as follows:

§ 26.21 Fitness-for-duty program.

(a) The licensees and other entities specified in § 26.3(a) through (c) shall establish, implement, and maintain FFD […]

(b) The licensees and other entities specified in § 26.3(f) that do not implement the requirements in subpart M, shall implement the requirements in this subpart.

5. Revise Sections 26.51, 26.53, and 26.63 as follows:

§ 26.51 Applicability.

(a) 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) . . .

(b) The requirements in this subpart apply to the FFD programs of licensees and other entities identified in § 26.3(f) ~~for the categories of individuals in § 26.602~~ that elect not to implement the requirements in subpart M for the categories of individuals in § 26.602 and those licensees and other entities that elect to implement the requirements in § 26.605.

§ 26.53 General provisions.

……

(e) Licensees and other entities in § 26.3(a) through (c), and, if applicable, (f) may also rely on a C/V's FFD program […]

(1) A C/V's FFD program may grant and maintain an individual's authorization, as defined in § 26.5, under the C/V's FFD program. However, only a licensee or other entity in § 26.3(a) through (c), and if applicable, (f) may grant or maintain […]

(3) If an individual is maintaining authorization under a C/V's FFD program, a licensee or other entity in § 26.3(a) through (c), and if applicable, (f) may grant authorization […]

(g) The licensees and other entities specified in § 26.3(a) and, as applicable, (c), ~~and~~ (d), and (f) shall identify any violation […]

(h) The licensees and other entities specified in § 26.3(a) and, as applicable, (c), ~~and~~ (d), and (f) […]

(i) The licensees and other entities specified in § 26.3(a) and, as applicable, (c), ~~and~~ (d), and (f) shall inform, in writing, any individual who is applying for […]

§ 26.63 Suitable inquiry.

……

(d) When any licensee or other entity in § 26.3(a) through (d), and, if applicable, (f) is legitimately seeking the information […]

6. Revise Section 26.73 as follows:

§ 26.73 Applicability.

(a) 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) […]

(b) The requirements in this subpart apply to the FFD programs of licensees and other entities identified in § 26.3(f) ~~for the categories of individuals in § 26.602~~ that elect not to implement the requirements in subpart M for the categories of individuals in §

26.602 and those licensees and other entities that elect to implement the requirements in § 26.605.

7. Revise Section 26.81 as follows:

§ 26.81 Purpose and applicability.

(a) 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) […]

(b) The requirements in this subpart apply to the FFD programs of licensees and other entities identified in § 26.3(f) ~~for the categories of individuals in § 26.602~~ that elect not to implement the requirements in subpart M for the categories of individuals in § 26.602 and those licensees and other entities that elect to implement the requirements in § 26.605.

8. Revise subpart I 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 subpart M. For the~~se~~ 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 in accordance with § 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, as applicable, any Certified Operator; and the requirements in § 26.205 through § 26.209 apply to the individuals identified in § 26.4(a).

§ 26.202 General provisions for facilities licensed under Part 53.

(a) *Policy*. Licensees shall 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 shall 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 examinations*. Licensees shall add the following KAs to the content of the training that is 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 shall 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 shall include the following information in a standard format in the annual FFD program performance report required under § 26.617:

(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 shall report:

(i) The number of instances when each applicable work hour control specified in § 26.205(d)(1)(i) through (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), (d)(3)(i) through (d)(3)(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 (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), (d)(3)(i) through (d)(3)(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 shall audit the management of worker fatigue as required by § 26.615.

§ 26.205 Work Hours

……

(d) *Work hour controls*. Licensees shall control the work hours of individuals who are subject to this section.

[…]

(7) Licensees may, as an alternative to complying with the minimum days off requirements in § 26.205(d)(3), comply with the requirements for maximum average work hours in this paragraph.

[…]

(iii) Each licensee shall state, in its FFD policy and procedures required by § 26.27 ~~and~~ or § 26.606(a), in addition to § 26.203(a) and (b), 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 § 26.27 ~~and~~ or § 26.606(a), in addition to § 26.203(a) and (b), 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).

[…]

§ 26.207 Waivers and exceptions.

(a) *Waivers*. Licensees may grant a waiver of one or more of the work hour controls in § 26.205(d)(1) through (d)(5)(i) and (d)(7), as follows:

[…]

(1) To grant a waiver, the licensee shall meet both of the following requirements:

[…]

(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 § 26.29 or 26.608, ~~and~~ in addition to § 26.202(c) or 26.203(c), and shall be qualified [...]

§ 26.211 Fatigue assessments.

(a) Licensees shall ensure that fatigue assessments are conducted under the following conditions:

(1) *For cause*. In addition to any other test or determination of fitness that may be required under §§ 26.31(c), ~~and~~ 26.77, and 26.607(c), 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 […]

(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 26.607(c). 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 26.608 and 26.202(c) may conduct a fatigue assessment. The fatigue assessment must be conducted face to face with the individual whose alertness may be impaired.

9. Add subpart M to part 26 as follows:

Subpart M — Fitness for Duty Programs for Facilities Licensed Under Part 53

§ 26.601 Applicability.

At the licensee's or other entity's discretion, a licensee or other entity in § 26.3(f) may establish, implement, and maintain an FFD program that meets the requirements of this subpart for the individuals specified in § 26.602. If a licensee or other entity in § 26.3(f) does not elect to implement an FFD program that meets the requirements of this subpart, then the individuals specified in § 26.602 shall be subject to an FFD program that meets all Part 26 requirements, except for those requirements in subparts K and M.

§ 26.602 FFD program applicability to categories of individuals.

~~The~~As designated by the licensee or other entity, the requirements of this subpart apply to those categories of individuals in § 26.4, as applicable, and any Certified Operator, as defined in § 26.5~~, as designated by the licensee or other entity~~.

§ 26.603 General provisions.

(a) *FFD Program Description*. As required by §§ 53.124~~5~~79(e)(3), [53.1266], 53.~~1275~~1369(y), and 53.~~1289~~1416(a)(24) of subpart H of Part 53, the applicant's description of the FFD program in its final safety analysis report must include—

(1) ~~A summary of~~If the ~~analysis~~applicant performed the analysis under paragraph (c)(2) of this section, ~~if performed~~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 meet 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 § 26.602 and how the program will be implemented offsite at an NRC-licensed facility authorized to ~~fabricate, construct~~assemble, test, and/or ~~test~~fuel a ~~nuclear~~manufactured reactor ~~module~~, if applicable;

(4) A description of the drug and alcohol testing and fitness determination process to be implemented ~~by~~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 ~~expected~~the measures and ~~metrics~~thresholds required by paragraph (d)(1) of this section.

(b) *FFD Program Implementation and Availability*. For the licensees and other entities in § 26.~~4~~3(f), other than the holder of a manufacturing license, the FFD program shall be ~~established,~~ implemented~~, and maintained before~~ no later than the start of construction activities, as defined in § 26.5, and ~~during reactor operation and~~ maintained

until the NRC's docketing of the license holder's certifications described in §§ 50.82(a)(1), 52.110(a), or 53.1070. For ~~licensees that have been issued~~holders of a manufacturing license, the FFD program shall be ~~established,~~ implemented~~,~~ no later than the start of activities that assemble the manufactured reactor and maintained ~~before the loading of nuclear fuel into the reactor vessel module and~~ until expiration of the manufacturing license.

(c) *Criterion and Analysis for an FFD Program*. ~~(1) *Criterion*. The criterion to be used for the analysis in § 26.603(c)(2) shall be the criterion in 10 CFR 53.830(a)(2)(i).~~

~~(2) *Analysis.*~~ In order 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 criterion in § ~~26.603(c)(1~~53.860(a)(2)(i) is met. The licensee or other entity must maintain the analysis until permanent cessation of operations under § 53.1070 of this chapter.

(d) *FFD Performance Monitoring and Review*. A licensee or other entity must establish performance measures and associated thresholds as described in § 26.603(d)(1) and monitor the effectiveness of its FFD program against these performance measures and thresholds, in a manner sufficient to provide reasonable assurance that individuals subject to the program can safely and competently perform assigned duties and responsibilities and are trustworthy and reliable to maintain the types of access making them subject to this subpart.

(1) The performance monitoring and review program (PMRP) shall 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 in a manner sufficient to provide reasonable assurance that the ~~10 CFR~~§ 26.23 performance objectives are met.

(A) If the licensee or other entity is subject to the requirements in § 26.604, then the monitoring program must include ~~a~~ performance measures for ~~the effectiveness of~~ : 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, who possessed FFD prohibited items, or who were impaired while in a work status.

(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 paragraph (d)(1)(i)(A) of this section. This monitoring program must also include performance measures for the pre-access and random positive testing rates~~,~~ and the number of subversion attempts~~;~~ categorized by licensee employee, contractor/vendor, and labor category.

~~(ii) *Monitoring Program*. Assessments must be conducted as data is received. Monitoring must enable year-to-year comparisons for the site and when data is available against FFD program and industry performance.~~

~~(iii) *Thresholds*.~~ (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 ~~p~~Part 26, ~~FFD~~the licensee's or other entity's fleet-level program ~~information~~performance if ~~the program has~~

~~more than one site subject to part 26~~applicable, and ~~generic~~ industry FFD performance data.

(iii) *Monitoring Program*. Licensees and other entities shall 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) *Biennial Review*. Licensees and other entities must re-evaluate their performance measures and thresholds every two years and adjust their performance measures and thresholds to maintain FFD program effectiveness based on historical site-specific~~, licensee's~~ performance; licensees' or other entities' fleet-level program performance, if applicable; and ~~comparable~~ industry performance or any identified areas for improvement.

(~~iv~~v) *Quantitative and Qualitative Reviews*. ~~-~~The ~~performance monitoring and review program~~PMRP shall include a documented review of the elements in § 26.603(d)(1)(i)-(iii) and the following qualitative elements.

(A) ~~*Appeals Process.*~~ *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)(ii), 26.611, and 26.613.

(B) *Laboratory Test Results and Medical Review Officer Performance*.~~-~~ The review must include a documented assessment whether the actions taken by the Medical Review Officer 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 §§ 26.607(n)(6) or 26.185.

(C) *Change Control Process*. The review must include a documented assessment of the changes made under § 26.603(e) to provided assurance that the summation of program changes haves not resulted in a reduction in FFD program effectiveness.

(2) *Corrective Actions*. Corrective actions shall 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(d)(1)(iv) shall 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 based on site- and licensee's fleet-level program , if applicable, 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 ~~before November 15~~to support the reporting of PMRP weaknesses and corrective actions as required in § 26.603(d)(i) every ~~even~~odd-numbered year, and the implementation of corrective actions ~~implemented~~ before May 15 of ~~the following~~that odd-numbered year.

(e) *FFD Program Change Control.* The licensee or other entity shall establish, implement, and maintain a change control process that meets the following requirements—

(1) The licensee or other entity may make changes to its FFD program under this subpart ~~without prior NRC approval~~ only 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 or laboratory processes or procedures, ~~including the full panel of drugs, drug metabolites, and cutoffs, implemented to maintain their U.S. Department of Health and Human Services' (HHS) laboratory certification~~or guidance issued by the HHS or NRC, as implemented by the licensee or other entity though its procedures as allowed by § 26.606.

(2)~~-~~ A licensee or other entity desiring to make a change that decreases FFD program effectiveness must ~~submit an application for amendment to its license, in addition to the filing requirements in §§ 53.1560 and 53.1565. The request must include~~implement a ~~detailed description of the change, the reason for the change, and the use of any~~ mitigating strategy ~~needed~~ to ~~provide~~maintain reasonable assurance that ~~if the change is approved,~~ the FFD program, as revised, will continue to meet the performance objectives in § 26.23 and not result in a reduction in program effectiveness.

(3) Except for phencyclidine, and notwithstanding paragraph (e)(1)(iii) of this section, 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 ~~credited~~ technical analysis used to justify meeting the ~~risk-informed determination~~ criterion ~~of this section~~in § 53.860(a)(2)(i) must be maintained, including updates to reflect changes made pursuant to § 26.603(e~~)~~), to the staffing, FFD programs, or offsite support resources described in the analysis, to show that the facility and its operation continues to meet the ~~risk-informed determination criteria~~criterion, if applicable.

(~~4~~5) The licensee shall retain a record of each change made under this section for a period of at least five 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 facilities that meet the FFD criterion~~.~~.

(a) *FFD Program*. Licensees and other entities with an analysis ~~as described in § 26.603(c)(2)~~ that demonstrates the criterion in § ~~26.603(c)(1~~ 53.860(a)(2)(i) is met, 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 § 26.602, as applicable;

(2) implements the program elements and requirements described in in § 26.603; and,

(3) implements the following requirements and subparts in this part:

(i) § 26.23, Performance objectives

(ii) § 26.606, Written policies and procedures, (a) and, if applicable (b)

(iii) § 26.608, FFD program training

(iv) § 26.609, Behavioral observation

(v) § 26.610, Sanctions

(vi) § 26.611, Protection of information

(vii) § 26.613, Review process

(viii) § 26.615, Audits

(ix) § 26.617, Recordkeeping and reporting

(x) § 26.619, Suitability and fitness determinations

(xi) Subpart A—Administrative Provisions

(xii) Subpart O—Inspections, Violations, and Penalties

§ 26.605 FFD program requirements for facilities that do not meet the FFD criterion.

(a) Licensees and other entities implementing § 26.604, at their discretion, and licensees and other entities that implement an FFD program under this subpart 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 ~~and~~or fueling of a manufactured reactor ~~module~~, as applicable. Th~~at~~is FFD program must contain the following elements:

(1) applies to those individuals described in § 26.602, as applicable;

(2) implements the program elements and requirements described in in § 26.603; and,

(3) implements the following requirements and subparts in this part—

(i) § 26.23, Performance objectives

(ii) § 26.606, Written policy and procedures

(iii) § 26.607, Drug and alcohol testing

(iv) § 26.608, FFD program training

(v) § 26.609, Behavioral observation

(vi) § 26.610, Sanctions

(vii) § 26.611, Protection of information

(viii) § 26.613, Review process

(ix) § 26.615, Audits

(x) § 26.617, Recordkeeping and reporting

(xi) § 26.619, Suitability and fitness evaluations; and

(xii) Subpart A—Administrative Provisions

(xiii) Subpart I—Fatigue Management

(xiv) Subpart O—Inspections, Violations, and Penalties

(b) Licensees and other entities implementing § 26.604, at their discretion, and licensees ~~and~~or other entities that implement an FFD program under this subpart, before the loading of fuel onsite into a reactor vessel; before receiving a manufactured reactor ~~vessel~~ module ~~loaded with fuel~~; 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 has shown to be significant to public health and safety, shall establish, implement, and maintain an FFD program that—

(1) applies to those individuals described in § 26.602, as applicable.

(2) implements the program elements and requirements described in § 26.603~~(a) (e);~~; and

(3) Implements the following requirements and subparts—

(i) § 26.23, Performance objectives

(ii) § 26.606, Written policy and procedures

(iii) § 26.607, Drug and alcohol testing

(iv) § 26.608, FFD program training

(v) § 26.609, Behavioral observation

(vi) § 26.611, Protection of information

(vii) § 26.613, Review process

(viii) § 26.615, Audits

(ix) Subpart A—Administrative Provisions

(x) Subpart C—Granting and Maintaining Authorization

(xi) Subpart D—Management Actions and Sanctions to be Imposed

(xii) Subpart H—Determining Fitness-for-Duty Policy Violations, unless using the HHS Guidelines for MRO evaluation of drug test results, and Determining Fitness

(xiii) Subpart I—Fatigue Management

(xiv) Subpart N—Recordkeeping and Reporting Requirements

(xiv) 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 shall 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 ~~and/or~~, drug and alcohol testing, or both, under this part.

(2) The FFD policy statement describes the performance objectives in § 26.23.

(3) 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 paragraph (b) of this section, Part 26-required sanctions, and required medical/clinical treatment and follow-up testing for FFD policy violations.

(b) Licensees and other entities shall 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 ~~be used in collecting, testing,~~collect and test for drugs and alcohol and for the shipping~~,~~ and ~~temporarily storing~~temporary storage of biological specimens used for ~~drugs and alcohol~~drug testing~~, and~~ at HHS-certified laboratories,

~~(ii) procedures for protecting~~(ii) the required 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) protection of 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 followup 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 or illicit substances;

(ii) Are impaired by any substance 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 off site; the

possible use or possession of alcohol on the NRC-licensed facility; impairment from any cause which in any way could adversely affect the individual's ability to safely and competently perform his or her 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.

§ 26.607 Drug and alcohol testing.

~~(a)(1)~~ To provide means to deter and detect substance abuse, licensees and other entities implementing § 26.604, at their discretion, and licensees and other entities implementing § 26.605 shall perform drug and alcohol testing that complies with the following requirements—

(~~2~~a) Split specimen collections of oral fluid or urine must be used for the test conditions described in paragraph (b) of this section. A split specimen collection need not be used if the licensee or other entity elects to use a ~~point of collection testing and assessment~~POCTA device for a screening test conducted during random testing under § 26.605(b)(2) and (i~~).~~) or a Protected Area portal monitor indication that drugs or alcohol were detected.

~~(2) If licensees or other entities use the HHS Guidelines for specimen collection, drug testing, or evaluation of test results then the licensee or other entity must incorporate the HHS Guidelines into its procedures.~~

(b) Individuals identified in § 26.602 shall be subject to drug and alcohol testing under the following conditions:

(1) *Pre-~~ access. Before~~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 ~~area of the NRC-licensed facility;~~areas of the NRC-licensed facility. A pre-access test must use an oral fluid or urine specimen collection that is sent to an HHS-certified laboratory for analysis and the collection must have been conducted no more than 14 days before the individual is granted unescorted access.

~~(2) *Random Testing*.~~ (2) *Random Testing*. All individuals 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 must be subject to random drug and alcohol testing onsite. 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 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; ~~and~~

(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*. ~~In~~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*. ~~(i) As~~(i) A post-accident test for drugs and alcohol must be conducted (A) as soon as practical after an accident involving a human error that was committed by an individual specified in § 26.602, where the human error may have caused or contributed to the accident~~,~~. ~~t~~The licensee or other entity shall test the individual(s) who committed or directed the error(s~~). The licensee or other entity~~) and need not test individuals who were affected by the accident and whose actions likely did not cause or contribute to the accident. The licensee or other entity shall describe in its procedures what constitutes a human error and accident.

~~(ii) A post-accident test shall be conducted~~(B) 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, if the accident results in—

(~~A~~*1*) An illness or personal injury to the individual(s) who caused or contributed to the event or another 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 it 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~~*2*) Damage to any safety- or security-related SSC.

(ii~~i~~) The conduct of a post-accident test for an accident involving human error, if conducted within 4 hours of the accident, satisfies the post-accident test requirement in paragraph (b)(4)(~~iii~~)(B) of this section; and

~~(5) *Followup*. As part of a followup plan~~(5) *Followup*. A followup test for drugs, alcohol, or both is part of a series of tests that are performed after an individual subject

to Part 26 has violated the FFD policy. Followup testing is used to verify an individual's continued abstinence from substance abuse.

(c) At a minimum, the following requirements shall be met—

~~(1~~(1) All urine or oral fluid specimens must be subject to validity testing and tested for the drugs listed in § 26.31(d), except as allowed by § 26.603(e)(3). If applicable, urine and oral fluid specimens must be tested for adulterants, biological markers, or both.

(2) For the use of urine as the biological specimen to be tested, the following requirements shall be implemented—

(i) § 26.115, Collecting a urine specimen under direct observation;

(ii) § 26.119, Determining "shy" bladder; and

(iii) § 26.~~161, Cutoff levels for validity~~163(a)(2), special analysis testing~~, and~~ .

~~(iv) § 26.163, Cutoff levels for drugs and drug metabolites.~~

~~(2~~(3) For alcohol testing onsite, the following requirements shall 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.

(~~3~~4) For all test conditions in paragraph (b) of this section and 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 back-up HHS-certified laboratory (with a different Certifying Scientist) for the specimen(s) to be tested. This contract must stipulate that the laboratory is 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) Licensees and other entities may add drugs and drug metabolites to their panel of drugs and drug metabolites to be tested if the requirements in § 26.~~31(d)(1)(i~~603(e) are met.

(e) The specimen collection and drug and alcohol testing procedures of FFD programs under this subpart 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.

(f) 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 and audited by the State (or State-designated entity) to conduct specimen collections and perform alcohol testing. The licensee or other entity shall audit these facilities, if used, prior to their initial use and then on a biennial basis to provide reasonable assurance that the facility procedures are comparable to those described in subpart E of this part for urine and oral fluid. The licensee or other entity must establish measures to help prevent subversion of the drug and/or alcohol test onsite or offsite.

(g) Any initial drug test performed by a licensee or other entity subject to this subpart must use an immunoassay, or a testing process implemented under the licensee's or other entity's change control process under § 26.603(e), that meets 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.

(h) If the licensee or other entity elects to use oral fluid for drug testing, the collection, packaging, temporary storage, and shipment of an oral fluid specimen to an HHS-certified laboratory must be performed in accordance with the instructions provided with the oral fluid collection kit or on the kit manufacturer's website. The kit must have received premarket approval from the FDA and must not expire before laboratory testing. All ~~site~~onsite collection processes shall be conducted by licensee- or other entity-designated ~~FFD program~~and trained personnel. The drugs, drug metabolites, ~~and~~ initial and confirmatory testing cutoffs, and biological markers, if applicable, shall be comparable to those established for urine testing in this part as determined by a documented forensic toxicologist review conducted pursuant to § 26.31(d)(1)(i)(D).

(i) *Point of collection testing and assessment*. (1) If the licensee or other entity elects to use a ~~point of collection testing and assessment~~POCTA device, then it may only be used for pre-access screening or the random drug and/or alcohol testing ~~using urine or oral fluid as the test specimen and only for screening. A~~process in paragraph (i)(3) of this section. Before the licensee or other entity uses a POCTA device, a forensic toxicologist must review and document their evaluation that the validity, accuracy, and precision of the device for alcohol and/or all the drugs and drug metabolites listed in §§ 26.161 and 26.163 is comparable to the performance achieved by initial testing conducted using a similar technology at an HHS-certified laboratory ~~before its use~~.

(2) If the performance of the ~~point of collection testing and assessment~~POCTA device used for random testing 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 ~~propose~~implement a mitigating strategy to maintain program effectiveness ~~to the NRC and obtain NRC approval~~ under § 26.603(e)(2~~) before its use.~~).

(3) If the use of a ~~point of collection testing and assessment~~POCTA device indicates a discrepant biological marker or that a test result ~~that~~ exceeds the initial test cutoff ~~and/or indicates that~~, 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 him/her subject to this subpart, and subject to an immediate drug~~/~~ and alcohol test using the alcohol testing process in paragraph (c)(2) of this section for a positive alcohol screen and either oral fluid or urine by a collection kit that is not a ~~point of collection testing and assessment~~POCTA device for a positive drug, drug metabolite, adulterated, substituted, or invalid drug screen, that enables validity, if required, initial, and confirmatory testing by an HHS-certified laboratory.

~~i~~(j) 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 paragraph (b)(1) of this section, 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. If used, this process shall 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 shall only include those listed as Schedule I 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 instructions provided with the hair specimen collection kit or those described on the kit manufacturer's website. The kit shall 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. Before the licensee begins to conduct hair testing, the initial and confirmatory testing cutoffs shall be comparable to those established for urine testing as determined by a forensic toxicologist review conducted pursuant to § 26.31(d)(1)(i)(D). Confirmed positive test results must be considered potentially disqualifying FFD information until proven otherwise by a review under § 26.613. Sanctions under this subpart shall 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.

(k) 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 in a protected area. If a licensee or other entity uses such an instrument, then before such use, a forensic toxicologist must review 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 to be tested under the FFD program and alcohol and that the instrument will 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, the individual must be subject to a POCTA screening test using the process described in § 26.607(i) or an oral fluid or urine test that is sent to an HHS-certified laboratory. 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.

(l) *Blood Testing*. The testing of blood specimens may only be conducted under the order of the licensee- or other entity-designated Medical Review Officer for a valid medical reason as confirmed by the Medical Review Officer pursuant to § 26.31(d)(5).

This testing must be subject to testing by a laboratory that meets quality control requirements that are comparable to those required for certification by the HHS (e.g., a hospital certified by the State, Commonwealth, or territory).

(~~k~~m) *Custody and Control Form*. For the collection of urine and oral fluid specimens, the licensee and other entity must use a custody and control form approved by the ~~U.S.~~ Office of Management and Budget. For the use of a ~~point-of-collection testing and assessment~~POCTA device, the licensee or other entity shall 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.

(~~l~~n) *Medical Review Officer.* Licensees or other entities shall—

(1) Require their designated ~~Medical Review Officer (~~MRO~~)~~ to review positive, adulterated, substituted, invalid, and dilute confirmatory drug and validity test results 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 perform the suitability and fitness evaluations required under § 26.619, or, if required, that are described in subpart H of this part.

(2) Require their MRO to meet the requirements in § 26.183 and, prior to conducting any activities under this part, ~~to~~ 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 NRC to include § 26.185 requirements. An MRO who performed the duties and responsibilities in § 26.185 and

26.187 for at least three continuous years in the last ten years prior to being hired or contracted meets the requirements in this paragraph.

(3) The MRO must also 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/procedures and evaluation of drug testing results.

(~~3~~4) Require their MRO to determine whether a biological specimen is positive, adulterated, substituted, invalid, or dilute by implementing the requirements in § 26.185. If § 26.185 is insufficient to make this determination, the guidance issued by State (in which the NRC-licensed facility resides) or Federal agencies or nationally recognized MRO training and certification organizations may be used to inform an MRO determination. An MRO need not review a confirmed alcohol positive test result by an evidentiary breath testing device as determined by § 26.607(c)(1)(vi) and (vii).

(~~4~~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 shall be completed as soon as reasonably practicable and documented.

(~~m~~(6) Require the MRO to review all specimens tested for a testing condition that results in a positive drug test received from an HHS-certified laboratory. 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 re-test. To resolve a discrepant condition, the MRO is authorized to test a specimen for a biological marker, adulterants, or additional drugs.

(o) *Limitations of testing*. Specimens collected under NRC regulations may only be designated or approved for 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, DNA testing,

serological typing, or any other medical or genetic test used for diagnostic or specimen identification purposes. No biological specimens may be collected and or tested in a manner different than described in this subpart.

§ 26.608 FFD Program Training.

(a) *FFD Program Training.* (1) Individuals must be trained in the FFD policy and procedure and their FFD program responsibilities~~.~~ prior to performing or directing the performance of those duties and responsibilities making him or her subject to Part 26. These responsibilities include reporting for work, either on or offsite, in a physiological and psychological condition that enables the safe and competent performance of assigned duties and responsibilities and informing licensee- or other entity-designated individual when the individual determines that this cannot be accomplished.

(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 off site;

(ii) use or possession of alcohol on site or use while on duty off site;

(iii) impairment from fatigue or any cause that, if left unattended, could result in inattentiveness or human errors; and

(iv) an 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, ~~NRC-licensed material~~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 him or her subject to this subpart;

(iii) be used to inform the licensee's or other entity's access authorization and insider mitigation programs under Part 73, if applicable; 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 Part 26, subpart C, or §§ 73.56 or 73.120.

(b) *Training Periodicity*. Training must be conducted before pre-access testing and refresher training must be conducted periodically.

(c) *Training Review*. The FFD training program must be periodically evaluated and revised 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 shall 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 shall require all individuals subject to the FFD program to report to the licensee- or other entity-designated official behaviors or activities by individuals subject to this part, that occur on or ~~offsite~~off site, that may

constitute an unreasonable risk to the safety or security of the NRC- licensed facility or ~~materials~~SNM or may cause harm to individuals. This reporting must include any information relating to character or reputation of the individual indicating that the ~~observed~~ individual cannot be trusted or relied upon to perform those duties and responsibilities or maintain access to NRC-licensed facilities, SNM, or sensitive information.

(c) Behavioral observation shall be performed visually, in-person or remotely by ~~video~~live video and audible streaming and capture, to observe the behavior of individuals in the workforce subject to the requirements in this subpart, and to detect and promptly report to plant supervision aberrant behavior or changes in behavior that might adversely reflect on an individual's fitness or trustworthiness and reliability.

(d) Not withstanding paragraph (c) of this section, for a reactor facility licensed with a minimum staff for operation, the licensee must implement a live video and audible streaming and capture system to conduct behavioral observation of NRC-licensed or certified operators who manipulate the controls of any utilization facility licensed under part 53.

§ 26.610 Sanctions.

Licensees and other entities that implement an FFD program under this subpart shall establish sanctions for FFD policy violations that, at a minimum, prohibit the individuals specified in § 26.602 from being assigned to perform or direct those duties and responsibilities making them applicable to this subpart. The severity of the sanction must escalate with the number of occurrences and severity of the FFD policy violation~~,~~ ~~with~~. The sanction must be long enough to act as a deterrence and, if the individual is a licensee employee, enable the individual to complete counseling or treatment. The sanction 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 nuclear power plant or within a transporter's facility or vehicle 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.

§ 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 shall establish and maintain a system of files and procedures to protect the personal information.

(b) Licensees and other entities shall 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 shall be obtained before making the individual subject to the FFD program. (i.e., before a pre-access test in § 26.607(b)(1)).

§ 26.613 Review process.

Licensees and other entities that implement an FFD program under this subpart shall establish and implement procedures for the review of a determination that an individual in § 26.602 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 shall ensure that audits are performed to ensure the continuing effectiveness of the FFD program, including 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.

(b) Each licensee and other entity shall ensure that FFD program elements that are not part of the FFD program performance and monitoring review described in § 26.603(d) are audited at a frequency that ensures their continuing effectiveness and that corrective actions are taken to resolve any problems identified. 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 ~~performance monitoring and review program~~PMRP in § 26.603(d~~).~~

~~(~~).(c) Licensees and entities may conduct joint audits or accept audits of C/Vs so long as the audit addresses the relevant C/Vs' services.

(d) Licensees ~~and~~or other entities need not audit HHS-certified laboratories if their panel of drugs and drug metabolites to be tested is reasonably equivalent to that by which the laboratory is certified by HHS. Licensees ~~and~~or other entities shall 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 provide reasonable assurance that the facility procedures are comparable to those described in subpart E, “Collecting Specimens for Testing,” for urine and oral fluid, of this part.

§ 26.617 Recordkeeping and reporting.

(a) Licensees and other entities that implement FFD programs under this subpart shall ensure that records pertaining to the administration of the 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. FFD performance data required by § 26.617 shall be retained until license termination.

(b) Licensees and other entities shall 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; 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 shall submit FFD program performance data (for January through December) to the NRC annually, before March 1 of the following year and shall use NRC Forms 890, Single Positive Test Form, and 891, Annual Reporting for Drug and Alcohol Tests.

(c) Licensees and other entities subject to this subpart shall describe in sufficient detail 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 with part 26, Subpart C, or § 73.56, 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 shall 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. These procedures must provide reasonable assurance that the individuals are fit to safely and competently perform their duties, and are trustworthy and reliable, as demonstrated by the avoidance of substance abuse. A suitability or fitness determination conducted for cause must be conducted face-to-face.

10. Revise subpart N of part 26 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, 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 identified in § 26.3(f) that elect not to implement the requirements in subpart M and those licensees and other entities that elect to implement the requirements detailed in § 26.605.

§ 26.711 General provisions.

…..

(c) The licensees and other entities specified in § 26.3(a) and, as applicable, (c), ~~and~~ (d), and (f) shall inform each individual […]

(d) Licensees and other entities shall ensure that only correct and complete information about individuals [. . .] a licensee and other entity specified in § 26.3(a) and, as applicable, (c), ~~and~~ (d), and (f) who has discovered the incorrect information […]

11. Part 53 is added to read as follows:

In the remainder of the consolidated preliminary proposed rule language, tracked text changes indicate preliminary proposed rule text that the NRC staff has revised since the last publicly released iteration.

PART 53—RISK-INFORMED, TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK FOR COMMERCIAL NUCLEAR PLANTS

Authority: To be added.

Subpart A—General Provisions

§ 53.010 Scope and purpose.

This part provides an optional framework 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 (68 Stat. 919), and Title II of the Energy Reorganization Act of 1974 (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 NRC enforcement action for violation of the provisions in § 53.050 ~~of this part~~.

§ 53.020 Definitions.

For the purpose of this part:

Anticipated operational occurrences (AOOs) means ~~anticipated~~ event sequences expected to occur one or more times during the life of a commercial nuclear ~~power plant. An event~~plant, which may include one or more reactor modules. Event sequences with ~~a~~

mean frequency~~y~~ies of 1×10^{-2}/plant-year and greater ~~is an AOO.~~ are classified as AOOs. AOOs take into account the expected response~~s~~ of all SSCs within the plant, regardless of safety classification. ~~AOOs are a type of *licensing basis event*.~~

Applicant means a person or an entity 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 ~~facility~~, 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 meets the following criteria:

(i) Has qualified in accordance with a fuel handler training program that meets the same requirements as training programs for non-licensed operators required by §§ 53.835 through 53.840 of this part, 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 nuclear power facility issued under this part.

Commercial nuclear plant means a ~~utilization~~ facility consisting of one or more commercial nuclear reactors and associated co-located support facilities, ~~which may include one or more reactor modules, that are used for producing power for commercial electric or other commercial purposes. The commercial nuclear plant includes~~including the collection of ~~sites,~~ buildings, radionuclide sources, and structures, systems, and

components for which a license(s) is being sought under this part., that are used for producing power for commercial electric power or other commercial purposes.

Commercial nuclear reactor [individual nuclear reactor; include utilization facility in this definition]

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

Consensus code or standard means any technical standard:

(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 such a a consensus code or standard for the safe design, manufacture, construction, or operation of commercial nuclear power plants.

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 contributing to meeting the safety requirements defined in Subpart B that are conducted on-site to build the commercial nuclear plant in support of subsequent operations, 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 and non-safety-related but safety significant structures, systems, or components (SSCs) of a facility, as defined in [*10 CFR 50.2*];;

(ii) SSCs ~~relied upon to mitigate accidents or transients or used in plant emergency operating procedures;~~

~~(iii) SSCs whose failure could prevent safety-related SSCs from fulfilling their safety-related function;~~

~~(iv) SSCs whose failure could cause a reactor scram or actuation of a safety-related system;~~

~~(v) SSCs~~ necessary to comply with 10 CFR part 73;

~~(vi) SSCs necessary to comply with [*10 CFR 50.48 and criterion 3 of 10 CFR part 50, appendix A*];~~ and

(~~v~~ii) Onsite emergency facilities~~, that is, technical support and operations support centers,~~ necessary to comply with ~~[*10 CFR 50.47 and 10 CFR part 50, appendix E*].~~§ 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 sewerage treatment facilities, and transmission lines;

(viii) Procurement or fabrication of components or portions of the proposed facility occurring at 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;

Decommission 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 multiple independent and redundant layers of defense in the design of a facility and its operating procedures to compensate for ~~potential human and mechanical failures so~~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 ~~key~~ 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 structures, systems, and components. DBAs are a type of licensing basis event and are based on the capabilities and reliabilities of safety-related structures, systems, and components needed to mitigate and prevent event sequences, respectively.

~~*Design control* means measures to ensure that applicable regulatory requirements and the design features and associated functional design criteria for structures, systems, and components are correctly translated into specifications, drawings, procedures, and instructions.~~

~~*Design features* means~~*Design features* means the active and passive structures, systems, or components and inherent characteristics of those structures, systems or components 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 ~~unplanned~~licensing basis events.

~~*Deterministic* means a characteristic of decisionmaking based on engineering analyses that are not primarily based on quantitative probabilistic considerations.~~

~~*End state* means the set of conditions at the end of an event sequence that characterizes the impact of the sequence on the plant or resulting releases of radionuclides to the environment. In most probabilistic risk assessments, end states typically include success states (i.e., those states with negligible impact) and release categories.~~

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 (e.g., minimal cut sets) that are similar in terms of ~~how they impact the performance of safety functions along the event sequence~~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 shall normally be prohibited. In any event, residents shall 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.

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 thermal power in a commercial nuclear plant.

Functional design criteria means requirements for the performance of SSCs. For safety-related SSCs, these criteria define requirements necessary to demonstrate compliance with safety criteria in § 53.210. For non-safety-related but safety~~-~~ significant SSCs, these criteria define requirements necessary to meet the safety criteria in § 53.220.

~~*Inherent characteristic*~~*License* means ~~an attribute of~~ a ~~design feature that has such a high degree of certainty in its performance that uncertainties need not be quantified.~~

~~*Initiating event* means a perturbation to the plant during a defined plant~~limited work authorization, construction permit, operating ~~state that challenges plant control and~~

~~safety systems and whose failure could potentially lead to an undesirable end state and/~~license, early site permit, combined license, or ~~radioactive material release. An initiating event is defined in terms of the change in plant status that results in a condition requiring a response to mitigate the event~~manufacturing license under this part, or ~~to limit the extent of plant damage caused~~a renewed license issued by the ~~initiating event~~Commission under 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 AOOs, unlikely event sequences, very unlikely event sequences, and DBAs.

~~*Light-water reactor* means a reactor that uses water that does not include deuterium as its coolant and neutron moderator.~~

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 in their behalf in the event of unlikely or very unlikely event sequences. 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.

~~*Manufacturing*~~*Manufactured reactor* means ~~activities conducted~~ a commercial nuclear reactor manufactured under a manufacturing license.

Manufactured reactor module means a manufactured reactor loaded with fuel prior to transport to a licensed location for installation and commercial operation.

Manufacturing license means a license issued under subpart H of this part that authorizes the manufacture of ~~nuclear power reactors~~a manufactured reactor or manufactured reactor module but not their construction, installation, or operation at the sites on which the commercial nuclear reactors are to be operated.

~~*Mechanistic source term* means the magnitude, mix, and timing of radionuclides that are released into the environment subsequent to an unplanned event, after accounting for any retention of radionuclides provided by reactor design features.~~

~~*Microreactor* means non-light-water reactors with an output of generally less than tens of megawatts thermal.~~

~~*Non-light-water reactor* means a reactor that does not use water that does not contain deuterium as its coolant and neutron moderator.~~

Non-Safety-Related but Safety Significant (NSRSS) means those SSCs ~~and human actions~~ that warrant special treatment and are not safety-related but are relied on to achieve adequate defense-in-depth or perform risk-significant functions.

Non-Safety-Significant (NSS) means those SSCs not warranting special treatment, are not safety-related, and are not relied on to achieve adequate defense-in-depth or to perform risk-significant functions.

Normal plant operation or normal operation or routine operation means operations that are expected to occur during planned operations or shutdown of the reactor.

~~*Performance-based* means an approach to decision-making that focuses on the desired objective of calculable or measurable, observable outcomes, rather than prescriptive design features, processes, techniques, or procedures. Performance-based~~

~~decisions lead to defined results with limited specific direction regarding how those results are to be obtained.~~

Person means (1) any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, government agency other than the Commission, 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 the actions of equipment and personnel of a commercial nuclear plant. Programmatic controls are specified in an application for a requested activity of the Commission, as provided in subpart H.

Prototype plant means a nuclear reactor that is used to test design features, such as the testing required under § 53.440(~~c~~a). The prototype 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.

Safety criteria means metrics that establish a level of safety based on requirements in § 53.210 and § 53.220.

Safety-related (SR) means those SSCs ~~and human actions~~ that warrant special treatment and are relied upon to demonstrate compliance with the safety criteria in § 53.210.

Site characteristics means the ~~meteorological, geological, seismological, topographical, hydrological~~actual physical, environmental, and ~~other characteristics of the site and surrounding area that may have a bearing on the consequences of radioactive material escaping from the nuclear plant as well as~~ demographic features of a site. ~~(§ 53.500)~~

~~*Small modular reactor* means~~ Site characteristics are specified in an early site permit or in a preliminary or final safety analysis report for a ~~power reactor, licensed under this part to produce heat energy up to 1,000 megawatts-thermal per module, which may be of modular design~~limited work authorization, construction permit, or combined license, as applicable.

Special nuclear material 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 Atomic Energy Act, determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing, but does not include source material.

Special treatment means those requirements, such as measures taken to satisfy functional design criteria, quality assurance, and programmatic controls, that provide assurance that ~~certain~~safety-related and non-safety-related but safety significant SSCs will provide defense-in-depth or perform risk-significant functions and that provide confidence that the SSCs will perform under the service conditions and with the reliability assumed in the analysis performed in accordance with § 53.450 to provide reasonable assurance of meeting 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 for a multiple number of units or at a multiple number of sites without reopening or repeating the review.

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.

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 ~~mean~~means infrequent event sequences that ~~have estimated frequencies below the frequency of~~are not expected to occur in the life of a commercial nuclear plant, but are less likely than AOOs~~. Unlikely event sequences are a subset~~, and take into account the expected response of ~~LBEs.~~ all SSCs within the plant regardless of safety classification.

Very unlikely event sequences ~~mean~~means rare event sequences that ~~have estimated frequencies well below the frequency of events~~are not expected to occur in the life of a commercial nuclear plant~~. Very~~, but are less likely than an unlikely event ~~sequences are a subset~~sequence, and take into account the expected response of ~~LBEs.~~ all SSCs within the plant regardless of safety classification.

§ 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 Nuclear Regulatory Commission 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 part 20 of this chapter).

(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 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 subpart H of 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 subpart H of 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 (~~iv~~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 under Subpart H of this part;

(ii) Safeguards contingency plan under Subpart H of this part;

~~(iii~~(iii) Cyber security plan under Subpart H of this part.

(iv) Change to security plan, guard training and qualification plan, ~~or~~ safeguards contingency plan, or cyber security plan made without prior Commission approval under § 53.1565; and

(~~iv~~v) Application for amendment of physical security plan, guard training and qualification plan, ~~or~~ safeguards contingency plan, or cyber security plan under § 53.1~~35~~1~~1~~0.

(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 under Subpart H of this part;

(ii) Change to an emergency plan under § 53.1565; and

(iii) Emergency implementing procedures under ~~[10 CFR 50 appendix E.V or in support of § §~~ 53.855 Emergency preparedness~~].~~.

(6) *Updated FSAR.* An updated Final Safety Analysis Report (FSAR) or replacement pages, under § 53.~~1321~~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. 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 description under § 53.1565, or a change to a licensee's NRC-accepted quality assurance 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. 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 quality assurance topical report from nonlicensees (i.e., architect/engineers, 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~~],~~ 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~~],~~ 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 meet 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, applicant for a license, 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 10 CFR part 2, subpart B.

(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 holder or applicant for an NRC license, permit, or design approval, or a contractor or subcontractor of a holder or applicant for an NRC license, permit, or 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 Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

(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) to 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 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 Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(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 holder or applicant for an NRC license, permit, or design approval, or a contractor or subcontractor of a holder or applicant for an NRC license, permit, or design approval, 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 holder or applicant for an NRC license, permit, or design approval, or a contractor or subcontractor of a holder or applicant for a Commission license, permit, or design approval.

(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, permit, or design approval, shall prominently post the revision of NRC Form 3, "Notice to Employees," referenced in 10 CFR 19.11(e)(1). 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 not 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 U.S. Nuclear Regulatory Commission Regional Office listed in appendix D to part 20 of this chapter, 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 Energy Reorganization Act of 1974, as amended, 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 this chapter 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, ~~or~~ 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 shall be complete and accurate in all material respects.

(b) Each applicant or licensee shall 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 or licensee violates this paragraph only if the applicant or licensee fails to notify the Commission of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification shall 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--

(1) Authorized by law, will not present an undue risk to the public health and safety, and are consistent with the common defense and security.

(2) The Commission will not consider granting an exemption unless special circumstances are present. Special circumstances are present whenever--

(i) Application of the regulation in the particular circumstances conflicts with other rules or requirements of the Commission; or

(ii) 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; or

(iii) 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; or

(iv) 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; or

(v) 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

(vi) 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 satisfying paragraph (a)(2) of this section, the exemption may not be granted until the Executive Director for Operations has consulted with the Commission.

(b) Any person may request an exemption permitting the conduct of construction activities prior to the issuance of a construction permit. 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 effected 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 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.

Issuance of such an exemption shall not be deemed to constitute a commitment to issue a construction permit. During the period of any exemption granted pursuant to this paragraph (b), any activities conducted shall be carried out in such a manner as will minimize or reduce their environmental impact.

–The Commission's consideration of requests for exemptions from requirements of the regulations of other parts in this chapter, which are applicable by virtue of this part, shall be governed by the exemption requirements of those parts.

§ 53.090 Combining licenses; elimination of repetition.

(a) An applicant for a license under this part may combine in its application several applications for different kinds of licenses under the regulations of this chapter.

(b) 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.

(c) The Commission may combine in a single license the activities of an applicant which would otherwise be licensed separately.

§ 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 are not under or within the jurisdiction of the United States.

§ 53.110 Attacks and destructive acts.

~~Licensees and applicants~~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 special nuclear material shall 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 special nuclear material shall 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 shall, after securing full information, find that the transfer is in accordance with the provisions of the act and give its consent in writing.

§ 53.117 License suspension and rights of recapture

Any license issued under this part shall 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 Nuclear Regulatory Commission 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 [TBD].

(b) The approved information collection requirements contained in this part appear in § 53.XX.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

[To be added.]

Subpart B—Technology-Inclusive Safety Requirements

§ 53.200 Safety objectives.

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, each commercial nuclear plant must take such additional measures as may be appropriate when considering potential risks to public health and safety. These safety objectives shall be carried out by meeting the safety criteria identified in this subpart.

§ 53.210 Safety criteria for design basis accidents.

Design features and programmatic controls must be provided for each commercial nuclear plant such that analyses of design basis accidents in accordance with § 53.240 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 mSv) total effective dose equivalent; 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) total effective dose equivalent.[1]

* * * * *

[1] A whole body dose of 25 rem has been stated to correspond numerically to the once-in-a-lifetime accidental or emergency dose for radiation workers which, according to NCRP [National Council on Radiation Protection and Measurements] recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use 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.

Design features and programmatic controls must be provided to:

(a) Ensure plant structures, systems and components (SSCs), personnel, and programs provide the necessary capabilities and maintain the necessary reliability to address licensing basis events in accordance with § 53.240 and provide measures for defense-in-depth in accordance with § 53.250; and

(b) Maintain overall cumulative plant risk from licensing basis events other than design basis accidents analyzed in accordance with § 53.450(e) such that the calculated risk to an average individual ~~wi~~thi~~n~~ the vicinity of the commercial nuclear plant ~~receiving a radiation dose with the potential for immediate health effects~~of prompt fatalities remains below five in 10 million years, and the calculated risk to ~~such an individual receiving a radiation dose with~~the population in the ~~potential to cause latent health~~

~~effects~~area near a commercial nuclear plant of cancer fatalities remains below two in one million years.

§ 53.230 Safety functions.

(a) The primary safety function is limiting the release of radioactive materials from the facility and must be maintained during routine operation and for licensing basis events over the life of the plant.

(b) Additional safety functions supporting the retention of radioactive materials during licensing basis events—such as controlling reactivity, heat generation, heat removal, and chemical interactions~~--~~—must be defined.

(c) The primary and additional safety functions are required to meet the safety criteria defined in §§ 53.210 and 53.220, or more restrictive alternative criteria adopted under § 53.470, and are fulfilled by the design features and programmatic controls specified throughout this part.

§ 53.240 Licensing basis events.

Licensing basis events must be identified for each commercial nuclear plant and analyzed in accordance with § 53.450 to support assessments of the safety requirements in this subpart. The licensing basis events must address combinations of malfunctions of plant SSCs, human errors, facility hazards, and the effects of external hazards ranging from anticipated operational occurrences to very unlikely event sequences ~~with estimated frequencies well below the frequency of events expected to occur in the life of the commercial nuclear plant.~~. The analysis of licensing basis events must include analysis of one or more design basis accidents in accordance with § 53.450(f). The analysis of licensing basis events must be used to confirm the adequacy of design features and programmatic controls needed to satisfy safety criteria defined in

§§ 53.210 and 53.220, or more restrictive alternative criteria adopted under § 53.470, and to establish related functional requirements for plant SSCs, personnel, and programs.

§ 53.250 Defense in depth.

Measures must be taken for each commercial nuclear plant to ensure appropriate defense in depth is provided to compensate for uncertainties such that there is ~~high confidence~~reasonable assurance that the safety criteria in this subpart are met over the life of the plant. The uncertainties to be considered 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 routine operation and for licensing basis events, and those related to the reliability and performance of plant SSCs and personnel, and programmatic controls. No single engineered design feature, human action, and or programmatic control, no matter how robust, should be exclusively relied upon to ~~meet the safety criteria of § 53.220 or the safety functions defined in accordance with § 53.230~~address the range of licensing basis events other than design basis accidents.

§ 53.260 Normal operations.

(a) *Maximum public dose*. Licensees under this part must ensure that ~~the contribution to total effective dose equivalent to individual members of the public from~~ normal plant ~~operation does~~operations do not result in public doses or dose rates in unrestricted areas that exceed the ~~public dose~~ limits provided in Subpart D to 10 CFR part 20.

(b) *As low as reasonably achievable*. ~~Design~~A combination of design features and programmatic controls must be established such that the estimated total effective

dose equivalent to individual members of the public from effluents resulting from normal plant operation are as low as is reasonably achievable in accordance with 10 CFR part 20 [consider also possible updates for consistency with requirements in 10 CFR 50.34a, Appendix I to part 50, and 40 CFR part 190].

§ 53.270 Protection of plant workers.

(a) *Maximum occupational dose*. Licensees under this part must ensure that radiological dose to plant workers does not exceed the occupational dose limits provided in subpart C to 10 CFR part 20.

(b) *As low as reasonably achievable.* As required by Subpart B to 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.

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 associatedcorresponding programmatic controls and human actions, the plant will satisfy the safety criteria defined in §§ 53.210 and 53.220., or more restrictive alternative criteria adopted under § 53.470. Design features must ensure that the safety functions identified in § 53.230, of limiting the release of radioactive materials from the facility, are fulfilled during licensing basis events.

§ 53.410 Functional design criteria for design basis accidents.

Functional 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. Corresponding human actions and programmatic controls ~~and interfaces~~ must be ~~established~~identified and implemented in accordance with this and other subparts to achieve and maintain the reliability and capability of SSCs relied upon to meet the ~~established~~defined functional design criteria and the safety criteria required in § 53.210, and to maintain consistency with analyses required by § 53.450~~.~~(f).

§ 53.420 Functional design criteria for licensing basis events other than design basis accidents.

Functional design criteria must be defined for each design feature required by § 53.400 and relied upon to demonstrate compliance with the safety criteria in § 53.220 ~~considering licensing basis events ranging from anticipated operational occurrences to very unlikely event sequences with estimated frequencies well below the frequency of events expected to occur~~and evaluation criteria in ~~the life of the commercial nuclear plant.~~§ 53.450(e), or more restrictive alternative criteria adopted under § 53.470. Corresponding human actions and programmatic controls ~~and interfaces~~ must be ~~established~~identified and implemented in accordance with this and other subparts to achieve and maintain the reliability and capability of SSCs relied upon to meet the safety criteria in § 53.220 and ~~to maintain consistency with analyses required by § 53.450~~evaluation criteria in § 53.450(e), or more restrictive alternate criteria under § 53.470.

§ 53.425 Design features and functional design criteria for normal operations.

Design features must be provided for each commercial nuclear plant such that, when combined with ~~associated~~corresponding programmatic controls ~~and human~~

~~actions, there is reasonable assurance~~, the requirements ~~for limiting the public dose from normal operations~~ in § 53.260 ~~will~~(a) can be met. Functional design criteria must be defined for each design feature relied upon to demonstrate compliance with § 53.260~~.~~(a). Corresponding programmatic controls, including monitoring programs, must be ~~established~~identified and implemented to confirm that the ~~public dose~~ criteria in § 53.260(a) are not exceeded. In addition, functional design criteria must be defined for ~~each~~ design feature~~s~~ to ensure that plant SSCs and ~~associated~~corresponding programmatic controls, including monitoring programs, ~~achieve public doses as low as is reasonably achievable as required by~~satisfy § 53.260(b).

§ 53.430 Design features and functional design criteria for protection of plant workers.

Design features must be provided for each commercial nuclear plant such that, when combined with ~~associated~~corresponding programmatic controls ~~and human actions, there is reasonable assurance~~, the requirements ~~for the protection of plant workers~~ in § 53.270 ~~will~~(a) can be met. Functional design criteria must be defined for each design feature relied upon to demonstrate compliance with § 53.270~~.~~(a). Corresponding programmatic controls, including monitoring programs, must be ~~established~~identified and implemented to confirm that the worker protection criteria in § 53.270(a) are not exceeded. In addition, functional design criteria must be defined for ~~each~~ design feature~~s~~ to ensure that plant SSCs and ~~associated~~corresponding programmatic controls, including monitoring programs~~, achieve occupational doses as low as is reasonably achievable as required by~~ satisfy § 53.270(b).

§ 53.440 Design requirements.

(a) 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.

(b) The design features required ~~to meet the safety criteria defined in §§~~by § 53.~~210 and 53.220~~400 must, wherever applicable, be designed using generally accepted consensus codes and standards ~~wherever applicable~~that have been endorsed or otherwise found acceptable by the NRC.

(~~b~~c) The materials used for safety related (SR) and non-safety related but safety significant (NSRSS) SSCs must be qualified for their service conditions over the plant lifetime.

(~~c~~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 safety related and non-safety related but safety significant SSCs must be evaluated and used to inform the design and the development of integrity assessment programs under § 53.870.

~~(d) 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.~~

~~(e) Design features must be demonstrated capable of fulfilling functional design criteria considering interdependent effects through analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof for the range of conditions under which the analysis required in § 53.450 assumes these features will function throughout the plant's lifetime.~~

~~(f~~(e)(1) SR and NSRSS structures, systems, and components 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 shall be used wherever practical throughout the facility, particularly in locations with SR and NSRSS structures, systems, and components.

(3) Fire detection and fire suppression systems of appropriate capacity and capability shall be provided and designed to minimize the adverse effects of fires on SR and NSRSS structures, systems, and components.

(4) Fire suppression systems shall be designed to ensure that their rupture or inadvertent operation does not significantly impair the ability of SR and NSRSS structures, systems, and components to perform their safety function to meet § 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 achieving and maintaining a subcritical condition during normal operations and following any licensing basis event 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 normal operations or any licensing basis event identified in accordance with § 53.240.

(i) The design ~~of~~, analysis, staffing, and programmatic controls for each commercial nuclear plant must consider ~~in the design, analysis, and development of programmatic controls~~ the number of reactor units, 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 ~~reduced~~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 ~~with the characteristics defined in § 50.150 of this chapter~~.

(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 nuclear power 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.

* * * * *

[1] Changes to the detailed parameters on aircraft impact characteristics set forth in guidance shall be approved by the Commission.

§ 53.450 Analysis requirements.

(a) *Requirement to have a probabilistic risk assessment.* A probabilistic risk assessment (PRA) of each commercial nuclear plant must be performed 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 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 in combination with other generally accepted ~~risk-informed~~ approaches for systematically evaluating engineered systems must be used:

(1) In ~~determining~~informing the selection of the licensing basis events, as described in § 53.240, which must be considered in the design to determine compliance with the safety criteria in Subpart B of this part.

(2) For ~~classifying~~informing the classification of SSCs and human actions according to their safety significance in accordance with § 53.460 and for identifying the environmental conditions under which the SSCs and operating staff must perform their safety functions.

(3) In evaluating the adequacy of defense-in-depth measures required in accordance with § 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~~, such as earthquakes,~~ identified in accordance with Subpart D of this part.

(c) *Maintenance and upgrade of analyses*. The PRA must be maintained and upgraded 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 licensing basis events (including but not limited to thermodynamics, reactor physics, fuel performance, and mechanistic source term codes) must be qualified for the range of conditions for which they are to be used.

(e) *Analyses of licensing basis events~~.~~ other than design basis accidents*. Analyses must be performed for licensing basis events ~~including anticipated operational occurrences, unlikely event sequences, and very unlikely event sequences with estimated frequencies well below the frequency of events expected to occur in the life of the commercial nuclear plant. The~~other than design basis accidents. These licensing basis events must be identified using insights from a PRA in combination with other generally accepted ~~risk-informed~~ approaches for systematically evaluating engineered systems to identify and analyze equipment failures and human errors. The analysis of licensing basis events other than design basis accidents must include definition of evaluation criteria for each event or specific categories of licensing basis events to determine the acceptability of the plant response to the challenges posed by internal and external hazards. The analyses 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 licensing basis event~~s~~, to satisfy the safety criteria of § 53.220, and provide defense in depth as required by § 53.250. The methodology used to identify, categorize, and analyze licensing basis events must include a means to identify event sequences deemed significant for controlling the risks posed to public health and safety.

(f) *Analysis of design basis accidents*. The analysis of licensing basis events required by ~~§§§~~ 53.240 ~~and 53.450(e)~~ must include analysis of design basis accidents that address possible challenges to the safety functions identified in accordance with § 53.230. ~~Design basis accidents must be selected from those unlikely event sequences within a frequency range of at least less than one hundred years and greater than one in 10,000 years as identified using insights from a PRA in combination with other generally accepted risk-informed approaches for systematically evaluating engineered systems to identify and analyze events considering equipment failures, human errors, and uncertainties. The events selected as design basis accidents should~~The events selected as design basis accidents must be those that, if not terminated, have the potential for exceeding the safety criteria in § 53.210. The design~~-~~ basis accidents selected must be analyzed using deterministic methods that address event sequences from initiation to a safe stable end state and assume only the safety-related SSCs identified in accordance with § 53.460 and human actions addressed by the requirements of Subpart F are available to perform the safety functions identified in accordance with § 53.230. The analysis must conservatively demonstrate compliance with the safety criteria in § 53.210.

(g) *Other required analyses*. ~~If not addressed within the PRA, in combination with other generally accepted risk-informed approach for systematically evaluating engineered systems under paragraph (b), analyses~~Analyses must be performed to assess:

(1) fire protection measures to demonstrate ~~reasonable assurance~~ that ~~no~~a fire or explosion in any plant area ~~can:~~would not

(i) ~~prevent~~prevent equipment from ~~performing its safety function to meet~~fulfilling the safety functions identified in accordance with § 53.230, or

(ii) ~~challenge~~challenge the safety criteria in §§ 53.210 and 53.220~~.~~, and

(2) measures provided to protect against aircraft impacts as required by ~~10 CFR 50.150~~§ 53.440(j).

§ 53.460 Safety categorization and special treatment.

(a) SSCs ~~and human actions~~ must be classified according to their safety significance. The 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 ~~and human actions~~, the conditions under which they must perform their safety function in § 53.230 must be identified. ~~Special Treatment (e.g., functional design criteria and programmatic controls)~~Special treatment must be established in accordance with this and other Subparts to provide appropriate confidence that the SSCs will perform under the service conditions and with the reliability ~~assumed in~~ consistent with the analysis performed in accordance with § 53.450 to ~~provide~~demonstrate reasonable assurance of meeting the safety criteria in §§ 53.210 and 53.220.

(1) The special treatments for SR SSCs must include meeting the applicable quality assurance ~~criteria from~~requirements in Subpart K of this part.

(2) The special treatments for NSRSS SSCs may include meeting selected quality assurance ~~criteria from~~requirements in Subpart K of this part when such treatment is needed to address performance requirements, equipment reliability, or uncertainties to meet the ~~safety~~ criteria in § 53.220~~.~~ and evaluation criteria in § 53.450(e), or more restrictive alternative criteria adopted under § 53.470.

(c) Human actions needed to prevent or mitigate licensing basis events must be ~~capable of being reliably~~ identified, be able to be performed reliably under the postulated environmental conditions ~~present~~, 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 provide reasonable assurance of meeting the ~~safety~~ criteria in §§ 53.210, 53.220, or more restrictive alternative criteria adopted under § 53.470 of this part, and 53.~~220.~~450(e).

§ 53.470 ~~Application of~~Maintaining analytical safety margins used to justify operational flexibilities.

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 ~~(e.g., emergency planning requirements under Subpart F of this part).~~ . 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 obtain additional analytical safety margins. 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.

§ 53.480 Earthquake ~~E~~engineering.

(a) Structures, systems, and components classified as safety-related or non-safety related but safety significant must be ~~designed~~able to withstand the effects of earthquakes, commensurate with their safety significance, without loss of capability to perform their safety functions.

(b) For the purpose of this section~~, the following terms are defined as~~:

Design Basis Ground Motions (DBGMs) are the vibratory ground motions for which certain structures, systems, and components 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 power 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 ~~only referenced~~used in § 53.720, "Response to natural events."

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 because of tectonic forces that result from earthquakes.

(c) Vibratory Ground Motion

(1) *Design Basis Ground Motions (DBGMs).*

(i) The DBGMs must be ~~characterized by free-field ground motion response spectra at the free ground surface. DBGM(s) must be~~ derived from the ~~s~~Site Ground Motion Response Spectra (GMRS) developed in accordance with § 53.510, by taking into consideration the ~~safety functions and~~functional design ~~performance~~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 ~~usually will be appropriate~~is acceptable that the design response spectra be smoothed spectra.

(ii) The commercial nuclear power plant must be designed so that, if the DBGMs occur, the following structures, systems, and components must remain functional and within applicable stress, strain, and deformation limits:

(A) Structures, systems, and components for which functional design criteria are established in accordance with §§ 53.410 and, as appropriate, 53.420; and

(B) Structures, systems, and components classified as safety-related or non-safety-related but safety significant commensurate with their 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 safety-related structures, systems, and components and, commensurate with their safety significance, those non-safety-related but safety significant SSCs that are relied on to achieve defense-in-depth or perform risk-significant functions.

(iv) The design of the commercial nuclear power plant must take into account the possible effects of the DBGM on the facility foundations by ground disruption, such as fissuring, lateral spreads, differential settlement, liquefaction, and landsliding.

(v) The SSCs fulfilling the safety functions ~~of structures, systems, and components~~ required by § 53.230 must be ~~met~~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 ~~through design, testing, or qualification methods~~.

(vi) The evaluation of SSCs required by this section to show they are able to function during and following earthquakes 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 safety-related structures,

systems, and components during the DBGMs and under the postulated concurrent loads, provided the necessary safety functions are maintained.

(2) Operating Basis Earthquake Ground Motion.

(i) The Operating Basis Earthquake Ground Motion must be characterized by response spectra. The value of the Operating Basis Earthquake Ground Motion must be set to one-third or less of the Design Basis Ground Motions response spectra.

(3) Reserved

(4) Required Seismic Instrumentation. Suitable instrumentation must be provided so that the seismic response of commercial nuclear power plant SR 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 power plant by providing reasonable assurance that in the event of deformation, the following structures, systems, and components will remain functional:

(i) Structures, systems, and components for which functional design criteria are established in accordance with §§ 53.410 and 53.420; and

(ii) Structures, systems, and components classified as safety related or non-safety related but safety significant in accordance with § 53.460.

(2) In addition to surface deformation induced loads, the design of safety features must take into account 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 power 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 power 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 external hazard frequencies and related SSC fragilities in determining reasonable assurance that the safety criteria defined in § 53.220 will be met. Corresponding functional design criteria, human actions, and programmatic controls~~, and interfaces~~ must be ~~established~~identified and implemented in accordance with this and other subparts to achieve and maintain the performance of SSCs relied upon to meet 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.

Subpart D—Siting Requirements

§ 53.500 General siting.

(a) Consideration must be given to the siting of each commercial nuclear plant such that, when combined with ~~associated~~corresponding design features 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. A siting assessment for each commercial nuclear plant must be performed and must ensure that external hazards and site characteristics that might contribute to the initiation, progression, or consequences of licensing basis events analyzed in accordance with § 53.~~2~~450 are identified and addressed by design features or programmatic controls. The

siting assessments must address the potential adverse impacts that ~~an advanced~~a commercial nuclear plant may have on nearby environs as a result of normal operations or radiological accidents~~ as required by Part 51, "Environmental protection regulations for domestic licensing and related regulatory functions," of this chapter.~~.

(b) Siting activities must meet the applicable special treatment requirements of § 53.460, including, where applicable, the quality assurance criteria from Subpart K of this part.

§ 53.510 External hazards.

(a) *Purpose.* Structures, systems, and components needed to ensure the safety criteria defined in ~~§§~~§§ 53.210 ~~-~~are met 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) of magnitudes up to the design basis external hazard levels without losing the capability to perform the safety functions defined in § 53.230. 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 manmade hazards with the potential to adversely affect plant functions. The external hazard frequencies and magnitudes must address uncertainties and variabilities in data, models, and methods relied on to characterize the external hazards.

(b) For the purpose of this section, the following terms are defined as:

Ground Motion Response Spectra (GMRS) are the site-specific ground motion response spectra resulting from the geologic investigations and evaluations of the site vicinity and region.

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 Investigations*. 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 ground motion response spectra 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 proposed 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 ground motion response spectra for the site. These uncertainties must be addressed through an appropriate analysis, such as PSHA.

(d) *Geological Siting Factors*~~.~~ are geological and seismic factors that may affect the design and operation of the proposed commercial nuclear power plant. The geologic and seismic siting factors considered for design 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. ~~However, each applicant shall investigate all geological and seismic factors that may affect the design and operation of the proposed commercial nuclear power plant irrespective of whether such factors are explicitly included in this section.~~

§ 53.520 Site characteristics.

~~Meteorological, geological, seismological, topographical, hydrological, and other~~Site characteristics ~~of~~that might contribute to the ~~site and surrounding area that may have a bearing on the~~initiation, progression, or consequences of ~~radioactive material escaping from the subject commercial nuclear plant should~~licensing basis events analyzed in accordance with § 53.450 must be identified, estimated, 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, low population zone, and provide a population center distance as defined in § 53.020.

(a) The offsite radiological consequences estimated by the supporting analyses required by § 53.450(f) must be used to ~~define~~confirm that:

(1) An ~~exclusion area of such size that an~~ individual located at any point on ~~its~~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) total effective dose equivalent (TEDE).

(2) ~~A low population zone of such size that an~~An individual located at any point on ~~its~~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.

(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 shall 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.

External hazards and site characteristics must be ~~incorporated into, confirmed to be consistent with, or otherwise~~ 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 external hazards or site characteristics over the lifetime of a commercial nuclear plant ~~should~~must be considered in the assessments performed under the facility safety program required by § 53.890.

~~**§ 53.550 Environmental considerations.**~~

~~Requirements to address environmental protection regulations must be addressed in accordance with 10 CFR part 51.~~

Subpart E—Construction and Manufacturing Requirements

§ 53.600 Construction and manufacturing - scope and purpose.

~~(a)~~ 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 this part. ~~The term construction, as defined in § 53.020, refers to those activities contributing to meeting the safety criteria defined in Subpart B that are conducted on-site to build the commercial nuclear plant in support of subsequent operations. The term manufacturing, as defined in § 53.020, refers to those activities conducted at one or more facilities under a ML to produce a manufactured reactor for transport to a licensed location for installation and operation.~~

~~(b) These requirements are intended to provide assurance that~~

§ 53.605 Reporting of defects and noncompliance.

Each construction permit and manufacturing ~~activities are managed and conducted such that when combined with associated design features~~license is subject to the terms and ~~programmatic controls, the plant will satisfy the safety criteria required~~conditions in ~~Subpart B throughout the plant's lifecycle.~~

~~**§ 53.610 Construction.**~~

~~(a) *Management*~~this section, and ~~*control*. Before starting construction activities, the licensee or permit holder must ensure that the following plans, programs,~~each combined license is subject to the terms and ~~organizational units are~~conditions in ~~place to manage and control the construction activities:~~this section until the date that the Commission makes the finding under § 53.1452(g) of this chapter.

~~(1) Design and analyses that are sufficiently complete to provide assurance that construction will conform with associated 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) Approved procedures describing the qualifications for personnel in key positions in the licensee's or permit holder's management and control organization and~~

~~the organizational responsibilities, authority, and interfaces with other parts of the licensee's or permit holder'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) A preliminary plan for coping with emergencies that includes an on-site emergency organization capable of providing first aid, transporting individuals to off-site treatment facilities, decontaminating any radiological hazard and establishing and maintaining arrangements with local off-site organizations that can provide support services, if needed.~~

~~(6) A fitness-for-duty program, in accordance with 10 CFR part 26, applicable to the licensee's or permit holder's construction management and control personnel and to the construction work force.~~

~~(7) A Quality Assurance (QA) Program meeting the requirements of Subpart K to this part.~~

~~(8) 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,.~~

~~(9) An information security program in accordance with 10 CFR 73.21, 73.22 and 73.23, as applicable.~~

~~(10) A cyber security program established in accordance with 10 CFR 73.54 or 73.110, as applicable.~~

~~(11) *Posting of requirements.* (i) Signs and labels, in accordance with subpart J of 10 CFR part 20, must be posted where there is a potential radiation hazard.~~

~~(ii~~(a) *Definitions*. For the purposes of this paragraph, the definitions in 10 CFR 21.3 apply.

(b) *Posting requirements*.

(1) Each individual, ~~licensee, permit holder,~~ partnership~~,~~. ~~c~~Corporation, dedicating entity, or other entity subject to the regulations in this ~~subpart must~~part shall post current copies of the regulations in this ~~sub~~part; Section 206 of the Energy Reorganization Act of 1974 (ERA); and procedures adopted under the regulations in this ~~subpart~~part. These documents must be posted in a conspicuous position on any premises within the United States where the activities subject to this part are conducted.

(~~iii~~2) If posting of the regulations in this ~~sub~~part or the procedures adopted under the regulations in this ~~sub~~part is not practicable, the licensee~~, permit holder~~ or firm subject to the regulations ~~in this subpart must~~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 the regulation, procedures~~,~~ and reports may be examined.

~~(b) *Construction activities.*~~

~~(1) Licensees or permit holders~~(c) *Procedures*. Each individual, corporation, partnership, or other entity holding a construction permit subject to this part, combined license (until the Commission makes the finding under § 53.1452(g)), and manufacturing license under § 53.1270 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 facility construction permit subject to this part, combined license (until the Commission makes the finding under § 53.1452(g)), and manufacturing license under § 53.1270 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 AEA, as amended, or any applicable regulation, order, or license of the Commission, relating to a substantial safety hazard;

(ii) Contains a defect; or

(iii) Undergoes any significant breakdown in any portion of the quality assurance program conducted under the requirements of Subpart K to this part which could have produced a defect in a basic component. These breakdowns in the quality assurance program 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 construction permit subject to this part, combined license (until the Commission makes the finding under § 53.1452(g)), or manufacturing license who obtains information reasonably indicating that the facility fails to comply with the AEA, as amended, 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 or responsible officer or designated person as discussed in paragraph (d)(5) of this section.

(2) The holder of a construction permit, combined license, or manufacturing license subject to this part, who 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 or responsible officer or designated person as discussed in paragraph (d)(5) of this section.

(3) The holder of a construction permit, combined license, or manufacturing license subject to this part, who obtains information reasonably indicating that the quality assurance program has undergone any significant breakdown discussed in paragraph (c)(3)(iii) of this section must notify the Commission of the breakdown in the quality assurance program through a director or responsible officer or designated person as discussed in paragraph (d)(5) of this section.

(4) A dedicating entity is responsible for identifying and evaluating deviations, and 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, construction permit, combined license, or manufacturing license. Evaluation of potential defects and failures to comply and reporting of defects and failures to comply under this section satisfies the construction permit holder's, combined license holder's, or manufacturing license holder's evaluation and notification obligations under 10 CFR part 21, and satisfies the responsibility of individual directors or responsible officers or holders of construction permits issued

under § 53.1268, holders of combined licenses (until the Commission makes the finding under § 53.1452(g) of this part), and holders of manufacturing licenses 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, provided that this must 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 facsimile, which is the preferred method of notification, to the NRC Operations Center at (301) 816-5151 or by telephone at (301) 816-5100 within 2 days following receipt of information by the director or responsible corporate officer under paragraph (d)(3) of this section, on the identification of a defect or a failure to comply. 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 Document Control Desk, U.S. Nuclear Regulatory Commission, by an appropriate method listed in § 53.040, with a copy to the appropriate 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 § 53.1655 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 all the basic components in use at the facility subject to the regulations in this part.

(7) In the case of a completed reactor manufactured under § 53.1240 of this chapter, 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 individual, corporation, partnership, deciding entity, or other entity subject to the regulations in this part shall ensure that each procurement document for a facility or a basic component specifies or is issued by the entity subject to the regulations, when applicable, that the provisions of 10 CFR part 21 or 10 CFR 53.1655 applies, as applicable.

(h) *Coordination with 10 CFR part 21*. The requirements of § 53.1655 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 10 CFR 73.71, or under § 53.1655 or 53.1530.

(i) *Records retention*. The holder of a construction permit, combined license, and manufacturing license must prepare and maintain records necessary to accomplish the purposes of this section, specifically –

(1) Retain procurement documents, which define the requirements that facilities or basic components must meet 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 the following:

(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 combined license; 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 modifications 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.

§ 53.610 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 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) Approved 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) A fitness-for-duty program, in accordance with 10 CFR part 26.

(6)(i) A Quality Assurance (QA) Program meeting the requirements of Subpart K of this part as required by 53.460(b).

(ii) Appropriate programmatic controls to provide special treatment for non-safety related but safety significant 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 10 CFR 73.21, 73.22 73.23, as applicable.

(9) A cyber security program established in accordance with 10 CFR 73.54 or 73.110, 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 until that person has been issued either a construction permit or combined license under this part, an early site permit under this part authorizing activities under § 53.1130, or a limited work authorization under this part.

(1) Licensees must meet the following requirements:

(i) As appropriate, considering the types and quantities of radioactive materials being brought onto the site:

(A) The licensee ~~or permit holder~~ must maintain and follow a special nuclear material (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 10 CFR 70.32. Prior to initial receipt of SNM onsite, the ~~permit holder (or~~ licensee~~)~~ shall 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 10 CFR 30.18).

(ii) For construction of a commercial nuclear ~~power plants to be operated on multi-unit sites~~plant involving multiple reactor units, plans and procedures must be in place ~~prior to the start of construction activities~~ to prevent and/or mitigate potential hazards to the 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 ~~at the multi-unit sites. [The term "site" refers to the contiguous real estate on which nuclear units are located and for which one or more licensees has the legal right to control access by individuals and to restrict and use for purposes of limiting the potential doses from radiation or radioactive material during normal operation of the units.]~~.

(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) ~~A~~For LWA holders, a plan must be developed for redress of activities performed under the ~~CP or~~ LWA should one of the following situations arise:

(A) ~~CP or~~ LWA work activities are terminated by the holder of the ~~CP or~~ LWA;

(B) The ~~CP or~~ LWA is revoked by the NRC; or

(C) The Commission denies the associated ~~operating~~construction permit or combined license application.

(2) ~~On-site~~Onsite fresh fuel ~~storage~~.

(i) For a CP holder or LWA holder, or for a COL holder before the Commission makes the finding under § 53.1452, onsite fresh fuel must be stored in compliance with 10 CFR 73.67 ~~or~~.

(ii) For an OL holder or for a COL holder after the Commission makes the finding under § 53.1452:

(A) Onsite fresh fuel must be in stored within a protected area in compliance with 10 CFR 73.55~~.~~ or 73.100.

(B) Before fuel is brought within a protected area, a cyber security program that meets the requirements of 10 CFR 73.54 or 73.110, a physical security program that meets the requirements of 10 CFR 73.55 or 73.100~~,~~ and an access authorization program that meets the requirements of 10 CFR 73.56 and 73.120 must be established.

(~~3~~C) Fire protection measures for work and storage areas (including adjacent fire areas that could affect the work or storage area) must be implemented before initial receipt of byproduct, source, or non-fuel SNM (excluding exempt quantities as described in 10 CFR 30.18). 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 ~~or permit holder~~ 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 ~~consider the results of~~ address the inspections, ~~pre-operational~~ tests, ~~and~~ analyses ~~that have been performed~~ and ~~the~~ acceptance criteria ~~that are necessary and sufficient~~specified in the combined

license under § 53.1440 or the equivalent verifications needed to ~~conclude that there is reasonable assurance~~support the ~~facility has been constructed and will be operated in conformity with the~~issuance of an operating license~~, the provisions of the Atomic Energy Act, and the Commission's rules and regulations.~~

~~(d) *Communication*. Procedures for communication among elements of the construction program must be established that require:~~

~~(1) Interfacing among construction activities, inspections, and other ongoing work.~~

~~(2) Coordination with operating units on the site.~~

~~(3) Coordination with site preparation activities for other units being built on the site to ensure site characteristics (e.g. drainage) remain acceptable.~~

~~(4) Coordination with NRC on planned inspections~~ under § 53.1387.

§ 53.620 Manufacturing.

(a) *Management and control*. ~~Before starting~~ Holders of manufacturing ~~activities, the licensee~~licenses must ensure that the following plans, programs, and organizational units are ~~in place~~developed and implemented to manage and control the manufacturing activities within the scope of the ML:

~~(1) Design and analysis performed in accordance with subpart C.~~

(1) Programs to ensure that the manufacturing of a manufactured reactor, portions of a manufactured reactor, or a manufactured reactor module complies with the design and analysis requirements in subpart C of this part. If a person other than the reactor or module manufacturer under the manufacturing license has authority to design the reactor or module, the manufacturing license must include that person on the license.

(2) An organizational and management structure responsible for ~~the~~ managing, controlling, and evaluating the adequacy of the reactor design and manufacturing activities.

(3) Approved 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) A fitness for duty program, in accordance with 10 CFR part 26~~, applicable to the licensee's management and control organization personnel and the manufacturing work force.~~.

(6) A QA program meeting the requirements of Subpart K of this part~~.~~ and, as appropriate, programmatic controls to provide special treatment measures for non-safety related but safety significant SSCs.

(7) A ~~Radiation Protection Program~~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 10 CFR 73.21, 73.22 and 73.23, as applicable.

~~(9) A cyber security program in accordance with 10 CFR 73.54 or 73.110, as applicable.~~

~~(10) *Posting of requirements.* (i) Signs and labels, in accordance with subpart J of 10 CFR part 20, must be posted where there is a potential radiation hazard.~~

~~(ii) Each individual, licensee, partnership, corporation, dedicating entity, or other entity subject to the regulations in this subpart must post current copies of the~~

~~regulations in this part, Section 206 of the Energy Reorganization Act of 1974 (ERA) and procedures adopted under the regulations in this subpart.~~

~~(iii) If the posting of the regulations in this subpart or the procedures adopted under the regulations in this subpart is not practical, the licensee or firm subject to the regulations in this subpart must, 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 the regulation, procedures, and reports may be examined.~~

(b) *Manufacturing activities*. ~~Licensees~~Holders of manufacturing licenses must meet the following requirements:

(1) The manufacturing process must be conducted within facilities ~~that are controlled by~~for which the manufacturing license holder~~. This~~ 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 ~~generally accepted consensus~~ codes and standards that have been endorsed or otherwise found acceptable by the NRC.

~~(3) Quality control of the manufacturing process and key steps within the process must be ensured by appropriate verifications, inspections, and tests as required by paragraph (a) of this section.~~

~~(4)~~(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 and prior to the loading of fresh fuel into a manufactured reactor module. 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:

(~~i~~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.

(~~ii~~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 10 CFR 30.18). The fire protection measures for areas associated with ~~fresh fuel~~fueling a manufactured reactor module (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~~3) An emergency plan for responding to the radiological hazards of an accidental release of ~~special nuclear~~radioactive material and to ~~any~~limit the health effects of the associated chemical hazards ~~directly incident thereto~~ of licensed material must be approved and implemented prior to the receipt of byproduct, source, or ~~special nuclear material~~ SNM (excluding exempt quantities as described in 10 CFR 30.18).

(~~iv~~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 special nuclear material (excluding exempt quantities as described in 10 CFR 30.18).

(~~v~~5) Prior to the receipt of fresh fuel for a manufactured reactor module at the manufacturer's facility, the following measures must be in place:

(~~A~~i) A physical security program for the storage of fresh fuel in accordance with 10 CFR 73.67~~, 73.55, or 73.100, as applicable~~.

~~(B) An access authorization program in accordance with 10 CFR 73.56.~~

~~(C) A cyber security program in accordance with 10 CFR 73.54 or 73.110, as applicable.~~

(~~D~~ii) A material control and accounting program in accordance with 10 CFR part 74.

(~~E~~iii) Measures to prevent criticality accidents in accordance with ~~10 CFR~~§§ 70.~~24.~~61 and 70.64 of this chapter and to detect potential criticality accidents in accordance with § 53.440(m).

(~~vi~~6) Procedures shall be in place to describe how the facility design and manufacturing process will 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. Manufacturing licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the facility site, including the subsurface, in accordance with ~~the approved radiation protection program~~§ 20.1406 of this chapter.

~~(vii) A post manufacturing inspection and acceptance process must be established and implemented prior to fuel loading or shipping. The process must consider the results of inspections, pre-operational tests and analyses that have been performed and the acceptance criteria that are necessary and sufficient to conclude that there is reasonable assurance the reactor has been manufactured in accordance with the ML.~~

~~(c) *Fuel loading*~~

(d) *Fuel loading*

(1) If the ML authorizes fuel loading into a manufactured reactor module at the manufacturing facility, the following must be in place prior to the receipt of SNM:

(i) Radiation monitoring instrumentation and alarms.

(ii) Criticality monitoring instrumentation and alarms.

(iii) Procedures, equipment, and personnel qualified to handle fresh fuel, load it into the reactor, monitor the reactivity, ~~conduct any low power physics tests necessary for acceptance~~ and secure the fuel and reactor assembly for shipment.

~~(iv) A physical security program that meets the requirements of 10 CFR 73.55 or 73.100, as applicable.~~

~~(v) An access control program that meets the requirements of 10 CFR 73.56.~~

~~(vi) A cyber security program must be established in accordance with 10 CFR 73.54 or 73.110, as applicable.~~

~~(d) *Communication.* The applicant must coordinate with NRC on planned manufacturing activities, inspections, and nuclear-related testing.~~

(2) The storage, movement, and loading of fresh fuel into the manufactured reactor module within the manufacturing facility must comply with the requirements of §§ 70.61, 70.62 and 70.64 of this chapter.

(3) The loading of fresh fuel into a manufactured reactor module and any changes to the configuration of reactivity-related systems for the manufactured reactor module will be performed by a certified fuel handler meeting the requirements in subpart F of this part.

(e) *Transportation.*

(1) A holder of a manufacturing license 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 ~~either~~ a ~~construction permit or a~~

combined license. The ~~construction permit or~~ combined license must authorize the construction of a nuclear power facility using the manufactured reactor(s).

(2) A holder of a manufacturing license shall 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 transporting the manufactured reactor to comply with all NRC-approved shipping requirements in the manufacturing license.

(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 prepared and approved prior to transport. The procedures must implement the protective measures and restrictions described in the ML to protect the reactor from damage, contamination, or accidental criticality, if containing fuel.

(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~~ of this subpart~~.

(2) Upon arrival at the site, the holder of the combined license must confirm that manufactured reactor~~ must be certified to be in compliance~~, portions of a manufactured reactor, or a manufactured reactor module complies with the ML, including all ITAAC, and ~~inspected~~perform inspections, using approved procedures, to verify ~~it~~the delivered product is in acceptable condition. These procedures must also include confirming appropriate interfaces between the manufactured reactor, portions of a manufactured reactor, or a manufactured reactor module and the remaining portions of the commercial nuclear power plant. ~~Upon completion of the inspections, but prior~~Prior to installation at the site, ~~it~~the holder of the combined license must ~~be concluded~~verify that:

(i) The manufactured reactor, portions of a manufactured reactor, or a manufactured reactor module has arrived with no damage or contamination that could affect its safe operation.

(ii) The ~~reactor has been~~ manufactured ~~in conformity~~reactor or manufactured reactor module are consistent with the ~~manufacturing license;~~ interface requirements included in the ~~provisions of the Act,~~COL and the ~~Commission's rules and regulations; and~~

~~(iii) The manufactured reactor~~ commercial nuclear plant can be operated safely in conformity with the approved design.

Subpart F—Requirements for Operation

§ 53.700 Operational objectives.

Each licensee shall define, 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 safety criteria defined in Subpart B are satisfied. Each licensee shall maintain the capabilities and reliabilities of facility structures, systems, and components to ensure that the safety functions identified in § 53.230 will be performed if called upon during normal operations and licensing basis events. Each licensee shall 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. Each licensee shall implement plant programs during operations sufficient to ensure that the safety functions identified in § 53.230 will be performed if called upon during normal operations and licensing basis events.

§ 53.710 Maintaining capabilities and availability of structures, systems, and components.

Controls must be provided for each commercial nuclear plant such that the capabilities and reliability of SSCs, when combined with associated programmatic controls and human actions, provide reasonable assurance that the safety criteria defined in §§ 53.210 and 53.220 will be met.

(a) Technical specifications must be developed and implemented that define conditions or limitations on plant operations that are necessary to provide reasonable assurance that SR SSCs fulfill the safety functions identified in § 53.230 and that satisfy the safety criteria of § 53.210. The technical specifications must describe the following requirements:

(1) Limits on the inventory of radioactive materials within the reactor system and supporting systems with the potential, individually or collectively, to cause a release exceeding the safety criteria in § 53.210 as a result of a design basis accident analyzed in accordance with § 53.450(f).

(2) Operating limits for the facility that if exceeded could lead to a failure to perform a required safety function necessary to meet the safety criteria in § 53.210.

(3) For each 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 provide reasonable assurance that the design basis accidents analyzed in accordance with § 53.450(e) 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 will be met.

(ii) *Surveillance requirements.* Surveillance requirements relate 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 attributes to be included are those attributes 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 (a)(1)-(3) of this section.

(5) 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. Each licensee must submit any reports to the Commission pursuant to approved technical specifications as specified in § 53.40.

(6). Decommissioning-related requirements apply only to commercial nuclear plants that have submitted the certifications required by subpart G of this part. Technical specifications involving limiting conditions for operation; surveillance requirements; design features; and administrative controls will be developed on a case-by-case basis.

(b) Controls on plant operations, including availability controls, must be developed and implemented to provide reasonable confidence that the configurations and special treatments for NSRSS SSCs provide the capabilities and reliabilities required to satisfy the safety criteria of § 53.220. 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 the commercial nuclear plant's system; and

(iii) Establish processes to ensure that all departments of the commercial nuclear plant affected by the configuration changes are formally notified and approve of the change.

(2) Describe the means by which the special treatments for each NSRSS SSC will be provided and maintained over the operating life of the commercial nuclear plant.

§ 53.715 Maintenance, repair, and inspection programs.

(a) A program to control maintenance activities and monitor the performance or condition of SR and SS SSCs must be developed and implemented to provide reasonable assurance that the safety criteria defined in §§ 53.210 and 53.220 of this part 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 a NSRSS SSC does not meet established special treatment requirements or performance goals related to capabilities or reliabilities, 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 provide reasonable assurance that the performance measures defined in §§ 53.210 and 53.220 of this part will be met.

§ 53.720 Response to natural events.

If vibratory ground motion exceeding that of the Operating Basis Earthquake Ground Motion or significant plant damage occurs, the licensee must shut down the commercial nuclear plant. If systems, structures, or components necessary for the safe shutdown of the commercial nuclear plant are not available after the occurrence of the Operating Basis Earthquake Ground Motion, the licensee must consult with the Commission and must propose a plan for the timely, safe shutdown of the commercial nuclear power plant. Prior to resuming operations, the licensee must demonstrate to the Commission that no functional damage has occurred to those features necessary for continued operation without undue risk to the health and safety of the public and the licensing basis is maintained.

§ 53.725 General staffing, training, personnel qualifications, and human factors requirements.

(a) *Purpose and applicability*. The regulations in §§ 53.725 through 53.840 address areas related to staffing, training, personnel qualifications, and human factors for applicants for or holders of operating licenses or combined licenses under this part. These regulations are organized as follows:

(1) Sections 53.725 through 53.755 address general requirements for operator staffing, training, personnel qualifications, and human factors. The regulations within

these sections are applicable to all applicants for and holders of operating licenses or combined licenses for commercial nuclear plants under this part, except where specifically stated otherwise.

(2) Sections 53.760 through 53.795 address operator licensing requirements. The regulations within this section are applicable to those applicants for and holders of operating licenses or combined licenses for commercial nuclear plants under this part who *do not* meet the criteria provided under § 53.740(b) and have not yet certified the permanent removal of fuel from the reactor vessel as described under § 53.1070.

(3) Sections 53.800 through 53.830 address certified operator requirements. The regulations within this section are provided as an alternative to §§ 53.760 through 53.795 for those applicants for or holders of operating licenses or combined licenses for commercial nuclear plants under this part who meet the criteria provided under § 53.740(b) and have not yet certified the permanent removal of fuel from the reactor vessel as described under § 53.1070.

(4) Sections 53.835 through 53.840 address general personnel training requirements. The regulations within this section are applicable to all applicants for and holders of operating licenses or combined licenses for commercial nuclear plants under this part.

(b) *Definitions*. As used in §§ 53.725 through 53.840:

Automation means a device or system that accomplishes (partially or fully) a function or task.

Auxiliary operator, as used within this part, means those staff of a commercial nuclear plant who operate plant components but are not required to be licensed or certified under the provisions of this part.

Certified operator means an individual certified under the provisions of §§ 53.800 through 53.830 to manipulate a control of a facility. Certified operators are not licensed by the Commission.

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.

Licensed operator means any individual licensed under the provisions of §§ 53.760 through 53.795 to manipulate a control of a facility.

Load following, as used within this subpart, means a commercial nuclear power plant automatically changing its generation of electricity to match expected electrical demand in response to externally originated instructions or signals.

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 power plant on which a simulation facility's configuration, system control arrangement, and design data are based. The reference plant may or may not be actually constructed.

Senior licensed operator means any individual licensed under the provisions of §§ 53.760 through 53.795 to manipulate the controls of a facility and to direct the licensed activities of licensed operators.

Simulation facility means an interface designed to provide a realistic imitation of the operation of a facility, used for either the conduct of examinations for operator licensing or operator certification, training, or to establish on-the-job training and experience prerequisites for operator licensing or operator certification eligibility.

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.

[§§ 53.726 to 53.729 to be added to address Communications and Information Collection Requirements.]

§ 53.730 Defining, fulfilling, and maintaining the role of personnel in ensuring safe operations.

Each licensee or applicant for an operating license or combined license under this part shall develop, implement, and maintain the following measures to ensure that human actions needed to fulfil safety functions, prevent or mitigate licensing basis events, or otherwise meet the safety criteria in §§ 53.210 and 53.220 and, if applicable, any alternative criteria used in accordance with § 53.470, are satisfied:

(a) *Human factors engineering design requirements*. The facility design must 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.

(b) *Human system interface design requirements.* The facility design must provide for the following to support operators in monitoring plant conditions and responding to plant events:

(1) features for displaying to operators 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. Examples include relief and safety valve position (i.e., open or closed) for barriers with such devices and ultimate heat sink and cooling system status and availability,

(4) instrumentation to measure, record, and readout key plant parameters related to the performance of SSCs and the integrity of barriers important to fulfilling the safety functions of § 53.230. 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 to 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, and

(6) monitoring of in-plant radiation and airborne radioactivity as appropriate for a broad range of routine and accident conditions.

(c) *Concept of operations.* A concept of operations that is of sufficient scope and detail to address how the facility and personnel will achieve the safety requirements of Subpart B must be provided. The concept of operations will, at a minimum, address the following:

(1) facility goals,

(2) the roles and responsibilities of 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 surveillance tasks.

(d) A functional requirements analysis and function allocation must be provided that are sufficient to satisfy 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, or inherent safety characteristics.

(e) *Programmatic requirements*. (1) A program, to begin during construction and follow into operation, for evaluating and applying operating experience must be developed and implemented.

(2) A program, to begin during construction and follow into operation, for developing and maintaining plant procedures must be developed and implemented. The scope of the program must include emergency procedures, reliability analyses, human factors engineering, crisis management, and operator training.

(f) *Staffing plan.* A staffing plan must be developed to include the numbers, positions, and qualifications of licensed operators and senior licensed operators or, if applicable, certified operators across all modes of plant operations, and the numbers, positions, and responsibilities of personnel providing support in areas such as plant

operations, equipment surveillance and maintenance, radiological protection, chemistry control, fire brigades, engineering, security, and emergency response.

(1) Applicants and licensees subject to the provisions of §§ 53.760 through 53.795 must also include within their staffing plans a description of how the proposed numbers, positions, and qualifications of licensed operators and senior licensed operators across all modes of plant operations will be sufficient to provide assurance that plant safety functions can be maintained. This description must be supported by human factors engineering analysis and assessments.

(2) Applicants and licensees must include within their staffing plans the numbers, positions, and responsibilities of personnel providing support in areas such as plant operations, equipment surveillance and maintenance, radiological protection, chemistry control, fire brigades, engineering, security, and emergency response. The numbers, positions, and responsibilities of the personnel not directly addressed by the requirements for licensed or certified operators must reflect the evaluations of human factors engineering design requirements and concept of operations in paragraphs (a) and (c) of this section as well as other requirements within this part and Part 73 for security-related matters.

(g) *Training and examination programs*. Develop and implement proposed programs capable of satisfying the following requirements:

(1) For those applicants subject to the provisions of §§ 53.760 through 53.795:

(i) The operator licensing initial training program required under § 53.785(a),

(ii) The operator licensing examination program required under § 53.785(b), and

(iii) The operator licensing requalification program required under § 53.785(c).

(2) For those applicants subject to the alternative provisions of §§ 53.800 through 53.830:

(i) The certified operator initial training program required under § 53.815(a),

(ii) The certified operator examination program required under § 53.815(b), and

(iii) The certified operator continuing training program required under § 53.815(c).

§ 53.735 General exemptions.

The regulations in §§ 53.725 through 53.840 do not require a license or certification for an individual who –

(a) Under the direction and in the presence of a certified operator, licensed operator, or senior licensed operator, manipulates the controls of a facility as a part of the individual's training in a facility licensee's training program as approved by the Commission to qualify for an operator license or certification under this part; or

(b) Under the direction and in the presence of a certified operator or senior licensed operator, manipulates the controls of a facility to load or unload the fuel into, out of, or within the reactor vessel.

§ 53.740 Conditions for operations staffing for operating or combined licenses under this part.

(a) Facility licensees must meet the requirements of either §§ 53.760 through 53.795 or §§ 53.800 through 53.830. In order to exercise the option to comply with the requirements of §§ 53.800 through 53.830 in lieu of §§ 53.760 through 53.795, facility licensees must meet all the criteria contained in paragraph (b) of this section.

(b) Facility licensees may comply with the requirements of §§ 53.800 through 53.830 in lieu of §§ 53.760 through 53.795 upon demonstrating the following:

[It should be noted that the staff continues to work on the development and refinement of the criteria listed under § 53.740(b). Two options (A and B, below) for possible criteria

are provided in the preliminary proposed rule language to support feedback from stakeholders.]

[Option A]

(1) The safety criteria of §§ 53.210 and 53.220 and, if applicable, any alternative criteria used in accordance with § 53.470, will be met without reliance on human actions for event mitigation;

(2) The safety functions of § 53.230 can be achieved without reliance on human actions for event mitigation;

(3) The requirements associated with defense in depth, as described under § 53.250, can be met without reliance on human actions for event mitigation;

(4) The analysis of licensing basis events in accordance with § 53.450 demonstrates that the evaluation criteria for each event sequence can be met without reliance on human actions for event mitigation; and

(5) The plant response to licensing basis events is not reliant on human actions to guarantee the performance of structures, systems and components. Compliance with this paragraph may be achieved through the use of structures, systems, and components that function through inherent characteristics or have engineered protections against human failures (e.g., system misalignments).

[Option B]

The safety criteria of § 53.210 and, if applicable, any alternative criteria used in accordance with § 53.470, can be met without mitigation by human actions, active engineered features, or passive design features with the exception of those passive features that are expected to survive licensing basis events and which are not subject to

being made unavailable (or otherwise defeated) by credible human errors of commission and omission.

(c) Except as provided under § 53.735, the facility licensee may not permit the manipulation of the controls of any facility by anyone who is not a licensed operator, senior licensed operator, or certified operator as provided within this part.

(d) Upon commencing the administration of licensed operator and senior licensed operator licensing examinations as provided under § 53.785(b), or of operator certification examinations as provided under § 53.815(b), the licensee must have an operator requalification program. The operator requalification program must, at a minimum, meet the requirements of § 53.785(c) for licensed operators and senior licensed operators or of § 53.815(c) for certified operators. The approved operator requalification program shall be subject to the requirements of Subpart I, “Maintaining and Revising Licensing Basis Information During Operations,” of this part.

(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 a licensed operator, senior licensed operator, or certified operator pursuant to this part.

(1) Load-following, as defined by § 53.725(b), must only be permitted if one of the following actions is immediately capable of refusing demands from the grid operator 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, or

(ii) an automated control system; or

(iii) an individual who is a licensed operator, senior licensed operator, or certified operator pursuant to this part.

(f) Facility licensees subject to the requirements of §§ 53.760 through 53.795 and that have not yet certified the permanent removal of fuel from the reactor vessel as described under § 53.1070 must designate senior licensed operators to be responsible for supervising the licensed activities of licensed operators.

(g) The facility licensee must maintain the staffing complement described under their approved facility staffing plan until such time as the permanent removal of fuel from the reactor vessel has been certified as described under § 53.1070. The approved staffing plan shall be subject to the requirements of Subpart I, "Maintaining and Revising Licensing Basis Information During Operations," of this part.

(h)(1) Notwithstanding any other provisions of this section, facility licensees subject to the requirements of §§ 53.760 through 53.795 must have present, during alteration of the core of a commercial nuclear plant unit (including fuel loading or transfer), a person holding a senior licensed operator license or a senior licensed operator license limited to fuel handling to directly supervise the activity and, during this time, the facility licensee shall not assign other duties to this person.

(2) For a holder of an operating license or combined license under this part subject to the requirements of §§ 53.800 through 53.830, a certified operator must be present during alteration of the core of a commercial nuclear plant unit (including fuel loading or transfer) to directly supervise the activity and, during this time, the licensee shall not assign other duties to this person.

(3) These requirements do not apply to those facilities capable of continuous refueling operations while operating at power.

(i) Notwithstanding any other provisions of this section, a holder of an operating license or combined license under this part subject to the requirements of §§ 53.800 through 53.830 and that have not yet certified the permanent removal of fuel from the reactor vessel as described under § 53.1070 must meet the following requirements:

(1) Licensees must maintain certified operators with responsibility for administrative tasks including compliance with technical specifications, operability determinations, implementation of maintenance and configuration controls, compliance with radioactive release limitations, responsibilities under the facility emergency plan (as applicable), and making notifications to local, state, and federal authorities as required by this part(*e.g., those covered under § 53.1630 Immediate Notification Requirements for Operating Commercial Nuclear Plants)* in addition to those items identified by facility-specific job task analyses conducted under § 53.815(a).

(2) The licensee must maintain a sufficient complement of certified operators to provide for the continuity of responsibility for facility operations at all times during the operating phase.

(3) The licensee must provide for a certified operator to continually monitor the operations of fueled units. At a minimum, this certified operator must have following capabilities:

(i) The ability to receive plant operating data, including reactor parameters and information needed for the evaluation of emergency conditions.

(ii) The ability to immediately initiate a reactor shutdown from his or her location.

(iii) The ability to promptly dispatch operations and maintenance personnel.

(iv) The ability to immediately implement responsibilities under the facility emergency plan, as applicable.

(4) Where reactivity manipulations require operator action, except as provided by § 53.735, an individual who is a certified operator under the provisions of this part must conduct those reactivity manipulations.

(5) The facility technical specifications must provide the necessary administrative controls to ensure the implementation of the certified operator program. These

administrative controls must, at a minimum, specify the responsibilities, organization, staffing, qualifications, and training associated with the certified operator program.

(j) 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 (contained in a license issued under this part) in an emergency situation 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.

(k) Any action by the holder of an operating license or combined license under this part permitted by paragraph (j) of this section must be approved, as a minimum, by one of the following, as applicable, prior to taking the action:

(1) a senior licensed operator; or

(2) a certified operator; or

(3) at a commercial nuclear plant that has certified the permanent removal of fuel from the reactor vessel as described under § 53.1070, by either a senior licensed operator, a certified operator, or a certified fuel handler.

§ 53.745 Medical requirements.

(a) An applicant for a licensed operator or senior licensed operator license must have a medical examination by a physician. A licensed operator or senior licensed operator must have a medical examination by a physician every two years. Operators certified under the provisions of §§ 53.800 through 53.830 must have a medical examination by a physician prior to certification and every two years thereafter.

(1) The physician must determine that the applicant for a license, licensed operator, senior licensed operator, certified operator trainee, or certified operator's medical condition and general health will not adversely affect the performance of

assigned operator job duties or cause operational errors endangering public health and safety.

(b) To certify the medical fitness of the applicant for a license, an authorized representative of the holder of an operating license or combined license under this part 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) 415-5877, or by visiting the NRC's Web site at http://www.nrc.gov and selecting forms from the index found on the home page.

(1) Form NRC-396 must certify that a physician has conducted the medical examination of the applicant as required in paragraph (a).

(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 and the Commission then makes a determination in accordance with § 53.780(b).

(c) The holder of an operating license or combined license under this part must document and maintain the results of medical qualifications data, test results, and each licensed operator, senior licensed operator, or certified operator’s medical history for either the current license period or while certified, respectively, and provide the documentation to the Commission upon request. The licensee must retain this documentation while an individual performs the functions of a licensed operator, senior licensed operator, or certified operator.

[§§ 53.750 to 53.755 to be added to address Violations and Criminal Penalties.]

§ 53.760 Operator licensing.

(a) *Applicability*. Sections 53.760 through 53.795 address operator licensing requirements. The regulations within this section are applicable to all applicants for, or holders of, operating licenses or combined licenses for commercial nuclear plants licensed under this part except for those who meet the criteria provided under § 53.740(b) and choose to follow §§ 53.800 through 53.830 and have not yet certified the permanent removal of fuel from the reactor vessel as described under § 53.1070.

(b) Reserved.

§ 53.765 License requirements.

A person must be authorized by the holder or applicant for an operating license or the holder of a combined license under this part to perform the function of a licensed operator or a senior licensed operator as defined in this part.

§ 53.770 Completeness and accuracy of information.

Information provided to the Commission by an applicant for an operator license or by a licensed operator or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensed operator must be complete and accurate in all material respects.

§ 53.775 Incapacitation because of disability or illness.

If, during the term of the license, the licensed operator develops a permanent physical or mental condition that causes the licensed operator to fail to meet the requirements of § 53.745(a) of this part, the commercial nuclear plant licensee must notify the Commission, within 30 days of learning of the diagnosis. For conditions for which a conditional license (as described in § 53.780(b) of this part) is requested, the

commercial nuclear plant licensee must provide medical certification on Form NRC 396 to the Commission (as described in § 53.745(b) of this part).

§ 53.780 Applications for licensed operators.

(a) *How to apply*. (1) The applicant 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 Web site at http://www.nrc.gov and selecting forms from the index found on the home page;

(ii) File an original of NRC Form 398, or an equivalent electronic submittal, together with the information required in paragraphs (a)(1)(iii), (iv), (v), and (vi) 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 meets the requirements of § 53.785(e). For licensed operators applying for a senior licensed operator license, certification that the licensed operator has successfully operated the controls of the facility as a licensed operator shall be accepted; and

(iv) Provide certification by the facility licensee of medical condition and general health on Form NRC - 396, to comply with § 53.745.

(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 in order 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 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 (1)(i) and (ii) of this section.

(b) *Disposition of an initial application.* (1) Requirements for the approval of an initial application. The Commission will approve an initial application for a license pursuant to the regulations in this part, 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 licensed operator or senior licensed 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 § 53.745(b).

(ii) *Examination.* The applicant has passed the requisite examination in accordance with § 53.785(b). These examinations determine whether the applicant for a licensed operator or senior licensed operator's license has learned to operate a facility competently and safely, and additionally, in the case of a senior licensed operator, whether the applicant has learned to supervise the licensed activities of licensed operators competently and safely.

(2) *Conditional license*. If an applicant's general medical condition does not meet the minimum standards under § 53.745(a) of this part, 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 which the applicant has passed. The Commission may in its discretion grant the request, if it determines that sufficient justification is presented.

§ 53.785 Training program.

(a) *Initial training program*. (1) A program that is based upon a systems approach to training, as defined by § 53.725(b), must be utilized for the training of applicants for licensed operator and senior licensed operator licenses. This training program must ensure that license 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. This program must be approved by the Commission prior to its use for training license applicants, as described under § 53.730(g). The approved initial operator licensing training program shall be subject to the requirements of Subpart I, “Maintaining and Revising Licensing Basis Information During Operations,” of this part.

(1) *Records*. The initial training program documentation must include the following:

(i) The facility licensee must maintain records documenting the participation of each licensed operator and senior licensed operator trainee in the initial training program. The records must contain documentation of the training administered. The facility licensee must retain these records during the period in which any trainees subsequently remain licensed as licensed operators or senior licensed operators at the facility.

(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.

(b) *Licensing examination*. (1) The facility licensee must establish and implement an examination program for testing a representative sample of the knowledge, skills, and abilities needed to safely perform licensed operator and senior licensed operator duties, to include both the examination methods and criteria to be used to assess passing performance. This program must be approved by the Commission prior to its use for examining license applicants, as described under § 53.730(g). The approved initial operator licensing examination program shall be subject to the requirements of Subpart I, “Maintaining and Revising Licensing Basis Information During Operations,” of this part.

(2) The facility licensee must make prepared examinations available to the Commission for review and approval in advance of their administration.

(3) The Commission will reserve the ability to either administer the examination or to allow the facility licensee to administer the examination. In any event, the facility licensee must ensure that sufficient advance notification is provided to the Commission to allow for a representative of the Commission to be afforded the opportunity to be present during examination administration.

(4) Completed examination documentation for each applicant must be promptly forwarded to the Commission for review in making operator licensing decisions.

(5) *Records.* The initial licensing program documentation must include the following:

(i) The facility licensee must maintain records documenting the participation of each licensed operator and senior licensed operator applicant in the initial licensing examination. The records must contain copies of examinations administered, the answers given by the applicant, and the results of evaluations and documentation of examinations and of any additional training administered in areas in which a licensed operator or senior licensed operator has exhibited deficiencies. The facility licensee must retain these records during the period in which the associated licensed operators or senior licensed operators remain licensed at the facility.

(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.

(c) *Requalification program.* (1) A program based upon a systems approach to training, as defined by § 53.725(b), must be utilized for the continuing training of licensed operators and senior licensed operators.

(i) This continuing training program must ensure that licensed operators and senior licensed operators at the facility will 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 in duration.

(ii) This program must be approved by the Commission prior to its use for continuing training, as described under § 53.730(g). The approved requalification

program for licensed operators and senior licensed operators shall be subject to the requirements of Subpart I, “Maintaining and Revising Licensing Basis Information During Operations,” of this part.

(2) The following requirements apply to licensed operators and senior licensed operator requalification training programs:

(i) The facility licensee must propose a biennial requalification examination program for testing 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. This program must be approved by the Commission prior to its use for examining licensed operators and senior licensed operators, as described under § 53.730(g). The approved requalification examination program for licensed operators and senior licensed operators shall be subject to the requirements of Subpart I, “Maintaining and Revising Licensing Basis Information During Operations,” of this part.

(ii) The following requirements apply to biennial requalification examination programs:

(A) The facility licensee must make prepared biennial requalification examinations available to the Commission for review.

(B) The facility licensee must ensure that a representative of the Commission is afforded the opportunity to be present during biennial requalification examination administration.

(C) The facility licensee must ensure that each licensed operator and senior licensed operator is administered a complete biennial requalification examination on a periodicity not to exceed 24 months.

(D) The facility licensee must promptly forward a summary of examination results for each licensed operator and senior licensed operator following completion of the biennial requalification examination

(3) *Records.* The requalification program documentation must include the following:

(i) The facility licensee must maintain records documenting the participation of each licensed operator and senior licensed operator in the requalification program. The records must contain copies of examinations administered, the answers given by the licensed operator or senior licensed operator, and the results of evaluations and documentation of examinations and of any additional training administered in areas in which a licensed operator or senior licensed operator has exhibited deficiencies. The facility licensee must retain these records until the licensed operator's or senior licensed operator's license is renewed.

(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, licensed operators, senior licensed operators, and facility licensees must not engage in any activity that compromises the integrity of any application, test, or examination required by §§ 53.760 through 53.795. The integrity of a test or 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 test or examination. This includes activities related to the preparation and certification of license applications and all activities related to the preparation, administration, and grading of the tests and examinations required by §§ 53.760 through 53.795.

(e) *Simulation facilities.* (1) This section addresses the use of a simulation facility for the administration of examinations, for training, to meet experience requirements for

applicants for licensed operator and senior licensed operator licenses, and for conducting human factors engineering analysis or assessments.

(2) Simulation facilities used for training purposes, meeting experience requirements, or for the conduct of examinations under § 53.785(b) must meet the following criteria as they relate to the facility licensee's reference plant:

(i) The simulator must be of sufficient scope and fidelity for individuals to acquire and demonstrate the necessary knowledge skills and abilities to safely perform licensed operator and senior licensed operator duties.

(ii) The simulator must utilize models relating to nuclear and thermal-hydraulic characteristics that either replicate the most recent core load in the commercial nuclear reactor licensed under Part 53 reference plant or, prior to initial fuel load, replicate the intended initial core load for the commercial nuclear reactor licensed under Part 53 reference plant.

(iii) Simulator fidelity has been demonstrated so that significant control manipulations are completed without procedural exceptions, simulator performance exceptions, or deviation from the approved training scenario sequence.

(3) Facility licensees that propose to use a simulation facility for training purposes, meeting experience requirements, or for the conduct of examinations under § 53.785(b) and (c) must request approval from the Commission. This request must include:

(i) A description of the components of the simulation facility intended to be used as they relate to paragraph (2), unless previously approved; and

(ii) A description of the performance tests for the simulation facility as part of the request as they relate to paragraph (2), and the results of these tests; and

(iii) A description of the procedures for maintaining examination and test integrity consistent with the requirements of § 53.785(d).

(4) Facility licensees that propose to use a simulation facility for conducting human factors engineering analysis or assessments must provide a simulator that is capable of supporting all testing needed to demonstrate that aspects of the safety case such as operator licensing, human factors engineering, and other operational areas will be conducted as described in the safety analysis report.

(5) The Commission will approve a simulation facility if it finds that the simulation facility is suitable for training purposes, meeting experience requirements, or the conduct of examinations under § 53.785(b) and (c) for the facility licensee's reference plant.

(6) *Continued assurance of simulator fidelity*. Facility licensees that maintain a simulation facility for training purposes, meeting experience requirements, or for the conduct of examinations under § 53.785(b) and (c) must:

(i) Conduct performance testing throughout the life of the simulation facility in a manner sufficient to ensure that paragraph (2) of this section is met;

(ii) The results of performance tests must be retained for four 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 the criteria of paragraph (2) of this section;

(iv) Make results of any uncorrected performance test failures that may exist at the time of the operating test or requalification program inspection available for NRC review, prior to or concurrent with preparations for each examination or requalification program inspection; and

(v) Maintain the provisions for license application, examination, and test integrity consistent with § 53.785(d).

(7) A simulation facility must meet the requirements of paragraphs (2) and (6) of this section for the Commission to accept the simulation facility for conducting examinations as described in § 53.785(b) of this part, requalification training as described in § 53.785(c) of this part, or for performing control manipulations that affect reactivity to establish eligibility for a licensed operator's or senior licensed operator license as described in § 53.780(a).

(f) *Waiver of examination and test requirements.* On application, the Commission may waive any or all of the requirements 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. This requirement includes demonstration of the following:

(1) operating experience at a comparable facility,

(2) proof of the applicant's past performance, and

(3) proof of the applicant's current qualifications.

(g) *Proficiency.* The facility must establish and implement a Commission-approved program to ensure that licensed operators and senior licensed operators will actively perform the functions of a licensed operator or senior licensed operator, respectively, as needed to maintain proficiency regarding shift 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.

§ 53.790 Conditions of licensed operator and senior licensed operator licenses.

(a) Each license contains and is subject to the following conditions whether stated in the license or not:

(1) Neither the license nor any right under the license may be assigned or otherwise transferred.

(2) The license is limited to the facility for which it is issued.

(3) The license is limited to those controls of the facility specified in the license.

(4) The license is subject to, and the licensed operator or senior licensed operator must observe, all applicable rules, regulations, and orders of the Commission.

(5) The licensed operator or senior licensed operator must maintain proficiency in accordance with the facility proficiency program.

(6) The licensed operator or senior licensed operator must complete a requalification program as described by § 53.785(c). The licensed operator or senior licensed operator must pass a complete biennial requalification examination as described by § 53.785(c).

(7) The licensed operator or senior licensed operator must have a biennial medical examination.

(8) The licensed operator or senior licensed operator must notify the Commission within 30 days about a conviction for a felony.

(9) The licensed operator or senior licensed operator must not consume or ingest alcoholic beverages within the protected area of power reactors. The licensed operator or senior licensed operator must not use, possess, or sell any illegal drugs. The licensed operator or senior licensed operator 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 Part 26 of this chapter, 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 fitness-for-duty program, in such a manner as to adversely affect his or her ability to safely and competently perform licensed duties.

(10) Each licensed operator or senior licensed operator at power reactors must participate in the drug and alcohol testing programs as required under 10 CFR Part 26.

(11) The licensed operator or senior licensed operator must comply with any other conditions that the Commission may impose to protect health or to minimize danger to life or property.

(b) *Expiration*. (1) Each licensed operator license and senior licensed operator license expires six 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 licensed operator or senior licensed operator 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 deposited in the mail.

(c) *Renewal*. (1) The applicant for renewal of a 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 with the appropriate Regional Administrator specified in § 53.726(b).

(iii) Provide written evidence of the applicant's experience under the existing license and the approximate number of hours that the licensed operator or senior licensed operator 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 licensed operator or senior licensed 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 licensed operator or senior licensed operator has been employed.

(vi) Provide certification by the facility licensee of medical condition and general health on Form NRC-396, to comply with § 53.745.

(2) The license will be renewed if the Commission finds that:

(i) The medical condition and the general health of the licensed operator or senior licensed operator 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 § 53.745(b).

(ii) The licensed operator or senior licensed operator –

(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 § 53.785(c); and

(C) Has passed the requalification examinations as required by § 53.785(c).

(iii) There is a continued need for a licensed operator to operate or for a senior licensed operator to supervise licensed operators at the facility designated in the application.

(iv) The past performance of the licensed operator or senior licensed operator 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 licensed operator's or senior licensed operator's docket.

§ 53.795 Issuance, modification, and revocation of licenses.

(a) *Issuance of licensed operator and senior licensed operator licenses.* If the Commission determines that an applicant for licensed operator license or a senior licensed operator license meets the requirements of the Act 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 licenses.* (1) The terms and conditions of all licenses are subject to amendment, revision, or modification by reason of rules, regulations, or orders issued in accordance with the Act 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 Act,

(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 Act, or the license, or of any rule, regulation, or order of the Commission, or

(iv) For any conduct determined by the Commission to be a hazard to safe operation of the facility.

(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 § 53.790(a)(10) or the consumption of alcoholic beverages within the protected area of

power reactors, or a determination of unfitness for scheduled work as a result of the consumption of alcoholic beverages.

§ 53.800 Operator certification.

Sections 53.800 through 53.830 address certified operator requirements. The regulations within this section are provided as an alternative to those of §§ 53.760 through 53.795 for applicants for, or holders of, operating licenses or combined licenses for commercial nuclear plants licensed under this part who meet the criteria provided under § 53.740(b) and have not yet certified the permanent removal of fuel from the reactor vessel as described under § 53.1070.

§ 53.805 Certification requirements.

A person must be the holder of a certification issued by the facility licensee to perform the function of a certified operator as described in this part. The processes used by the facility licenses to establish, administer, and maintain their certified operator programs must comply with the provisions of this part.

§ 53.810 Incapacitation because of disability or illness.

If a certified operator develops a permanent physical or mental condition that causes the certified operator to fail to meet the requirements of § 53.745, the facility licensee must immediately remove that individual from the performance of certified operator duties. For those medical circumstances where a medical restriction can accommodate the medical issue, the facility licensee may permit the individual to continue to perform certified operator duties provided that compliance with the relevant restrictions is established and maintained.

§ 53.815 Training program.

(a) *Initial training program*. (1) A program that is based upon a systems approach to training, as defined by § 53.725(b), must be utilized for the training of certified operator trainees. This training program must ensure that certified operator trainees at the facility will possess the knowledge, skills, and abilities necessary to protect the public health. This program must be approved by the Commission prior to its use for certified operator trainees, as described under § 53.730(g). The approved initial certified operator training program shall be subject to the requirements of Subpart I, “Maintaining and Revising Licensing Basis Information During Operations,” of this part.

(2) *Records*. The initial training program documentation must include the following:

(i) The facility licensee must maintain records documenting the participation of each certified operator trainee in the initial training program. The records must contain documentation of the training administered. The facility licensee must retain these records during the period in which the any trainees subsequently remain certified as certified operators at the facility.

(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.

(b) *Certification examination.* The facility licensee must establish and implement an examination program for testing a representative sample of the knowledge, skills, and abilities needed to safely perform certified operator duties, to include both the examination methods and criteria to be used to assess passing performance. This program must be approved by the Commission prior to its use for examining certified operator trainees, as described under § 53.730(g). The approved initial certified operator

examination program shall be subject to the requirements of Subpart I, “Maintaining and Revising Licensing Basis Information During Operations,” of this part.

(1) The facility licensee must afford the Commission the opportunity to review prepared examinations.

(2) The facility licensee must ensure that a representative of the Commission is afforded the opportunity to be present during examination administration.

(3) Completed examination documentation for each certified operator must be retained by the facility licensee and made available to the Commission upon request.

(4) *Records.* The certification program documentation must include the following:

(i) The facility licensee must maintain records documenting the participation of each certified operator trainee in the certification examination. The records must contain copies of examinations administered, the answers given by the trainee, and the results of evaluations and documentation of examinations and of any additional training administered in areas in which a certified operator has exhibited deficiencies. The facility licensee must retain these records during the period in which the associated certified operators remain certified at the facility.

(ii) Each record required by this part must be legible throughout the retention period specified by regulation. The record may be the original, a reproduced copy, or an electronic copy provided that the copy is authenticated by authorized personnel.

(c) *Continuing training program.* (1) A program based upon a systems approach to training, as defined by § 53.725(b), must be utilized for the continuing training of certified operators. This continuing training program must ensure that certified operators at the facility will maintain the knowledge, skills, and abilities necessary to protect the public health. This program must be approved by the Commission prior to its use for continuing training, as described under § 53.730(g). The approved requalification

program for certified operators shall be subject to the requirements of Subpart I, “Maintaining and Revising Licensing Basis Information During Operations,” of this part.

(2) The facility licensee must propose a requalification examination program for testing a sample of the topics included under the systems approach to training, to include the examination methods, the criteria to be used to assess passing performance, and the periodicity for requalification examination administration. This program must be approved by the Commission prior to its use for examining certified operators, as described under § 53.730(g). The approved requalification examination program for certified operators shall be subject to the requirements of Subpart I, “Maintaining and Revising Licensing Basis Information During Operations,” of this part. The following requirements apply to certified operator requalification examination programs:

(i) The facility licensee must ensure that a representative of the Commission is afforded the opportunity to be present during requalification examination administration.

(ii) The facility licensee must ensure that each certified operator is administered a complete requalification examination within the periodicity specified within the facility licensee’s certified operator requalification examination program.

(3) *Records.* The continuing training program documentation must include the following:

(i) The facility licensee must maintain records documenting the participation of each certified operator in the continuing training program. The records must contain copies of examinations administered, the answers given by the certified operator, and the results of evaluations and documentation of examinations and of any additional training administered in areas in which a certified operator has exhibited deficiencies. The facility licensee must retain these records while the associated certified operators remain certified at the facility.

(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.* Certified operator trainees, certified operators, and facility licensees must not engage in any activity that compromises the integrity of any test or examination required by §§ 53.800 through 53.830. The integrity of a test or 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 test or examination. This includes all activities related to the preparation, administration, and grading of the tests and examinations required by §§ 53.800 through 53.830.

(e) *Simulation facilities.* (1) This section addresses the use of a simulation facility for the administration of examinations, for training, to meet experience requirements for certified operators, and for conducting human factors engineering analysis or assessments.

(2) Simulation facilities used for training purposes, meeting experience requirements, or for the conduct of examinations under § 53.815(b) and (c) must meet the following criteria as they relate to the facility licensee's reference plant:

(i) The simulator must be of sufficient scope and fidelity for individuals to acquire and demonstrate the necessary knowledge skills and abilities to safely perform certified operator duties.

(ii) The simulator utilizes models relating to nuclear and thermal-hydraulic characteristics that either replicate the most recent fuel load in the commercial nuclear plant reference plant or, prior to initial fuel load, replicate the intended initial fuel load for the commercial nuclear plant reference plant.

(iii) Simulator fidelity has been demonstrated so that significant control manipulations are completed without procedural exceptions, simulator performance exceptions, or deviation from the approved training scenario sequence.

(3) Facility licensees that propose to use a simulation facility for conducting human factors engineering analysis or assessments must provide a simulator that is capable of supporting all testing needed to demonstrate that aspects of the safety case such as operator certification, human factors engineering, and other operational areas will be conducted as described in the safety analysis report.

(4) Continued assurance of simulator fidelity. Facility licensees that maintain a simulation facility for training purposes, meeting experience requirements, or for the conduct of examinations under § 53.815(b) and (c) must:

(i) Conduct performance testing throughout the life of the simulation facility in a manner sufficient to ensure that paragraph (2) of this section is met. The results of performance tests must be retained for four years after the completion of each performance test or until superseded by updated test results;

(ii) 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 (2) of this section;

(iii) Make results of any uncorrected performance test failures that may exist at the time of the examination or requalification program inspection available for NRC review, prior to or concurrent with preparations for each examination or requalification program inspection; and

(iv) Maintain the provisions for examination and test integrity consistent with § 53.815(d).

(5) A simulation facility must meet the requirements of paragraphs (2) and (3) of this section for the Commission to accept the simulation facility for conducting examinations as described in § 53.815(b) of this part, requalification training as described in § 53.815(c) of this part, or for performing control manipulations that affect reactivity to establish eligibility for operator certification as described in § 53.820(d).

(f) *Waiver of examination and test requirements*. The facility licensee may waive any or all of the requirements for an examination in accordance with their approved training and qualification program.

(g) *Proficiency.* The facility must establish and implement a program to ensure that certified operators will 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 Issuance of certificates.

The facility licensee must ensure that the following requirements have been met prior to the issuance of a certified operator certification to any individual:

(a) The individual has completed a minimum educational level of either a high school diploma or general equivalency diploma.

(b) The individual must have satisfactorily completed a training program meeting the requirements of § 53.815(a).

(c) The individual must have passed an examination meeting the requirements of § 53.815(b).

(d) 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 meets the requirements of § 53.815(e).

(e) The individual must meet the medical condition and general health provisions of § 53.745(a).

(1) *Conditional certification*. If an individual's general medical condition does not meet the minimum standards under § 53.745(a) of this part, for those medical circumstances where a medical restriction can accommodate the medical issue, the facility licensee may permit the individual to perform certified operator duties provided that compliance with the relevant restrictions is established and maintained.

§ 53.825 Conditions of certificates.

The facility licensee must ensure that each certificate is subject to the following conditions:

(a) Neither the certificate nor any right under the certificate may be assigned or otherwise transferred.

(b) The certificate is limited to those controls of the facility specified in the certificate.

(c) The certified operator must complete a continuing training program as described by § 53.815(c).

(1) The certified operator must pass a complete continuing training examination as described by § 53.815(c).

(d) The certified operator must have a biennial medical examination.

(e) The certified operator must maintain proficiency in accordance with the facility proficiency program.

(f) The certified operator must not consume or ingest alcoholic beverages within the protected area of power reactors. The certified operator must not use, possess, or sell any illegal drugs. The certified operator must not perform activities requiring certification 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 certified operator duties. For the purpose of this paragraph, with respect to alcoholic beverages and drugs, the term "under the influence" means the certified operator exceeded, as evidenced by a confirmed test result, the lower of the cutoff levels for drugs or alcohol contained in Part 26 of this chapter, or as established by the facility licensee. The term "under the influence" also means the certified 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 for its fitness-for-duty program, in such a manner as to adversely affect his or her ability to safely and competently perform certified operator duties.

(g) Each certified operator at power reactors must participate in the drug and alcohol testing programs as required under 10 CFR Part 26.

(h) The facility licensee must notify the Commission within 30 days about a conviction of a certified operator for a felony.

§ 53.830 Expiration.

Commercial nuclear plant licensees must, at a minimum, terminate operator certifications upon termination of a certified individual’s employment with the commercial nuclear plant licensee, or upon determination by the commercial nuclear plant licensee that the certified individual no longer needs to maintain a certification.

§ 53.835 Training and qualification of commercial nuclear plant personnel.

(a) *Applicability.* Sections 53.835 through 53.840 address personnel training requirements. The regulations within this section are applicable to all applicants for operating licenses or combined licenses and facilities licensed under this part.

(b) Reserved.

§ 53.840 Training and qualification requirements.

(a)(1) Prior to fuel load, each commercial nuclear plant operating license applicant and each holder of an operating license must, with sufficient time to provide trained and qualified personnel to operate the facility, ensure a training program is established, implemented, and maintained that meets the requirements of paragraphs (b) and (c) of this section.

(2) Each holder of a combined license must establish, implement, and maintain the training program that meets the requirements of paragraphs (b) and (c) of this section, as described in the final safety analysis report with sufficient time to provide trained and qualified personnel to operate the facility.

(b) 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 and certified fuel handlers).

(c) The training program must incorporate the instructional requirements necessary to provide qualified personnel to operate and maintain the facility 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 as well as changes to the facility, procedures,

regulations, and quality assurance requirements. The training program must be periodically reviewed by facility licensee management for effectiveness.

(2) Sufficient records must be maintained by the facility licensee to maintain program integrity and kept available for NRC inspection to verify the adequacy of the program.

§ 53.845 Programs.

Programs must be provided for each commercial nuclear plant such that, when combined with associated design features and human actions, the plant will satisfy the safety criteria defined in §§ 53.210 and 53.220. Programs must also support continued assurance that the safety functions identified in § 53.230 are maintained during normal operations and licensing basis events. The required plant programs 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 licensed commercial nuclear plant.

§ 53.850 Radiation protection.

(a) Each licensee under this part must develop and implement 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.

(b) Each licensee 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 reasonably achievable. The program

shall be contained in an Offsite Dose Calculations Manual (ODCM), shall be implemented by procedures, and shall include remedial actions to be taken whenever the program limits are exceeded. The ODCM shall:

(i) 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

(ii) 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.

(c) [*Additional provisions may be added if needed*]

§ 53.855 Emergency preparedness.

Each licensee under this part must develop and maintain, an emergency response plan that provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

(a) The emergency plan must contain information needed to demonstrate compliance with the elements set forth in:

(1) 10 CFR 50.160 of this chapter; or

(2) the requirements in appendix E to 10 CFR part 50 and the planning standards in § 50.47.

(b) [Reserved]

§ 53.860 Security program.

(a) *Physical Protection Program.* Each licensee under this part must establish, maintain, and implement a physical protection program meeting the following requirements:

(1) The licensee must implement security requirements for the protection of special nuclear material based on the form, 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 meet the provisions set forth in either 10 CFR 73.55 or 73.100, unless the licensee meets the following criterion.

(i) The radiological consequences from a hypothetical, unmitigated 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.

(ii) The licensee must perform a site-specific analysis to demonstrate that the criterion in § 53.860(a)(2)(i) is met. The licensee must maintain the analysis until the permanent cessation of operations under § 53.1070.

(b) *Fitness for Duty***.** Each licensee under this part must establish, maintain, and implement a fitness for duty (FFD) program that meets the requirements in 10 CFR part 26.

(c) *Access Authorization*. Each licensee under this part must establish, maintain, and implement an Access Authorization program that meets the requirements in 10 CFR 73.120 if the criterion in § 53.860(a)(2)(i) is met, or § 73.56, if the criterion is not met.

(d) *Cyber Security*. Each licensee under this part must establish, maintain, and

implement a cyber security program that meets the requirements in 10 CFR 73.110 or 73.54.

(e) *Information Security*. Each licensee under this part must establish, maintain, and implement an information protection system that meets the requirements of 10 CFR 73.21, 73.22, and 73.23, as applicable.

§ 53.865 Quality assurance.

(a) Each licensee under this part is responsible for the establishment and execution of the quality assurance program (QAP) in accordance with Subpart K 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. QA activities must be based upon written procedures.

§ 53.870 Integrity assessment programs.

Each licensee under this part must develop and implement an integrity assessment program to monitor, evaluate and manage:

(a) The effects of plant aging on SR and NSRSS SSCs as well as any NSS SSCs whose failure could affect the performance of plant safety functions. 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 accepted consensus codes and standards;

(b) Cyclic or transient load limits to ensure 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 the

capabilities and reliabilities of SSCs satisfy the functional design criteria of §§ 53.410 and 53.420.

§ 53.875 Fire protection.

(a)(1) Each licensee 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 outline 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: 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 structures, systems, or components so that the capability to meet the requirements of § 53.210 is ensured.

(b)(1) Each licensee under this part must develop a performance-based or deterministic fire protection program that seeks to meet 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 structures, systems, and components must be designed and located to minimize, consistent with other safety requirements, the probability and effect of fires and explosions.

(ii) Noncombustible and fire- resistant materials shall be used wherever practical throughout the facility, particularly in locations with SR and NSRSS structures, systems, or components.

(iii) Fire detection and fighting systems of appropriate capacity and capability shall be provided and designed to minimize the adverse effects of fires on SR and NSRSS structures, systems, and components.

(iv) Firefighting systems shall be designed to ensure that their rupture or inadvertent operation does not significantly impair the safety capability of these structures, systems, and components.

§ 53.880 Inservice inspection/inservice testing.

(a) Each applicant and licensee under this part must develop and implement programs for In-Service Inspection (ISI) and In-Service Testing (IST) prior to receiving an operating license. 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 the risk insights so as to maintain the SSC reliability and performance consistent with the design. Risk insights must also be used to determine when to conduct the inspections and tests (e.g., full power, shutdown, refueling) so as to minimize risk to the plant and the public. The ISI/IST program must be documented in a written manual and managed by qualified personnel reporting to the Plant Manager.

(b) Prior to starting plant operation, baseline inspections and testing must be performed using the same techniques as will be used for future inspections and testing. These inspection and testing results must be used as benchmarks for evaluating the results of future inspections and tests. 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 or not 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 tests. 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 done. The ISI/IST results and corrective actions must be documented and retained over the life of the plant.

§ 53.885 Criticality safety program.

Each licensee under this part must have a criticality safety program. The program must address the requirements in 10 CFR 70.24 of this chapter for maintaining a monitoring system capable of detecting a criticality, having emergency procedures, and providing radiation protection for plant workers.

§ 53.890 Facility safety program.

Each licensee must establish and implement a facility safety program (FSP) that routinely and systematically evaluates potential hazards; operating experience related to plant SSCs, human actions, and programmatic controls affecting the safety functions required by § 53.230; and the resulting changes in risks to the public from operation of the facility over its operating lifetime. An FSP must include a risk-informed, performance-based process to proactively identify new or revised internal or external hazards to the facility and performance issues related to plant SSCs, human actions, and programmatic controls; assess changes in the risks posed to the public from the licensed commercial nuclear plant; and, when appropriate, must consider measures to

mitigate or eliminate the resulting risks using the criteria defined in § 53.895. The FSP must be implemented and supported by a written FSP as required in § 53.900.

§ 53.895 Facility safety program performance criteria.

(a) Each licensee for an commercial nuclear plant must take 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 § 53.900. Performance objectives for design features and programmatic controls must be established such that the risks to public health and safety from a commercial nuclear plant due to normal operation or licensing basis events must not be a significant addition to other societal risks.

(1) Each licensee must assess risk reduction measures related to the release or potential release of radioactive materials in plant effluents during normal operation whenever such a release could result in a member of the public receiving an annual radiation dose in excess of 0.3 millirems from liquid effluents or 1 millirem from gaseous effluents. The assessment and risk reduction measures must maintain doses to members of the public as low as is reasonably achievable in accordance with § 53.260 taking into account the state of technology, the economics of improvements in relation to the state of technology, operating experience, and the economics of improvements in relation to benefits to the public health and safety.

(2) Each licensee must assess potential risk reduction measures related to licensing basis events, identified hazards, or other specific contributors to the overall cumulative risk from unplanned events as follows:

(i) For new or revised hazards, plant features, or other contributors to licensing basis events with an estimated upper bound frequency above one in 1,000 years, licensees must consider risk reduction measures whenever the estimated radiation dose

to a member of the public exceeds 2.5 millirem and the estimated frequency weighted cumulative dose to nearby populations increases by 5 person-rem.

(ii) For new or revised hazards, plant features, or other contributors to licensing basis events with an estimated lower bound frequency below one in 1,000 years, licensees must consider risk reduction measures whenever the estimated frequency weighted cumulative dose to nearby populations increases by 5 person-rem and either the frequency of a member of the public receiving a radiation dose with the potential for immediate health effects approaches five in 100 million years or a radiation dose with the potential to cause latent health effects approaches two in 10 million years.

(iii) For new or revised hazards, plant features, or other contributors to licensing basis events with an estimated dose to a member of the public less than or equal to a threshold value used for operational flexibilities in accordance with § 53.470, licensees must consider risk reduction measures whenever changes to the estimated consequences reduce the margin to the subject threshold value by more than ten percent and the estimated frequency weighted cumulative dose to nearby populations increases by 5 person-rem.

(iv) The assessment and risk reduction measures must maintain doses to members of the public as low as is reasonably achievable taking into account the state of technology, the economics of improvements in relation to the state of technology, information available on potential hazards, operating experience, and the economics of improvements in relation to benefits to the public health and safety.

(b) Possible risk reduction measures for commercial nuclear plants whose licenses refer to certified designs or manufacturing licenses must also follow the change control and reporting provisions of subpart I of this part related to changes to standardized designs. Licensees need not pursue risk reduction measures under this

section if the changes would require a license amendment under Subpart I due to changes in a certified design.

§ 53.900 Facility safety program plan.

(a) General. Each licensee must adopt and implement an FSP using a written FSP plan that, at a minimum, contains the elements in this section. This FSP plan must be approved by NRC under the process required in § 53.905.

(b) Scope. (1) Each licensee must set forth in its FSP plan a statement describing the facility or facilities covered by the plan. The description must include the facility, personnel, programmatic controls, and facility environs that influence the assessments used in assessing potential risks in accordance with subparts B and C of this part and potential reduction measures using the performance criteria in § 53.895. The scope of the program plan must consider new or revised information related to:

(i) The performance of SSCs in terms of their capability and availability to perform the required safety functions required by § 53.230 during normal operation and licensing basis events and assessing potential risk reduction measures using the performance criteria in § 53.895;

(ii) The role of personnel in making decisions, operating plant SSCs, or otherwise supporting the safety functions required by § 53.230 and assessing potential risk reduction measures using the performance criteria in § 53.895;

(iii) The programmatic controls required within this part or otherwise implemented by a licensee to ensure capabilities and availabilities of SSCs and personnel performing the safety functions required by § 53.230 and assessing potential risk reduction measures using the performance criteria in § 53.895;

(iv) Natural and manmade hazards with the potential to affect plant SSCs or personnel supporting the safety functions required by § 53.230 and assessing potential risk reduction measures using the performance criteria in § 53.895; and

(v) Operating experience related to plant SSCs, personnel, or programmatic controls supporting the safety functions required by § 53.230 and assessing potential risk reduction measures using the performance criteria in § 53.895.

(2) Each licensee must set forth in its FSP plan the methods used to analyze the technologies identified under paragraph (f)(1)(i) of this section against the criteria provided in § 53.895.

(3) Each licensee must set forth in its FSP plan a description of its overall safety philosophy and intended safety culture to be practiced by its management, employees and contractors; and

(4) Each licensee must identify the required participants in the FSP plan, 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 as required by § 53.895.

(c) Implementation. Each licensee must describe in its FSP plan the process the licensee will use to implement and maintain its FSP. As part of the licensee's implementation process, the licensee must describe roles and responsibilities of each position that has significant responsibility for implementing the FSP, including those held by employees and other persons utilizing or providing significant services as identified by the licensee pursuant to paragraph (b)(3) of this section.

(d) Facility safety program training:

(1) Each manager, employee, and contractor identified under paragraph (b)(3) of this section will be trained on the licensee's FSP.

(2) Each licensee must establish and describe in its FSP plan the licensee's facility safety program training plan. An FSP training plan must set forth the procedures by which managers, employees, and contractors identified under paragraph (b)(3) of this section will be trained on the licensee's FSP. An FSP training plan must help ensure that all personnel who are responsible for implementing and supporting the FSP understand the goals of the program, are familiar with the elements of the program, and have the requisite knowledge and skills to fulfill their responsibilities under the program.

(3) For each position identified pursuant to paragraph (b)(3) of this section, the training plan must describe the frequency and content of the FSP training that the position receives.

(4) Training under this subpart F may include, but is not limited to, classroom, computer-based, or correspondence training.

(5) The licensee must keep a record of all training conducted under this part and update that record as necessary. The FSP training plan must set forth the process used to maintain and update the necessary training records required by this part.

(6) The FSP training plan must set forth the process used by the licensee to ensure that it is complying with the training requirements set forth in the training plan.

(e) Risk-informed hazard management program. Each licensee must establish a risk-informed hazard management program as part of the licensee's FSP. The risk-informed hazard management program must be fully described in the FSP plan. The risk-informed hazard management program must establish:

(1) The processes or procedures used in the risk-informed hazard analysis to identify internal and external hazards having the potential to increase the frequency or consequences of radiological releases from normal operation or licensing basis events;

(2) The processes or procedures used in the risk-informed hazard analysis to analyze identified hazards and support assessments against the criteria provided in § 53.895;

(3) The methods used to identify and implement actions that mitigate or eliminate hazards based on assessments against the criteria provided in § 53.895;

(4) The methods used to ensure changes to the facility design or operations do not adversely affect measures in place to mitigate or eliminate hazards or that such changes have been assessed pursuant to the appropriate change control and have been incorporated into models used for assessments against the criteria provided in § 53.895;

(5) The methods used to maintain records of identified hazards and risks and the mitigation or elimination of the identified hazards and risks throughout the life of the facility; and

(6) The position title(s) of the individual(s) responsible for administering the risk-informed hazard management program.

(f) Technology assessment program. Each licensee must establish a technology assessment program as part of the licensee's FSP. The technology assessment program must be fully described in the FSP plan. The technology assessment program must establish:

(1) 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 from a facility during normal operations or licensing basis events;

(2) The methods used to analyze the technologies identified under paragraph (f)(1) of this section against the criteria provided in § 53.895;

(3) The methods used to identify and implement actions related to technologies identified under paragraph (f)(1) of this section based on assessments against the criteria provided in § 53.895;

(4) The methods used to maintain records of technology assessments throughout the life of the facility; and

(5) The position title(s) of the individual(s) responsible for administering the technology assessment program.

(g) Internal facility safety program assessment. (1) The licensee must describe in the FSP plan methods to annually confirm:

(i) The FSP is fully implemented and effective;

(ii) The licensee's overall safety philosophy and intended safety culture are being implemented and effective;

(iii) The facility safety program training program is implemented and effective; and

(iv) The facility continues to meet the performance criteria set forth in § 53.230 and effectively consider risk reduction measures using the performance criteria set forth in § 53.895.

(2) As part of its FSP plan, the licensee must describe the processes used to:

(i) Conduct internal FSP assessments;

(ii) Internally report the findings of the internal FSP assessments 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;

(iii) Develop, track, and review recommendations as a result of the internal FSP assessments;

(iv) Develop improvement plans based on the internal FSP assessments; and

(v) Manage revisions and updates to the FSP plan based on the internal facility safety program assessments.

§ 53.905 Review, approval, and retention of facility safety program plans.

(a)

The NRC will review the FSP plan to determine if the elements prescribed in this part are sufficiently addressed in the applicant's submission. Approval of an FSP plan under this part does not constitute approval of the specific actions the licensee will implement under its FSP plan pursuant to § 53.900 and must not be construed as establishing an NRC standard regarding those specific actions.

(b) Updates and revisions to the FSP plan must be provided to the NRC in accordance with the requirements in Subpart I of this part.

§ 53.910 Procedures and guidelines.

(a) Each licensee under 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 responding to possible unplanned events.

(b) The program required by paragraph (a) of this section must include but is not necessarily limited to development, implementation, maintenance, and supporting activities of the following procedures and guidelines:

(1) Plant operations

(2) Maintenance under § 53.715

(3) Program requirements under this subpart

(4) Emergency operating procedures if human intervention is needed to respond to licensing basis events with a frequency greater than one in ten thousand years accounting for uncertainties

(5) Accident management guidelines if human intervention is needed to respond to licensing basis events with a frequency less than one in ten thousand years accounting for uncertainties

(c) reserved

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Subpart G—Decommissioning Requirements

§ 53.1000 Scope and purpose.

Each applicant for or holder of an operating license or combined license under this part must meet the requirements for decommissioning under this subpart. 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 commercial nuclear plant licenses, and ultimately supporting unrestricted use of the sitethe license are in §§ 53.1070 through 53.1080.

§ 53.1010 Financial Aassurance for Ddecommissioning.

(a) This section establishes requirements for indicating to the NRC how a licenseean applicant for or holder of an operating license or combined license under this part will provide reasonable assurance that funds will be available for the decommissioning process. For commercial nuclear plant licensees licensed under this

~~part, reasonable~~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 ~~G~~government agencies (e.g., Federal Energy Regulatory Commission (FERC) and State Public Utility Commissions (PUC)) 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 operating license or ~~a~~ combined license under 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 operating license or combined license must implement and maintain the plan.

(1)(i) Before the Commission issues an operating license under 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 § 53.1020.

(ii) No later than 30 days after the Commission issues the notice of intended operation under § 53.~~1307~~1452 for a COL under this part, the licensee must update the decommissioning report to certify that it has provided financial assurance for decommissioning in the amount proposed in ~~in~~ the application and approved by the NRC in accordance with § 53.1020.

(2) The amount of financial assurance for decommissioning to be ~~provided or actually~~ provided must be adjusted annually using a rate at least equal to that stated in § 53.1030.

(3) 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.

(4) The amount ~~stated in the applicant's or licensee's certification~~of financial assurance for decommissioning to be provided must be based on a site-specific cost estimate for decommissioning the facility in accordance with § 53.1020. ~~As part of the certification, a~~A copy of the financial instrument obtained to satisfy the requirements of § 53.1040 must be submitted to ~~NRC~~the NRC as part of the application for an operating license or combined license under this part.

§ 53.1020 Cost ~~E~~estimates for ~~Required Decommissioning Funds~~required decommissioning funds.

~~Each applicant~~Cost estimates for ~~an operating license or a combined license under this part~~decommissioning must ~~include in the application a~~be site-specific. Site-specific decommissioning cost ~~estimate for decommissioning the facility. The cost estimate~~estimates must account for the engineering, labor, equipment, transportation, disposal, and related charges needed to support termination of the ~~NRC~~ license. ~~The cost estimates prepared for this section~~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 costs for removed components and materials in appropriate facilities; and any other associated costs supporting the ~~ultimate~~ release of the property and termination of the license. ~~The cost estimate report~~They must also address the ~~planned~~ approach to annual adjustments ~~to the cost estimates~~ required by § 53.1030. Finally, site-specific decommissioning cost estimates 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~~adjustments to cost estimates for decommissioning.

Each holder of an operating license or combined license under this part must annually adjust the ~~NRC-approved~~ cost estimate for decommissioning to account for escalation in labor, energy, and waste burial costs. Licensees may elect to use either ~~the~~a site-specific adjustment ~~factors~~ factor, approved as part of the plan and associated decommissioning report required by § 53.1010 in paragraph (a) of this section ~~as reviewed and approved by the NRC with the cost estimates required by § 53.1010~~ or ~~use~~ the generic ~~adjustments~~adjustment factor in paragraph (b) of this section.

(a) A site-specific adjustment factor ~~for this section~~ must at a minimum 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 ~~for this section~~ 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 ~~Financial Instruments~~Methods for ~~Decommissioning Funds~~providing financial assurance for decommissioning.

Financial assurance 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 § 53.1~~34~~570 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 ~~at the time permanent termination of operations is expected.~~. 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 shall 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 § 53.1020 may take credit for projected earnings on the prepaid decommissioning trust funds, using up to a 2 percent annual real rate of return ~~from the time of future funds' collection through the time of permanent termination of operations or the projected decommissioning period, provided that the site-specific estimate is based on a period of safe storage that is specifically described in the estimate. This includes the periods of safe storage, final dismantlement, and license termination.~~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 ~~at the time permanent termination of operations is expected.~~. 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 shall 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 ~~l~~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 § 53.1020 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 permanent termination of operations or the decommissioning period, provided that the site-specific estimate is based on a period of safe storage that is specifically described in the estimate. This includes the periods of safe storage, final dismantlement, and license termination.~~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 meet 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 §§ 53.1020, 53.1060, or 53.135~~0~~75 of this part.

(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. ~~For non-profit entities, such as colleges, universities, and non-profit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in appendix E 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) For ~~a commercial nuclear plant licensee that is~~ 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 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 §§ 53.1020, 53.1060, or 53.1~~3~~5~~0~~75. To be acceptable to the NRC as a method of decommissioning funding assurance, the terms of the contract(s) shall 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 ~~commercial nuclear~~ 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) 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.

§ 53.1045 ~~Financial Management of Decommissioning Funds~~Requirements for 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 § ~~50~~53.1020 may be used for decommissioning planning. For licensees that have submitted the certifications required under § 53.1~~3~~5~~0~~75 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

decommissioning cost estimate 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 shall 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 ~~power reactor~~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 ~~power~~ 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 this subsection shall not operate in such a way as to require the sale or transfer either in whole or in part, or other disposition of any such prohibited investment that was made before the publication date of this rule, and provided further 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 power 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 the Federal

Energy Regulatory Commission'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 shall 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 (~~c)~~ 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 shall 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 shall 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 ~~Review~~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 the 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 ~~Requirements~~and recordkeeping requirements.

(a) Each holder of an operating license under this part or holder of a combined license under this part after ~~fuel loading~~the date that the Commission has made the finding under § 53.1452 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 §§ 53.1020 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 § 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 shall submit this report annually.

(b) Each holder of a combined license under this part shall, 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 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.~~1307~~1452(a), the licensee shall submit a 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 ~~the requirements of paragraph (e) of this section~~§ 53.1040.

(c) Each licensee shall 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 shall 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)(~~1~~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 § 53.1~~3~~5~~0~~75, 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 commercial nuclear plant licensee~~(d) Each holder of an operating license or combined license under this part shall at or about 5 years prior to the projected end of operations submit a preliminary decommissioning cost estimate 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 shall 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 decommissioning cost estimate (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 shall 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 ~~provide information on changes to the decommissioning plans or the means to restore~~include additional financial assurance ~~in the ability~~ 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.

~~(a) For commercial nuclear plant licensees—~~

~~(~~For each holder of an operating license or combined license under this part—

(a)(1~~)(i~~) When ~~a~~the licensee has determined to permanently cease operations the licensee shall, within 30 days, submit a written certification to the NRC, consistent with the requirements of § 53.040(b)(8);

~~(ii~~(2) When appropriate to support decommissioning activities and the eventual permanent removal of fuel from the reactor vessel, the licensee must review the operational technical specifications and determine 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)(i) Once fuel has been permanently removed from the reactor vessel, the licensee shall submit a written certification to the NRC that meets the requirements of § 53.040(b)(9); and

(~~A~~ii) The licensee ~~shall~~may 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 shall be subject to the training requirements of §§ 53.835 through 53.840~~. Additionally, each certified fuel handler shall, both prior to qualification and biennially thereafter, pass a medical examination by a physician to determine that the medical condition and general health of the certified fuel handler will not adversely affect the performance of assigned job duties or cause operational errors endangering public health and safety.~~.

(~~2~~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.

(~~3~~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.

(~~4)(i~~d)(1) Prior to or within 2 years following permanent cessation of operations, the licensee shall submit a PSDAR and site-specific DCE in accordance with § 53.1060(e).

(~~ii~~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, ~~which~~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.

(~~5~~e) Licensees shall 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 § 53.1~~3~~50~~9~~75, have been submitted.

(~~6~~f) Licensees shall not perform any decommissioning activities, as defined in § 53.020, that—

(~~i~~1) Foreclose release of the site for possible unrestricted use;

(~~ii~~2) Result in significant environmental impacts not previously reviewed; or

(~~iii~~3) Result in there no longer being reasonable assurance that adequate funds will be available for decommissioning.

(~~7~~g) In taking actions permitted under § 53.1~~32~~540 following submittal of the PSDAR, the licensee shall 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~~.~~.

(~~8~~h) Licensees may use ~~the~~ decommissioning trust funds ~~within~~consistent with the ~~restrictions included in~~limitations of § 53.1045(a). Licensees must report on the status of ~~the~~decommissioning trust funds ~~in accordance~~consistent with the ~~schedules and required content~~requirements of ~~submittals included in~~ § 53.1060.

~~(9) All commercial nuclear plant licensees~~(i) Licensees must submit an application for termination of license in accordance with § 53.1~~3~~5~~0~~75. The application for termination of license must ~~accompany~~be accompanied or ~~precede an NRC-approved~~preceded by a license termination plan to be submitted for NRC ~~review~~approval.

(~~i~~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.

(~~ii~~2) The license termination plan must include—

(~~A~~i) A site characterization;

(~~B~~ii) Identification of remaining dismantlement activities;

(~~C~~iii) Plans for site remediation;

(~~D~~iv) Detailed plans for the final radiation survey;

(~~E~~v) A description of the end use of the site, if restricted;

(~~F~~vi) An updated site-specific estimate of remaining decommissioning costs;

(~~G~~vii) A supplement to the environmental report, pursuant to § 51.53, describing any new information or significant environmental change associated with the licensee's proposed termination activities; and

(~~H~~viii) Identification of parts, if any, of the facility or site that were released for use before approval of the license termination plan.

(~~iii~~3) The NRC shall notice receipt of the license termination plan ~~amendment application~~ and make the license termination plan ~~application~~ 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 ~~application~~. The NRC shall publish a notice in the Federal Register and in a forum, such as local newspapers, ~~which~~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.

(~~10~~j) If the license termination plan ~~application~~ 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 ~~review and if appropriate~~ 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.

(~~11~~k) The Commission shall terminate the license if it determines that—

(~~i~~1) The remaining dismantlement has been performed in accordance with the approved license termination plan, and

(~~ii~~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.

§ 53.1080 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 ~~facility~~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. ~~Nuclear power reactor licensees~~Holders of an operating license or combined license under 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~~subpart D of this 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 ~~facility~~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 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 ~~facility~~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.~~1320 and the licensed site boundary~~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 ~~review~~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 shall 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, 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 ~~facility~~commercial nuclear plant or site. The NRC shall publish a document in the Federal Register and in a forum, such as local newspapers, ~~which~~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.

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 ~~to construct and/or operate, or manufacture, a commercial nuclear plant (including an early site permit)~~ under this part, and any amendments to the applications, must be submitted to the U.S. Nuclear Regulatory Commission in accordance with § 53.040 of this chapter, as applicable.

(2) Each applicant for a construction permit, early site permit, combined license, or manufacturing license under this part shall, upon notification by the presiding officer designated to conduct the public hearing required by the Atomic Energy 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 U.S. Nuclear Regulatory Commission as specified in § 53.040 of this chapter, 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 shall certify that the updated copies of the application contain the current contents of the application submitted in accordance with the requirements 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 which 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 of this chapter, 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 or license, including, whenever appropriate, a construction permit 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 or commercial nuclear plant license under this part, including, whenever appropriate, a construction

permit, combined license, operating license, manufacturing license, or early site permit, other than a license exempted from part 170 of this chapter, shall be accompanied by the fee prescribed in part 170 of this chapter. No fee will be required to accompany an application for renewal, amendment, or termination of a construction permit, operating license, combined license, or manufacturing license, except as provided in § 170.21 of this chapter.

(f) *Environmental report*. An application for a construction permit, operating license, early site permit, design certification, combined license, or manufacturing license for a commercial nuclear plant shall be accompanied by an Environmental Report required under subpart A of part 51 of this chapter.

§ 53.1101 Requirement for license.

Except as provided in § 53.1120 of this chapter, no person within the United States shall 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 in one application several applications 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 shall state, 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, state citizenship.

(2) If applicant is a partnership, state 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, state:

(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;

(iii) Whether it is owned, controlled, or dominated by an alien, a foreign corporation, or foreign government, and if so, give details.

(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) Except as provided in paragraph (g)(2) of this section, if the application is for an operating license or combined license 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) of this chapter, the applicant shall submit radiological emergency response plans of State and local governmental entities in the United States that are wholly or partially within the plume exposure pathway emergency planning zone (EPZ),[2] ~~as well as~~and, for applicants choosing to comply with10 CFR 50.47 and Appendix E, the plans of State governments wholly or partially within the ingestion pathway EPZ.[3] 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 meet the requirements of this paragraph. ~~Generally~~Generally, for applicants choosing to follow 10 CFR 50.47 and Appendix E, the plume exposure pathway EPZ for a commercial nuclear plant shall consist of an area about 10 miles (16 km) in radius and the ingestion pathway EPZ shall 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 shall 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 shall focus on such actions as are appropriate to protect the food ingestion pathway.

(2) [To be added when EP for SMR and ONT final rule is published.]

(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.

(j) If the application contains Restricted Data or other defense information, it shall be prepared in such manner that all Restricted Data and other defense information are separated from the unclassified information.

(k) [Reserved]

* * * * *

[2] Emergency planning zones (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.

[3] If the State and local 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.

§ 53.1112 Environmental conditions.

(a) Each construction permit, early site permit, and combined license under part 53 of this chapter may include conditions to address environmental issues during construction. These conditions are to be set out in an attachment to the permit or license, which is incorporated in and made a part of the permit or license. These conditions will be derived from information contained in the environmental report submitted pursuant to § 53.1100(f) 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 combined license, under part 53 of this chapter, and each license for a commercial nuclear plant for which the certification of permanent cessation of operations required under § 53.1070(a)(1) of this part 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 pursuant to §§ 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, construction permit, early site permit, standard design approval, or manufacturing license, or before the Commission has adopted a final standard design certification rule, the applicant shall agree in writing that it will not permit any individual to have access to 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, construction permit, 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, shall be ineligible to apply for and obtain a license.

§ 53.1120 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 Act, 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 Administration facilities of the types subject to licensing pursuant to section 202 of the Energy Reorganization Act of 1974 are involved;

(1)(i) The processing, fabrication or refining of special nuclear material or the separation of special nuclear material, or the separation of special nuclear material 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) 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;

(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.

(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.

(c) The transportation or possession of any utilization facility by a common or contract carrier or warehousemen in the regular course of carriage for another or storage incident thereto.

§ 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 the provisions of the regulations contained in part 2 of this chapter.

§ 53.1124 Relationship between sections.

(a) *Limited work authorization.* (1) An application for a limited work authorization under this part may be submitted as part of an application for a construction permit or combined license under this part as required in § 53.1130(a)(2).

~~To be added~~

~~(b) *Early site permit*.~~

~~To be added~~

(2) A holder of an early site permit may request a limited work authorization.

(b) *Early site permit*. (1) An application for a construction permit or combined license under this part may, but need not, reference an early site permit.

(2) An application for an early site permit under this part may be submitted prior to an application for a construction permit or a combined license in connection with the site for which the early site permit is sought.

(c) *Standard design approval.*

~~To be added~~

An application for a standard design approval under this part may, but need not, reference an operating license or custom combined license 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 this part may, but need not, reference an operating license or custom combined license that is essentially the same as the standard design for which certification is being requested.

~~To be added~~

(e) *Manufacturing license.* (1) A ~~commercial nuclear power~~manufactured reactor or manufactured reactor module manufactured under a manufacturing license (ML) issued under this part may only be transported to and installed at a site for which ~~either a construction permit (CP), operating license (OL), or~~ a combined license (COL) under this part has been issued. Manufactured reactor modules licensed for factory installation of fuel can only be shipped to sites for which an appropriate license, including for the possession of special nuclear material, has been issued.

(2) A manufacturing license applicant under this part may reference a standard design certification under § 53.1230 or a standard design approval under § 53.1200 in its application.

(3) ~~A manufacturing license applicant must comply with 10 CFR 53.620 for all manufacturing activities.~~

~~(4)~~ If licensed under this part for factory installation of fuel, a license for receipt, possession, handling, and storage of special nuclear material under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” must be obtained prior to receipt of the fuel at the manufacturer’s facility.

~~(g) *Construction permit.*~~

~~To be added~~

~~(h) *Operating license.*~~

~~To be added~~

~~(i) *Combined*~~(f) *Construction permit.* An application for a construction permit under this subpart may, but need not, reference a standard design certification or standard design approval issued under §§ 53.1230 and 53.1200 of this subpart, respectively, or an early site permit issued under § 53.1140 of this subpart. 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 construction permit that references a standard design certification issued under § 53.1230 of this subpart only if the entity that sponsored and obtained the certification supplies the design for the applicant's use.

(g) *Operating license.* (1) An application for an operating license under this part may, but need not, reference a standard design certification or standard design approval issued under §§ 53.1230 and 53.1200 of this subpart, respectively, or an early site permit issued under § 53.1140 of this subpart. 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 an operating license that references a standard design certification issued under § 53.1230 of this subpart only if the entity that sponsored and obtained the certification supplies the design for the applicant's use.

(2) The holder of a construction permit issued under § 53.1300 of this part must, at the time of submission of the final safety analysis report (FSAR), file an application for an operating license.

(h) *Combined licenses.* An application for a combined license under this subpart may, but need not, reference a standard design certification, standard design approval, or manufacturing license issued under §§ 53.1230, 53.1200, and 53.1270 of this

subpart, respectively, or an early site permit issued under § 53.1140 of this subpart. 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 combined license that references a standard design certification issued under § 53.1230 of this subpart only if the entity that sponsored and obtained the certification supplies the design for the applicant's use.

§ 53.1130 Limited work authorizations.

~~(a) *Requirement for construction permit, early site permit authorizing limited work authorization activities, combined license, or limited work authorization*. No person may begin the construction of a commercial nuclear plant on a site on which the facility is to be operated until that person has been issued either a construction permit or combined license under this Part, an early site permit under this Part authorizing the activities under paragraph (b) of this section, or a limited work authorization under paragraph (b) of this section.~~

~~(b~~(a) *Request for limited work authorization*. (1) Any person to whom the Commission may otherwise issue either a license or permit ~~-~~related to ~~an~~a commercial nuclear plant may request a limited work authorization 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 construction permit or combined license is otherwise required under ~~paragraph (a)~~§ 53.610 ~~of this section~~.

(2) An application for a limited work authorization may be submitted as part of a complete application for a construction permit or combined license in accordance with 10 CFR 2.101(a)(1) through (a)(5), or as a partial application in accordance with 10 CFR

2.101(a)(9). An application for a limited work authorization by the holder of an early site permit must be submitted as a complete application in accordance with 10 CFR 2.101(a)(1) through (a)(4).

(3) The application must include:

(i) A safety analysis report required by 10 CFR 53.130~~0~~9, or 10 CFR 53.141~~0~~ 6 of this chapter, 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 construction permit or combined license under this part but limited to those portions of the facility that are within the scope of the limited work authorization. The safety analysis report must demonstrate that activities conducted under the limited work authorization 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 limited work authorization;

(ii) An environmental report in accordance with § 51.49 of this chapter; and

(iii) A plan for redress of activities performed under the limited work authorization, should limited work activities be terminated by the holder or the limited work authorization be revoked by the NRC, or upon effectiveness of the Commission's final decision denying the associated construction permit or combined license application, as applicable.

(~~c~~b) *Issuance of limited work authorization*. (1) The Director of the Office of Nuclear Reactor Regulation may issue a limited work authorization only after:

(i) The NRC staff issues the final environmental impact statement for the limited work authorization in accordance with 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 limited work authorization, have been met. The applicant is technically qualified to engage in the activities authorized. Issuance of the limited work authorization 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 limited work authorization that would constitute good cause for withholding the authorization.

(2) Each limited work authorization will specify the activities that the holder is authorized to perform.

(~~d~~c) *Effect of limited work authorization*. Any activities undertaken under a limited work authorization are entirely at the risk of the applicant and, except as to the matters determined under paragraph (~~e)(1~~d) of this section, the issuance of the limited work authorization has no bearing on the issuance of a construction permit or combined license with respect to the requirements of the Act, and rules, regulations, or orders issued under the Act. The environmental impact statement for a construction permit or combined license application for which a limited work authorization was previously issued will not address, and the presiding officer will not consider, the sunk costs of the holder of limited work authorization in determining the proposed action (i.e., issuance of the construction permit or combined license).

(~~e~~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 limited work authorization 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 limited work authorization, or upon effectiveness of the Commission's final decision denying the associated construction permit application or the underlying combined license application, as applicable.

§ 53.1140 Early site permits.

Sections §§ 53.1141-53.1188 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 ~~nuclear power facilities~~reactor modules 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 or for a combined license 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 construction permit or a combined license 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. The site safety analysis report 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 subpart D of this part;

(vii) The location and description of any nearby industrial, military, or transportation facilities and routes;

(viii) The existing and projected future population profile of the area surrounding the site;

~~(ix) An analysis of licensing basis events associated with potential designs and their results, as described in § 53.240, considered in the design to determine compliance with the safety criteria in §§ 53.210 and 53.220, or more restrictive alternative evaluation criteria elected under § 53.470 of this part. This analysis description must address the elements in §§ 53.450(e) and 53.450(f), as applicable for the licensing basis events associated with potential designs that the applicant may be considering.~~ (ix) A description and safety assessment of the site on which a facility is to be located. The assessment must address the requirements of § 53.500.

(x) Information demonstrating that site characteristics are such that adequate security plans and measures can be developed;

(xi) A description of the quality assurance program required by ~~§ 53.1570~~subpart K of this part applied to site-related activities for the future design, fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site.

(2) A complete environmental report as required by 10 CFR 51.50(b).

(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 § 53.855 of this chapter, 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 of this chapter. 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~~be accompanied by 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, 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 a limited work authorization under 10 CFR 53.1130 be issued in conjunction with the early site permit. The application must include the information otherwise required by 10 CFR 53.1130.

(d) Each applicant for an early site permit 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.

§ 53.1149 ~~Standards for review~~Review of applications.

(a) *Standards for review of applications.* Applications filed under this subpart will be reviewed according to the applicable standards set out in 10 CFR Part 53. In addition, the Commission shall prepare an environmental impact statement during review of the application, in accordance with the applicable provisions of 10 CFR Part 51. The Commission shall determine, after consultation with FEMA as applicable, whether the information required of the applicant by § 53.1146(b)(1) shows that there is not 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 the applicable standards of § 53.855 of this chapter, 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.

~~§ 53.1152~~(b) *Administrative review of applications; hearings*.

An early site permit 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 shall 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 (ACRS).

The Commission shall refer a copy of the application for an early site permit to the ACRS. The ACRS shall report on those portions of the application which concern safety.

§ 53.1158 Issuance of early site permit.

(a) After conducting a hearing under § 53.~~1152~~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 meets 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 or combined license referencing an early site permit, the Commission shall 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 construction permit or combined license, shall be set forth as terms or conditions of the construction permit or combined license.

(c) The early site permit shall specify those 10 CFR 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 in accordance with 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 application or a combined license 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 construction permit or combined license 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 construction permit or combined license, a referenced early site permit is subsumed, to the extent referenced, into the construction permit or combined license.

§ 53.1167 Limited work authorization after issuance of early site permit.

A holder of an early site permit may request a limited work authorization in accordance with § 53.1146(c) of this part.

§ 53.1170 Transfer of early site permit.

An application to transfer an early site permit will be processed under 10 CFR 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 10 CFR 2.309. If a hearing is granted, notice of the hearing will be published in accordance with 10 CFR 2.309.

(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 § 53.116~~1~~4(b).

(d) The Commission shall refer a copy of the application for renewal to the ACRS. The ACRS shall report on those portions of the application which concern safety and shall apply the criteria set forth in § 53.1176.

§ 53.1176 Criteria for renewal.

(a) The Commission shall grant the renewal 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 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 site permit 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.

(b) A denial of renewal for failure to comply with 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 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, in accordance with 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 power plant, the Director may terminate the permit.

§ 53.1185 Reporting of defects and noncompliance; revocation, suspension, modification of permits for cause.

For purposes of 10 CFR part 21, § 53.605, and ~~10 CFR~~§ 53.1585, an early site permit is a construction permit.

§ 53.1188 Finality of early site permit determinations.

(a) *Commission finality*.

(1) While an early site permit is in effect under §§ 53.116~~1~~4 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 or combined license, or the findings required by § 53.1452, or in any enforcement hearing other than one initiated by the Commission under paragraph (a)(1) of this section, if the application for the construction permit or combined license references an early site permit, the Commission shall 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 power plant, the Commission shall 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 § 53.1565 of this chapter 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 power plant, the Commission shall treat as resolved changes that are equivalent to those that could be made under § 53.1565 of this chapter 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 construction permit, operating license, or combined license 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 construction permit, operating license, or combined license 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 ~~power~~ 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 shall 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 construction permit or combined license 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 shall meet the requirements of paragraph (a)(1) of this section.

(d) *Variances*. An applicant for a construction permit, operating license, or combined license 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 shall apply the same technically relevant criteria applicable to the application for the original or renewed early site permit. Once a

construction permit or combined license referencing an early site permit is issued, variances from the early site permit will not be granted for that construction permit or combined license.

(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 meet the requirements of 10 CFR 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 Advisory Committee on Reactor Safeguards of standard designs for a commercial nuclear plant under this part or major portions thereof.

§ 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 design for the entire facility or the design of major portions thereof.

§ 53.1206 Contents of applications for standard design approvals; general information.

The application must contain all of the information required by 10 CFR 53.1109 (a) through (c) and (j).

§ 53.1209 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. If an applicant seeks approval of a major portion of the design, the scope of the application for which approval is sought must include all functional design criteria ~~as can be identified at that stage of design.~~necessary to demonstrate compliance with the criteria in §§ 53.210, 53.220 and 53.450(e), as applicable, for the major portion 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 portion of the standard design for which NRC staff approval is sought, and functional or physical boundary conditions between the major portion 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, design certification, manufacturing license, or combined license application.

(a) *Final safety analysis report.* The application must contain a final safety analysis report (FSAR) that describes the facility~~, presents the design bases~~ and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility, or major portion 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 Subpart D 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) *General plant description*. A general description of the plant including reactor type, the intended use of the reactor, nuclear design (e.g., neutron spectrum, reactor~~

control, multi-module reactor control), overall layout of the plant including significant plant features and SSCs, maximum power level, and the nature and inventory of radioactive materials.

(3) *Design features–licensing basis events*. A description of the design features required by § 53.400 that, when combined with associated programmatic controls and human actions, demonstrate that the plant will satisfy the safety criteria defined in §§ 53.210 and 53.220. The description must also demonstrate how design features meet the requirements of § 53.440.

(4) *Design Features and Functional Design Criteria – Normal Operations*. A description of the functional design criteria for each design feature required by § 53.425 to demonstrate that the safety criteria defined in § 53.260 are not exceeded during normal operations.

(5) *Functional Design Criteria – Licensing Basis Events*. A description of the functional design criteria required by §§ 53.410 and 53.420 for each design feature required by § 53.400 to demonstrate that the safety criteria defined in §§ 53.210 and 53.220 are met during licensing basis events.

(6) *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 meet 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 *information.* Except as specified in this paragraph, an application for a multi-module nuclear power reactor design, 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 a

given module to ensure the safe operation of the overall nuclear plant to be licensed under this part.

(7) *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 for each design feature relied upon to demonstrate compliance with § 53.270.

(8) *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(a) are not exceeded.

(9) *Codes and Standards*. A description of generally accepted consensus codes and standards used to design the design features required to meet the safety criteria defined in §§ 53.210 and 53.220, as required by § 53.440(a), to the extent generally accepted engineering consensus codes and standards are applied to the design of the reactor.

(10) *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(b).

(11) *Safety and Security*. A description of how safety and security were considered together in the design process such that, where possible, security issues were effectively resolved through design and engineered security features, as required by § 53.440(c).

(12) *Probabilistic Risk Assessment*. A description of the probabilistic risk assessment (PRA) required by § 53.450(a) and its results.

(13) *Analyses*. A description of the analyses performed to meet the requirements in § 53.450(b)-53.450(g) that includes the following information:

~~(i) A description of the analysis of licensing basis events and their results, as described in § 53.240, considered in the design to determine compliance with the safety criteria in §§ 53.210 and 53.220. This analysis description must include the following:~~

~~(A) Address the elements in §§ 53.450(e) and 53.450(f)~~

~~(B) In accordance with § 53.460(c):~~

~~(1) Describe any human actions that are necessary to prevent or mitigate licensing basis events;~~

~~(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 Subpart F of this part.~~

~~(ii) For an application for~~ standard design approval ~~of~~for a ~~multi-module~~ commercial nuclear plant ~~design, the possible operating configurations of the reactor modules, including common systems, interface requirements, and system interactions, as required by 53.440(i).~~

~~(iii) (A) The classification of SSCs and human actions according to their safety significance in accordance with § 53.460(a).~~

~~(B) For SR and NSRSS SSCs and human actions, the conditions under which they must perform their safety functions required by § 53.230, including environmental conditions.~~

~~(C) A description of how SSCs needed to ensure compliance with the safety criteria defined in § 53.210 are designed to withstand the effects of external hazards as required by § 53.510.~~

~~(iv) The defense-in-depth measures required by § 53.250.~~

~~(v) 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).~~

(vi) Events that challenge plant control and safety systems whose failure could lead to an undesirable end state and/or radioactive material release. These include internal events, such as human errors and equipment failures, and external events, such as earthquakes, identified in accordance with Subpart D of this part, as required by § 53.450(b)(5).

(vii) The analytical codes used in modeling plant behavior in analyses of licensing basis events (e.g., thermodynamics, reactor physics, fuel performance, mechanistic source term) and how these codes are qualified for the range of conditions for which they were used, as required by § 53.450(d).

(viii) If not described in addressing paragraph (14)(i) above, the results of other analyses required by § 53.450(g).

(14) *Special Treatments*. A description of special treatment (e.g., functional design criteria and programmatic controls) established as required by § 53.460 to provide appropriate confidence that the SSCs will perform under the service conditions and with the reliability assumed in the analysis performed in accordance with § 53.450 to provide reasonable assurance of meeting the safety criteria in §§ 53.210 and 53.220.

(15) *Analytical Margins*. A description of any alternative evaluation criteria more restrictive than those defined in §§ 53.220 and 53.450(e) adopted to demonstrate analytical margins supporting operational flexibilities, if applicable, that are incorporated into design features and programmatic controls, and that are maintained within programs required in other Subparts, as required by § 53.470.

(16) *Quality Assurance*. A description of the quality assurance program applied to the design of the structures, systems and components of the commercial nuclear plant, as required by § 53.460(b). The description of the quality assurance program for a

~~commercial nuclear plant must include a discussion of how the applicable requirements of Subpart K of this part are satisfied.~~

~~(17) *Design Features and Controls to Address the Minimization of Contamination*. The~~ must include the design information equivalent to that required ~~by § 20.1406 of this chapter.~~

~~(18) *Interface Requirements*. A description, analysis, and evaluation of the interfaces between the~~for a standard design ~~and the balance~~certification as defined in §~~§~~ 53.1239(a)(2)-(26) for those portions of ~~the~~a commercial nuclear ~~power~~ plant ~~that may impact the ability of the plant to meet the functional~~included in the standard design ~~criteria, performance objectives, or the safety criteria required in §§ 53.210 or 53.220~~approval.

~~(b) *Other Application Content*.~~

§ 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) *Technical Specifications*. Proposed technical specifications prepared in accordance with the requirements of § 53.710(a) of this chapter for those areas addressed by the design approval.~~

~~(2) *Availability Controls* (if not included in the FSAR). A description of the controls on plant operations, including availability controls, to provide reasonable assurance that the configurations and special treatments for NSRSS SSCs provide the capabilities and reliabilities required to satisfy the safety criteria of § 53.220~~ (1) *Availability Controls (if not included in the FSAR)*. A description of the controls on plant operations, including availability controls, to provide reasonable assurance that the configurations and special

treatments for NSRSS SSCs provide the capabilities and reliabilities required to satisfy the safety criteria of § 53.220.

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(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 a Design Integrity Assessment Program that addresses the elements described in § 53.440(c).

(52) *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.

(cb) 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.

(dc) 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(da).

§ 53.1212 ReviewStandards for review of applications.

Applications filed under this section will be reviewed for compliance with the standards set out in 10 CFR parts 20, 53, and 73.

§ 53.1215 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

The Commission shall refer a copy of the application to the ACRS. The ACRS shall 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 ~~this section~~§§53.1200 through 53.1221 and receipt of a report by the Advisory Committee on Reactor Safeguards under § 53.1215 of this section, the NRC staff shall 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) Duration of design approval. 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 or an operating license under this part ~~53~~ or a combined license or manufacturing license under this part ~~53~~ that references the final 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 review of any standard design certification or individual facility license application that incorporates by reference a standard design approved in accordance with this paragraph 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 10 CFR 53.1580 and must be approved by the Executive Director for Operations or his or her designee before issuance of the request.

(d) The Commission will require, before granting a construction permit, combined license, operating license, or manufacturing license which references a standard design approval, that information supporting required design and analysis application content be completed and available for audit if the information is necessary for the Commission to make its safety determinations, 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.

Section 53.1230 through 53.1263 sets forth the requirements and procedures applicable to Commission issuance of rules granting standard design certifications for commercial nuclear plants licensed 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 10 CFR 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. The Commission will require, before design certification, that information supporting required design and analysis application content 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, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components (SSCs), and must include the following information:

(1) *Site Parameters*. The site parameters postulated for the design in accordance with Subpart D 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*) 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-module reactor control), overall layout of the plant including significant plant features and SSCs, maximum power level and the nature and inventory of radioactive materials.

(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 associated programmatic controls and human actions, demonstrate that the plant will satisfy the safety criteria defined in §§ 53.210 and 53.220. The, or more restrictive alternative criteria adopted under § 53.470 of this part, during licensing basis events.

(ii) A description must also demonstrateof how design features meet the requirements of § 53.440.(a) – (i) and (k) – (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 that the criteria defined in § 53.260 are not exceeded during normal operations.

(5) *Design Features and Functional Design Criteria – aircraft impact*. (i) A description of the functional design criteria for each design feature required by § 53.425 to demonstrate that the safety criteria defined in § 53.260 are not exceeded during normal operations.

(5) *Functional Design Criteria – Licensing Basis Events*. A description of the functional design criteria required by §§ 53.410 and 53.420 for each design feature required by § 53.400440(j) to demonstrate that the safety criteria defined in §§ 53.210

and 53.220 are met during licensing basis eventsaddress the impact of a large, commercial aircraft.

(ii) A description of how these design features and functional design criteria meet the requirements in § 53.440(j).

(6) 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 meet 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 of this part, and necessary to maintain consistency with analyses required by § 53.450.

(ii) For an application for a multi-module commercial nuclear power reactor designplant, 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 aany given module to ensure the safe operation of the overall commercial nuclear plant to be licensed under this part.

(7(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 for each design feature relied upon to demonstrate compliance with § 53.270.

(~~8~~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~~(a)~~ are ~~not exceeded~~satisfied.

(~~9~~11) *Codes and Standards*. A description of generally accepted consensus codes and standards used to design the design features ~~required to meet the safety criteria defined in §§ 53.210 and 53.220, ~~, as required by § 53.440(~~a), to the extent generally accepted engineering consensus codes and standards are applied to the design of the reactor.~~b).

(~~10~~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(~~b~~c).

~~(11~~ (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*. A description of how safety and security were considered together in the design process ~~such that, where possible, security issues were effectively resolved through design and engineered security features~~, as required by § 53.440(~~c~~e).

~~(12~~ (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-module commercial nuclear plant, the possible operating configurations of the reactor modules, 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 § 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 Assessment*. A description of the probabilistic risk assessment (PRA) required by § 53.450(a), and its results.

(~~13~~19) *Analyses*. A description of the analyses performed to meet the requirements in §§ 53.450(b) – 53.450(g), that includes the following information:

(i) A description of the analysis of licensing basis events and ~~their~~its results, as described in § 53.240~~, considered in the design to determine compliance with the safety criteria in §§ 53.210 and 53.220.~~. This analysis description must:

(A) Address the elements in §§ 53.450(e) and 53.450(f~~)~~); and

(B) In accordance with § 53.460(c):

(*1*) Describe any human actions that are necessary to prevent or mitigate licensing basis events;

(*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 Subpart F of this part.

~~(ii) For an application for standard design certification of a multi-module commercial nuclear plant design, the possible operating configurations of the reactor modules, including common systems, interface requirements, and system interactions as required by § 53.440(i).~~

~~(iii) (A) The classification of SSCs and human actions according to their safety significance in accordance with § 53.460(a).~~

~~(B) For SR and NSRSS SSCs and human actions, the conditions under which they must perform their safety functions required by § 53.230, including environmental conditions.~~

(C(ii)(A) A description of how SSCs needed to ensure the safety criteria defined in § 53.210 are designed to withstand the effects of external hazards as required by § 53.510.

(iv (B) The information necessary to demonstrate that the commercial nuclear plant complies with the earthquake engineering criteria in § 53.480.

(iii) The defense-in-depth measures required by § 53.250.

(viv) 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).

(viiv) Events that challenge plant control and safety systems whose failure could lead to an undesirable end state and/or radioactive material release. These include internal events, such as human errors and equipment failures, and external events, such as earthquakes, identified in accordance with Subpart D of this part, as required by § 53.450(b)(45).

(viii) The analytical codes used in modeling plant behavior in analyses of licensing basis events (e.g., thermodynamics, reactor physics, fuel performance, mechanistic source term) and how these codes are qualified for the range of conditions for which they were used, as required by § 53.450(d).

(viiii) If not described in addressing paragraph (13)(i) above, the results of other analyses required by § 53.450(g).

(14(20) *Special Treatments*. A description of special treatment (e.g., functional design criteria and programmatic controls)treatments established as required by § 53.460 to provide appropriate confidence that the SSCs will perform under the service conditions and with the reliability assumed in the analysis performed in accordance with § 53.450 to provide reasonable assurance of meeting the safety criteria in §§ 53.210 and 53.220.

(~~15~~21) *Analytical Margins*. A description of any alternative ~~evaluation criteria more restrictive than those defined in §§ 53.220 and 53.450(e)~~criteria adopted to demonstrate analytical margins supporting operational flexibilities, if applicable, ~~that are incorporated into design features and programmatic controls, and that are maintained within programs required in other Subparts,~~ as required § 53.470.

(~~16~~22) *Quality Assurance.* A description of the quality assurance program applied to the design of the structures, systems and components of the commercial nuclear plant, as required by § 53.460(b). The description of the quality assurance program for a commercial nuclear plant must include a discussion of how the applicable requirements of Subpart K of this part were satisfied.

(23) *Design Features and Controls to Address the Minimization of Contamination.* The information required by § 20.1406 of this chapter.

(~~18~~24) *Interface Requirements*. (i) A description analysis, and evaluation of the interfaces between the standard design and the balance of the commercial nuclear power plant that may impact the ability of the plant to meet the functional design criteria, performance objectives or the safety criteria required in §§ 53.210 or 53.220, or more restrictive alternative criteria adopted under § 53.470 of this part.

~~(b) *Other Application Content*. In addition to the FSAR, the application must also include the following:~~

~~(1) *Environmental report*. An environmental report as required by 10 CFR 51.55.~~

~~(2) *Technical Specifications*. Proposed technical specifications prepared in accordance with the requirements of § 53.710(a) of this chapter for those areas addressed by the design certification.~~

~~(3~~ (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 ITAAC required by § 53.1241.

(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 paragraph (a)(24)(i) of this section.

(25) *Availability Controls (if not included in the FSAR)*. A description of the controls on plant operations, including availability controls, to provide reasonable assurance that the configurations and special treatments for NSRSS SSCs provide the capabilities and reliabilities required to satisfy the safety criteria of § 53.220.

(4) *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.

(5(26) *Technical Specifications*. Proposed technical specifications prepared in accordance with the requirements of § 53.710(a) of this chapter for those areas addressed by the design certification.

§ 53.1241 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 10 CFR 51.55.

(2) *Availability Controls* (if not included in the FSAR). A description of the controls on plant operations, including availability controls, to provide reasonable assurance that the configurations and special treatments for NSRSS SSCs provide the capabilities and reliabilities required to satisfy the safety criteria of § 53.220, or more restrictive alternative criteria adopted under § 53.470 of this part.

(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.

~~(6) *Integrity Assessment Program*. A description of a Design Integrity Assessment Program that addresses the elements described in §§ 53.440(c).~~

~~(7~~ (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.

(~~c~~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.

(~~d~~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(~~d~~a).

§ 53.1242 Review of applications.

(a*) Standards for review of applications.* Applications filed under this subpart will be reviewed for compliance with the standards set out in 10 CFR parts 20, 51, 53, and 73.

~~*(b) 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 review will follow the processes for referencing a standard design approval, to the extent practicable.~~

~~(c~~ (b) *Administrative review of applications.* (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 shall initiate the rulemaking after an application has been filed under § 53.1233 and shall 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 ~~(a),~~ the Commission decides that a legislative hearing should be held, the information required by § 2.1502(c) 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 shall publish a document in the *Federal Register* of its decision to hold a legislative hearing. The document shall contain the information specified in ~~paragraph (c) of this section~~§ 2.1502(c) and specify whether the Commission or a presiding officer will conduct the legislative hearing.

(3) Notwithstanding anything in § 2.390 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 shall 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 (ACRS).

The Commission shall refer a copy of the application to the ACRS. The ACRS shall 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 Advisory Committee on Reactor Safeguards under § 53.1245, 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 meets the applicable standards and requirements of the Atomic Energy 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 shall 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, as applicable.

§ 53.1251 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 ~~issuance~~the rule.

(b) A standard design certification continues to be valid beyond the date of expiration in any proceeding on an application for a combined license or an operating license 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 combined license that references the design certification.

(c) An applicant for a construction permit, operating license, combined license, or ~~a~~ manufacturing license 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 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, in accordance with the provisions of § 53.1251.

(c) The Commission shall refer a copy of the application for renewal to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS shall report on those portions of the application which concern safety and shall apply the criteria set forth in § 53.1257.

§ 53.1257 Criteria for renewal.

(a) The Commission shall 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 Atomic Energy Act 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 shall grant the amendment request if it determines that the amendment will comply with the Atomic Energy Act 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)~~,~~ ~~w~~While a standard design certification rule is in effect under § 53.~~1248~~1251 or § 53.1260, 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) Is necessary to correct material errors in the certification information; or

(v) 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.

(2)(i) In a rulemaking under § 53.1248, 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)(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 § 53.1248, 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 shall 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, in making the findings required for issuance of a combined license, construction permit, operating license, or manufacturing license, or for any hearing under § 53.1452, the Commission shall treat as resolved those matters resolved in connection with the issuance or renewal of a design certification rule.

(b) The Commission will require, before granting a construction permit, combined license, operating license, or manufacturing license which references a design certification rule, that information normally supporting required design and analysis application content be completed and available for audit if the information is necessary for the Commission to make its safety determinations, 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 53.129~~1~~5 set out the requirements and procedures applicable to Commission issuance of a license under 10 CFR Part 53 authorizing manufacture of multiple ~~commercial nuclear~~manufactured reactors or manufactured reactor modules to be installed at sites not identified in the manufacturing license application. ~~The commercial nuclear reactor modules authorized for manufacture may be fueled at the place of manufacture, if authorized in the license, or be transported without fuel.~~

§ 53.1273 Filing of applications.

(a) Any person, except one excluded by § 53.1118, may file an application for a manufacturing license under this section with the Director, Office of Nuclear Reactor Regulation.

(b) Applications related to manufactured reactor modules for which fuel is to be installed at the manufacturer's facility and ~~fueled~~ the manufactured reactor modules are to be transported to a licensed site must also possess, apply for, or reference licenses and certifications required by 10 CFR Parts 70 and 71.

§ 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 ~~in final safety analysis report.~~.

(a) *Final safety analysis report~~.~~ siting and design.* The application must include a final safety analysis report 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 manufacturing and installation specifications by an applicant who seeks to use the manufactured reactor or manufactured reactor module, and permit the preparation of acceptance and inspection requirements by the NRC. The application must include the following information:

~~(b)~~ (1) *Site Parameters.* The site parameters postulated for the design in accordance with Subpart D 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.* ~~(1) The application must include~~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)-(26) for those portions of a commercial nuclear plant included in the ~~reactor module to be~~ manufactured~~.~~

~~(2) In addition to the design information for the nuclear reactor~~ reactor or manufactured reactor module ~~required by paragraph (b)(1) of this section, the final safety analysis report must also provide:~~ .

~~(i)~~(3) *Quality assurance program.* A description of the quality assurance program, as required by § 53.620(a)(6), applied to the design, fabrication, and testing of the structures, systems, and components of the manufactured reactor or manufactured reactor module;

~~(ii)~~(4) *Conceptual designs*. Representative conceptual designs for one or more commercial nuclear plants using the manufactured reactor ~~modules~~or manufactured reactor module;

~~(iii)~~(5) *Operating configurations*. If multiple ~~nuclear~~manufactured reactors or manufactured reactor modules may be installed at a commercial nuclear plant, a description of the possible operating configurations ~~of the modules with~~, 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 or manufactured reactor module to ensure the safe operation of any ~~module~~ commercial nuclear reactor already operating;

(~~3~~)(i6) *Interface requirements.* ~~Applications for a manufacturing license must describe the~~(i) The interface requirements between the manufactured reactor or manufactured reactor module and the remaining portions of the commercial nuclear power plant or connections to other facilities outside of the commercial nuclear plant.

(ii) ~~Interface~~Confirmation that interface requirements ~~must be~~are verifiable through inspections, testing, or analysis ~~and~~. These requirements must be sufficiently detailed to allow for completion of the final safety analysis by license applicants that reference the ~~nuclear~~manufactured reactor or manufactured reactor module manufactured under this subpart. Applicants for ~~an OL under § 53.1360 or~~a COL under § 53.1410 will need to verify the interface requirements at the installation site. ~~Where appropriate, the~~ The method to be used for verification of interface requirements ~~will need to be addressed under the processes for inspections, testing, analyses and acceptance criteria (ITAAC) for COL applicants under § 53.1410.~~

~~(iii) Applications for a manufacturing license referencing a standard design certification under § 53.1230~~ must ~~describe the disposition~~be included as part of ~~ITAAC~~

~~contained in the certified design, including those to be completed at the manufacturing facility and those that would be completed at the installation site. ITAAC to be addressed at the installation site will need to be addressed~~the proposed ITAAC required by ~~applications for an OL under § 53.1360 or COL under § 53.1410.~~ § 53.1282.

(~~iv~~iii) The final safety analysis report must identify potential pathways for radionuclides produced within the manufactured reactor or manufactured reactor module to enter interfacing systems to support development of radiation monitoring programs required under Subpart F.

(~~c~~)b) *Final safety analysis report -* *Manufacturing information*. The ~~application~~*final safety analysis report* 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 or manufactured reactor module~~, as required by Subpart E~~. The description should clearly define which activities are proposed to be within the scope of the manufacturing license and those, such as the making of a component to be procured from a separate company for installation in the manufactured reactor module, that are not considered to be within the scope of the manufacturing license.

(2) A description of the organizational and management structure singularly responsible for direction of design and manufacture of the manufactured reactor or manufactured reactor modules. The information should include a description of the management plan, technical qualifications, and controls in place to meet the requirements of § 53.620, including those for any facility performing an activity within the scope of the manufacturing license.

(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 ~~nuclear~~manufactured reactor, portions of the manufactured reactor, or the manufactured reactor module. Where applicable, the description should identify where the inspections and tests are used to close ITAAC from a standard design ~~approvals~~certification issued under § 53.~~1200 or standard design certifications under § 53.1230~~1248 referenced in the application for a manufacturing license.

(~~d~~c) *Deployment of the completed ~~nuclear~~manufactured reactor or manufactured reactor module*. The application must include the following information related to the deployment of a manufactured ~~nuclear~~reactor or manufactured reactor module:

(1) Procedures governing the preparation of the manufactured reactor, portions of the manufactured reactor, or manufactured reactor module for shipping to the site where it is to be operated, the conduct of shipping, and verifying the condition of the ~~manufactured reactor module~~shipped items upon receipt at the site;

(2) Details of the interaction of the design ~~and manufacture within the applicant's organization and the manner by which the applicant will ensure close integration between the designer and any party involved in the manufacture of a reactor module;~~

~~(3) Details of the interaction of the design~~, manufacture, and installation of a manufactured reactor or manufactured reactor module within the applicant's organization and the manner by which the applicant will ensure close integration between the designer, ~~manufacturer~~contractors, and any facility in which the manufactured reactor or manufactured reactor module is to be installed;

(~~4~~3) A description of the measures used for the control of interfaces, including the consideration of key site parameters, ~~among~~between the ~~designer,~~holder of the

~~manufacturer~~manufacturing license and the ~~owner/operator~~holder of the combined license for the commercial nuclear plant~~, as required by § 53.490~~ at which the manufactured reactor or manufactured reactor module is to be installed;

~~(5) Confirmation that the interface requirements for the manufactured reactor are verifiable through inspections, testing or analysis and that they can be incorporated into the safety analysis for a CP, OL or COL. Where appropriate, the verification of interface requirements will need to address ITAAC for standard design certifications referenced in a manufacturing license and deployed to a site with a CP, OL, or COL. Certain verifications may also need to be addressed, as applicable, under the processes for ITAAC for COL applicants under § 53.1410.~~

~~(6) A description of the proposed post-construction inspections, tests, analyses and verifications, including acceptance criteria, that are necessary and sufficient to provide reasonable assurance that the manufactured reactor was built as designed and is compatible with the rest of the plant. If the application references a standard design certification issued under § 53.1248, the ITAAC contained in the certified design must apply to those portions of the manufactured reactor covered by the standard design certification.~~

~~(e~~ (d) *Special considerations for factory fueling.* In addition to the above paragraphs, an application for a manufacturing license for a ~~nuclear~~manufactured reactor module that includes the installation of fuel at the factory must include the following information related to the fueling operations and the needed precautions to prevent inadvertent criticality and to otherwise ensure the safety of workers and the public during the manufacture, storage, and transport of ~~the nuclear~~each manufactured reactor module:

~~(1) The application for a manufacturing license for a nuclear reactor module must include a~~(1) A description of the safety program and integrated safety analysis required

by Subpart H of Part 70 of this Chapter. The description shall include the procedures to be used for receipt, storage and loading of the fuel into the manufactured ~~nuclear~~ reactor module. The description may be in the form of a reference to the applicable Part 70 application and license, if issued, or within the safety analysis report supporting the manufacturing license if a combined application is used for the manufacturing license and Part 70 license.

(i) The application should specifically address the measures taken for fuel loading, in-factory inspections and non-nuclear testing, including precautions to be taken to prevent inadvertent criticality, and an analysis of the safety and security of the ~~nuclear~~manufactured reactor module within the factory, during possible periods of storage, and during transportation to the licensed site. The storage and transport of a fueled manufactured reactor module must comply with applicable regulations in Parts 70, 71, and 73 of this chapter.

(ii) The application should specifically address the functional design criteria and design features included in the manufactured ~~nuclear~~ reactor module or physical or programmatic ~~measures added to the module~~controls implemented, during manufacturing, storage, or transport to prevent inadvertent criticality during various conditions ~~and~~, including when subject to potential hazards and human errors.

(2) A description of the procedures governing the transfer of authorities and responsibilities for the manufactured ~~nuclear~~ reactor module from the holder of the manufacturing license to the holder of the ~~licenses~~COL for the installation site.

(3) A description of the controls needed to meet the requirements of § 53.620 to address the receipt, storage, and loading of special nuclear material into a manufactured reactor module, including:

(i) The fitness for duty program, in accordance with § 53.620(a)(~~4~~5) and 10 CFR part 26.

(4ii) A Radiation Protection Program in accordance with § 53.620(a)(7).

(5iii) An information security program in accordance with § 53.620(a)(8).

(6) A cyber security program in accordance with § 53.620(a)(9).

(7(iv) A physical security program in accordance with § 53.620(b)(1)(iv)(Ec)(5).

(8v) A fire protection program in accordance with § 53.620(b)(1)(iv)(Bc)(2).

(9vi) An emergency plan in accordance with § 53.620(b)(1)(iv)(Cc)(3).

(10vii) A description of the plant staff training program in accordance with § 53.620(b)(1)(iv)(Dd).

§ 53.1282 Contents of applications for manufacturing licenses; other application content.

The application must contain:

(a)(1) *Inspections, tests, analyses, and acceptance criteria (ITAAC)*. The proposed inspections, tests, and analyses that the licensee who will be operating the reactor shall 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 or reactor module has been manufactured in conformity with the manufacturing license; the provisions of the Act, and the Commission's rules and regulations; and

(ii) The manufactured reactor or manufactured reactor module 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 ~~an~~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 § 53.1321 must indicate that the application includes this notification.

(b) *Environmental report*. (1) An environmental report as required by 10 CFR 51.54.

(2) If the manufacturing license application references a standard design certification, the environmental report need not contain a discussion of severe accident mitigation design alternatives for the manufactured reactor or manufactured reactor module as used in a commercial nuclear plant. Nonetheless, an application for a manufacturing license that references a standard design certification ~~that~~but includes the installation of fuel at the factory must discuss severe accident mitigation design alternatives for the reactor module while at the factory and must also discuss severe accident mitigation alternatives for the factory itself.

(c) *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.

(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 § 53.440(a).

§ 53.1285 Review of applications.

(a) *Standards for review* ~~of applications, referral to ACRS, and issuance of a manufacturing license.~~

~~(a) *Review* of applications.~~ Applications filed under this subpart 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 a manufacturing license 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 module or an evaluation of alternative energy sources. All hearings on manufacturing licenses are governed by the hearing procedures contained in 10 CFR part 2, subparts C, E, G, L, and N.

~~(c)~~

§ 53.1286 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

The Commission shall refer a copy of the application to the ACRS. The ACRS shall report on those portions of the application which concern safety.

~~(d)~~

§ 53.1287 Issuance of manufacturing license. ~~(1~~

(a) After completing any hearing under this section, and receiving the report submitted by the ACRS, the Commission may issue a manufacturing license if the Commission finds that:

(~~i~~1) Applicable standards and requirements of the Act and the Commission's regulations have been met;

(~~ii~~2) There is reasonable assurance that the manufactured reactor or manufactured reactor modules will be manufactured, and can be transported, incorporated into a commercial nuclear plant, and operated in conformity with the manufacturing license, the provision of the Act, and the Commission's regulations;

(~~iii~~3) The proposed manufactured reactor or manufactured reactor modules 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 or manufactured reactor modules without undue risk to the health and safety of the public;

(~~iv~~4) The applicant is technically qualified to design and manufacture the proposed ~~nuclear power~~manufactured reactor or manufactured reactor modules;

(~~v~~5) The proposed inspections, tests, analyses and acceptance criteria are necessary and sufficient, within the scope of the manufacturing license, to provide reasonable assurance that the manufactured reactor or manufactured reactor module has been manufactured and will be operated in conformity with the license, the provisions of the Act, and the Commission's regulations;

(~~vi~~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

(~~vii~~7) The findings required by subpart A of part 51 of this chapter have been made.

(~~2~~b) Each manufacturing license issued under this subpart shall specify:

(~~i~~1) Terms and conditions as the Commission deems necessary and appropriate;

(~~ii~~2) Technical specifications for operation of the manufactured reactor or manufactured reactor module, as the Commission deems necessary and appropriate;

(~~iii~~3) Site parameters and design characteristics for the manufactured reactor or manufactured reactor module; and

(~~iv~~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 or manufactured reactor module.

(~~3)(i~~c)(1) A holder of a manufacturing license may not transport or allow to be removed from the place of manufacture the manufactured reactor or manufactured reactor module except to the site of a licensee with ~~either a construction permit, operating license, or~~ a combined license under subpart H of this part. ~~The construction permit, operating license or~~The combined license must authorize the construction and operation of a nuclear power facility using the manufactured reactors or manufactured reactor modules.

(~~ii~~2) A holder of a manufacturing license shall include, in any contract governing the transport of a manufactured reactor, portions of the manufactured reactor, or manufactured reactor module from the place of manufacture to any other location, a provision requiring that the person or entity transporting the ~~manufactured reactor module to~~items comply with all NRC-approved shipping requirements in the manufacturing license.

§ 53.1288 Finality of manufacturing licenses; information requests.

(a)(1) Notwithstanding any provision in 10 CFR 53.1590, during the term of a manufacturing license the Commission may not modify, rescind, or impose new requirements on the design of the ~~nuclear~~manufactured reactor or manufactured reactor module ~~being manufactured~~, or the requirements for the manufacture of the nuclear manufactured reactor or manufactured reactor module, unless the Commission determines that a modification is necessary to bring the design of the reactor module or its manufacture into compliance with the Commission's requirements applicable and in effect at the time the manufacturing license 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 ~~nuclear~~reactor or manufactured reactor module which is imposed by the Commission under paragraph (a)(1) of this section will be applied to all manufactured reactor or reactor modules manufactured under the license, including those that have already been transported and sited, except those manufactured reactors or manufactured reactor modules 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 ~~construction permit, operating license,~~ combined license, 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 ~~nuclear~~manufactured reactor or manufactured reactor module manufactured under this subpart is referenced or used, the Commission shall treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the manufacturing license, including the adequacy of design of the manufactured reactor or manufactured reactor module, 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 or manufactured reactor module to be manufactured.

(b~~)(1) The holder of a manufacturing license may not make changes to the design of the nuclear reactor module authorized to be manufactured without prior Commission approval. The request for a change to the design must be in the form of an application for a license amendment, and must meet the requirements of §§ 53.1510, 53.1520, and as applicable 53.1525.~~

~~(2)~~ An applicant ~~or licensee~~ who references or uses a ~~nuclear~~ manufactured reactor or manufactured reactor module manufactured under a manufacturing license under this subpart 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 module ~~in accordance with § 53.1530~~.

~~(c) Except for information requests seeking to verify compliance with the current licensing basis of either the manufacturing license or the manufactured reactor module, information requests to the holder of a manufacturing license or an applicant or licensee using a manufactured reactor module 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 must be in accordance with § 53.1580 and must be approved by the Executive Director for Operations or his or her designee before issuance of the request.~~

§ 53.1291 Duration~~, transfer, and renewal~~ of manufacturing licenses.

~~(a) *Duration.*~~ A manufacturing license issued under this subpart may be valid for not less than 5, nor more than 15 years from the date of issuance. Upon expiration of the manufacturing license, the manufacture of any uncompleted manufactured reactors or manufactured reactor modules must cease unless a timely application for renewal has been docketed with the NRC.

~~(b)~~

§ 53.1293 Transfer~~.~~ of manufacturing licenses.

A manufacturing license may be transferred in accordance with § 53.1570 of this chapter.

~~(c)~~

§ 53.1295 Renewal. (1 of manufacturing licenses.

(a)(i) Not less than 12 months, nor more than 5 years before the expiration of the manufacturing license, or any later renewal period, the holder of the manufacturing license 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.

(ii) The filing of an application for a renewed license must be in accordance with subpart A of 10 CFR part 2 and 10 CFR 53.1100.

(iii) A manufacturing license, 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 in accordance with § 53.1291(a), the holder of a manufacturing license may not begin manufacture of a manufactured reactor or manufactured reactor module less than 6 months before the expiration of the license.

(iv) Any person whose interest may be affected by renewal of the permitlicense may request a hearing on the application for renewal. The request for a hearing must comply with 10 CFR 2.309. If a hearing is granted, notice of the hearing will be published in accordance with 10 CFR 2.104.

(v) The Commission shall refer a copy of the application for renewal to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS shall report on those portions of the application which concern safety and shall apply the criteria set forth in § 53.1285.

(2b) The Commission may grant the renewal if the Commission determines:

(i) The manufacturing license complies with the Atomic Energy Act, as amended, and the Commission's regulations and orders applicable and in effect at the time the manufacturing license was originally issued; and

(ii) Any new requirements the Commission may wish to impose are:

(A) Necessary for adequate protection to public health and safety or common defense and security;

(B) Necessary for compliance with the Commission's regulations and orders applicable and in effect at the time the manufacturing license was originally issued; or

(C) 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.

(~~3~~c) A renewed manufacturing license may be issued for a term of not less than 5, nor more than 15 years, plus any remaining years on the manufacturing license then in effect before renewal. The renewed license shall be subject to the requirements of § 53.1288.

§ 53.1300 Construction permits.

Sections 53.1300 through 53.1348 set out the requirements and procedures applicable to Commission issuance of a construction permit for commercial nuclear plants. A construction permit for the construction of a commercial nuclear plant under this part will be issued before the issuance of an operating license if the application is otherwise acceptable and will be converted upon completion of the facility and Commission action, into an operating license as provided under §§ 53.1360 through 53.1405.

~~**§ 53.1303 Relationship to other sections.**~~

~~An application for a construction permit under this part may, but need not, reference an early site permit, standard design approval, manufacturing license, or standard design certification issued under this part.~~

§ 53.1306 Contents of applications for construction permits; general information.

An application for a construction permit must supplement the information required by § 53.1109 with 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 ~~§ 53.1670~~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. The applicant must submit estimates of the total construction costs and related fuel cycle costs of the facility and shall indicate the source(s) of funds to cover these costs.

(2) Each application for a construction permit 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 ~~it~~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; 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 an applicant's ability to continue the conduct of the activities authorized by the construction permit 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 ~~in preliminary safety analysis report~~.

(a) *Preliminary safety analysis report.* The application must contain a preliminary safety analysis report (PSAR) that describes the facility~~, presents the design bases~~ and the limits on its operation, and presents a preliminary safety analysis of the structures, systems, and components of the facility as a whole. The PSAR shall 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:

(~~a~~1) *Site information.* An application for a construction permit 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)-(~~viii~~x).

(~~b~~2) *Design information*. Except as specified in this paragraph, an application for a construction permit for a commercial nuclear ~~reactor~~plant must include the design information equivalent to that required for a standard design certification as defined in §§ 53.1239(a)(2)-(~~19~~26).

(~~1~~i) *Quality assurance program.* A description of the quality assurance program, as required by § 53.610(a)(~~7~~6), applied to the design, fabrication, construction and testing of the structures, systems and components of the facility.

(2ii) *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 required in § 53.1369 that supports an application for an operating license.

(3iii) *Planned research or testing*. Descriptions of how design features and related functional design criteria will fulfil the safety criteria in Subpart B, or more restrictive alternative criteria adopted under § 53.470 of this part, and how that have 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 construction permit, 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 operating license.

(4iv) *Programmatic controls and interfaces.* Descriptions of the programmatic controls and interfaces may include those expected to be provided in the final safety analysis report or other licensing basis documents because they are necessary to achieve and maintain the reliability and capability of SSCs relied upon to meet the established safety criteria, and functional design criteria, and performance objectives required in Subpart B, and to maintain consistency with analyses required by § 53.450.

(c3) *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.

(d4) *Emergency preparedness*. 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 shall be described:

~~(e~~(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, and Federal governmental agencies with responsibility for coping with emergencies, including identification of the principal agencies.

(iii) Protective measures to be 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 and local governments and the public in the event of an emergency. A nuclear power plant applicant with an EPZ extending beyond the site boundary shall 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 facility(ies) in assessing information, recommending protective action, and disseminating information to the public.

(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.

(~~f~~c) *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.

§ 53.1312 Contents of applications for construction permits; other application content.

(a) In addition to the PSAR, the application must also include the following:

(1) *Environmental report.*

(i) An environmental report either in accordance with 10 CFR 51.50(~~c~~a) if a limited work authorization under ~~in~~ § 53.1130 is not requested in conjunction with the construction permit application, or in accordance with §§ 51.49 and 51.50(~~c~~a) of this chapter if a limited work authorization is requested in conjunction with the construction permit application.

(ii) If the applicant wishes to request that a limited work authorization under § 53.1130 be issued before issuance of the construction permit, the application must include the information otherwise required by § 53.1130, in accordance with either 10 CFR 2.101(a)(1) through (a)(4), or 10 CFR 2.101(a)(9).

(b) If the construction permit application references an early site permit, standard design approval, manufacturing license, or standard design certification, 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, license or certification, provided, however, that the PSAR incorporates the material by reference and where appropriate confirms that the site and design of the facility falls within parameter limits established in the referenced NRC approval, license, 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, license, or certification will be satisfied by the date of issuance of the operating license. If the PSAR does not demonstrate that the site or design of the facility falls within the site characteristics and design parameters, the application shall include appropriate requests for a departure, variance, or exemption ~~that complies with the requirements of this part related to the subject~~from the referenced NRC approval, license, or certification that complies 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 ~~Standards for review~~Review of applications.

(a) *Standards for review of applications.* Applications filed under this subpart will be reviewed according to the standards set out in 10 CFR parts 20, 51, 53, ~~[54],~~ 73, and 140.

~~**§ 53.1318 Finality of referenced NRC approvals, licenses and certifications.**~~

~~If the application for a construction permit under this part references an NRC approval; license, which may be an early site permit; or certification, the scope and nature of matters resolved for the application are governed by the relevant provisions addressing finality, including §§ 53.1188, 53.1263, and 53.1221.~~

~~§ 53.1321~~(b) *Administrative review of applications; hearings*.

A proceeding on a construction permit 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 construction permit applications are governed by the procedures contained in 10 CFR part 2.

§ 53.1318 Finality of referenced NRC approvals, licenses and certifications.

If the application for a construction permit under this part references an early site permit, standard design approval, manufacturing license, 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, 53.1263, and 53.1288.

§ 53.1324 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

The Commission shall refer a copy of the application to the ACRS. The ACRS shall report on those portions of the application that concern safety and shall 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(c)(1)(ii) and (iv), and the Director of the Office of Nuclear Reactor Regulation makes the determination required by § 53.1130(c)(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 shall implement an approved site redress plan.

§ 53.1330 Exemptions, departures, and variances.

(a) Applicants for a construction permit under this subpart, or any amendment to a construction permit, 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 construction permit who has filed an application referencing a NRC approval, 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, license, or certification. In determining whether to grant the departure, variance, or exemption, the Commission shall apply the same technically relevant criteria as were applicable to the application for the original or renewed approval, license, or certification. ~~Once a construction permit referencing an early site permit is issued, variances from the early site permit will be addressed under the provisions of § 53.1188(d).~~.

§ 53.1333 Issuance of construction permits.

(a) After conducting a hearing in accordance with § 53.13~~2~~15 and receiving the report submitted by the ACRS, the Commission may issue a construction permit 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, 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 criteria contained in §§ 53.210 and 53.220, or more restrictive alternative criteria adopted under § 53.470 of this part, 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 construction permit shall contain the terms and conditions for the permit, as the Commission deems necessary and appropriate. The Commission may, in its discretion, incorporate in any construction permit 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.

A construction permit 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 construction permit or by amendment to the construction permit. 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. The Commission may, in its discretion, incorporate in any construction permit provisions requiring the applicant to furnish periodic reports of the progress and results of research and development programs designed to resolve safety questions.

~~**§ 53.1339 Construction activities.**~~

~~A construction permit holder must meet the requirements in § 53.610 prior to beginning construction activities. The permit holder must notify NRC at least 30 days prior to the start of construction that all requirements described in § 53.610 have been or will be met.~~

§ 53.1342 Duration of construction permit.

(a) A construction permit will state the earliest and latest dates for completion of construction or alteration of the facility~~:~~.

(b) If the proposed construction or alteration of the facility is not completed by the latest completion date, the construction permit 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.

§ 53.1345 Transfer of construction permits.

A construction permit may be transferred in accordance with § 53.1570 of this part.

§ 53.1348 Termination of construction permits.

When a permit holder has determined to permanently cease construction, the holder shall, 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.

~~**§ 53.1363 Relationship to other sections.**~~

~~(a) The holder of a construction permit issued under § 53.1300 of this section must, at the time of submission of the final safety analysis report (FSAR), file an application for an operating license under this section.~~

~~(b) An application for an operating license under this part may, but need not, reference an early site permit, standard design approval, manufacturing license, or standard design certification issued under this part.~~

§ 53.1366 Contents of applications for operating licenses; general information.

An application for an operating license must supplement the information required by § 53.1109 with 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 ~~shall~~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 ~~shall~~must submit estimates for total annual operating costs for each of the first five years of operation of the facility. The applicant ~~shall~~must also indicate the source(s) of funds to cover these costs.

(2) Each application for an operating license 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 ~~it~~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; 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) 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.

§ 53.1369 Contents of applications for operating licenses; technical information ~~in final safety analysis report~~.

Final safety analysis report. The application must contain a final safety analysis report (FSAR) that describes the facility~~, presents the design bases~~ and the limits on its operation, and presents a safety analysis of the structures, systems, and components of the facility as a whole. The final safety analysis report shall 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. The application must include the following information:

(a) *Site information*. An application for an operating license 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)-(~~viii).~~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, relating to site evaluation factors identified in subpart D of this part.

(b) *Design information*. Except as specified in this paragraph, an application for an operating license for a commercial nuclear ~~reactor~~plant must include the final design information equivalent to that required for a standard design certification as defined in §§ 53.1239(a)(2)-(~~19~~26).

(1) The completed design, including any changes during construction, must be described.

(2) Where any design feature had not been fully developed or demonstrated at the time of application for the construction permit, 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) *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.

(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*. Description of location and capabilities to be established for command and control, support, and coordination of onsite and offsite, as applicable, functions during reactor accident conditions.

(g) *Role of personnel.* (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:

(i) Human Factors Engineering Design Requirements

(ii) Human System Interface Design Requirements

(iii) Concept of Operations

(iv) Functional Requirements Analysis and Function Allocation

(2) initial estimates of staffing plans and the anticipated operations staffing using the criteria in § 53.740.

(3)(i) A description of the program for evaluating and applying operating experience.

(ii) A description of a program for developing and maintaining plant procedures.

(h) *Training and examination programs.* A description of training and examination programs required by § 53.730(g).

(i) *Emergency plan*. Emergency plans complying with the requirements of § 53.855 of this Part.

(1) Include all emergency plan certifications, as applicable, that have been obtained from the State and local governmental agencies with emergency planning responsibilities that are wholly or partially within the emergency planning zone plume exposure pathway. These certifications must state 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) These agencies are committed to executing their responsibilities under the plans in the event of an emergency.

(2) 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) If complete and integrated emergency plans were approved as part of an early site permit, or submitted, reviewed and approved as part of the construction permit application, new certifications meeting the requirements of paragraph (14)(i) of this section are not required.

(j) *Organization.* A description of the applicant's organizational structure, allocations or responsibilities and authorities, and personnel qualifications requirements for operation.

(k) *Maintenance program*. A description of a maintenance program that meets the requirements in § 53.715 of this part.

(l) *Quality assurance*. A description of the quality assurance program that meets the requirements of § 53.865 of this part.

(m) *Radiation protection program*. A radiation protection program description that meets the requirements of § 53.850.

(n) *Security program*. A physical security plan that describes how the applicant will meet the requirements of § 53.860 of this part (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 program 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.

(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 shall include plans for dealing with threats, thefts, and radiological sabotage, as defined in part 73 of this chapter, 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 shall include the information contained in the applicant's safeguards contingency plan. (Implementing procedures required for this plan need not be submitted for approval.)[4]

(p) *Security training and qualification*. A training and qualification plan must describe how the applicant will meet the criteria set forth in 10 CFR 73.100 or appendix B to 10 CFR part 73.

(q) *Cyber security plan*. A cyber security plan in accordance with the criteria set forth in § 73.54 or 73.110 of this chapter.

(r) *Security, safeguards and cyber security plan implementation*. A description of the implementation of the security program, safeguards contingency plan, security training and qualification plan, and cyber security plan. Each applicant who prepares a physical security program, a safeguards contingency plan, a security training and qualification plan, or a cyber security plan shall 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.

(s) *Fire protection program*. A fire protection program description that meets the requirements of § 53.875.

(t) *Inservice inspection/inservice testing program*. An inservice inspection/inservice testing program description that meets the requirements of § 53.880.

(u) *Criticality safety program*. A criticality safety program description that meets the requirements of § 53.885.

(v) *Facility safety program.* A facility safety program plan that meets the requirements of § 53.900.

(w) *General employee training*. A description of the training program required to meet § 53.840 and its implementation.

(x) *Fitness-for-duty program*. A description of the fitness-for-duty program required by 10 CFR part 26 and its implementation.

(y) 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 construction permit stage have been resolved.

(z) 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 § 53.440(~~d~~a).

(aa) *Technical specifications*. Proposed technical specifications prepared in accordance with the requirements of § 53.710(a).

* * * * *

[4] A physical security plan that contains all the information required in both 10 CFR 73.55 or 10 CFR 73.100 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.

~~(a)~~ In addition to the FSAR, the application must also include the following:

(~~1~~a) *Environmental report*. An environmental report in accordance with 10 CFR 51.~~50(c).~~ 53(b).

~~(2) *Technical specifications*. Proposed technical specifications prepared in accordance with the requirements of § 53.710(a).~~

(~~3~~b) *Availability controls (if not included in the FSAR*). A description of the controls on plant operations, including availability controls, to provide reasonable assurance of safe operation and that the configurations and special treatments for NSRSS SSCs provide the capabilities and reliabilities required to satisfy the safety criteria of § 53.220, or more restrictive alternative criteria adopted under § 53.470 of this part, if not addressed by Technical Specifications ~~per~~ under § 53.1369(a)(~~2) above.~~27).

§ 53.1375 Review of applications.

(a) *Standards for review of applications.*

Applications filed under this subpart will be reviewed according to the standards set out in 10 CFR parts 20, 26, 51, 53, [54], 73, and 140. Upon receipt of an application, the NRC will:

(~~a~~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;

(~~b~~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;

(~~c~~3) Publish notice of the application once each week for 4 consecutive weeks in the *Federal Register*.

~~**§ 53.1378**~~(b) *Administrative review of applications; hearings*.

A proceeding on an operating license 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 operating licenses are governed by the procedures contained in 10 CFR part 2.

§ 53.1381 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

The Commission shall refer a copy of the application to the ACRS. The ACRS shall report on those portions of the application that concern safety and shall apply the standards referenced in § 53.1375, in accordance with the finality provisions in § 53.1390.

§ 53.1384 Exemptions, departures, and variances.

(a) Applicants for an operating license under this subpart, or any amendment to an operating license, 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 operating license who has filed an application referencing a 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 shall 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.

(a)(1) After receiving the report submitted by the ACRS, the Commission may issue an operating license if the Commission finds that:

(i) ~~The applicable standards~~Construction of the facility has been substantially completed in conformity with the construction permit and ~~requirements~~the application as amended, the provisions of the Act, and the ~~Commission's~~rules and regulations ~~have been met;~~of the Commission;

(ii) Any required notifications to other agencies or bodies have been duly made;

(iii) ~~There is reasonable assurance that the~~ The facility ~~has been constructed~~will operate in conformity with ~~its construction permit and will be operated in conformance with its operating license~~the application as amended, the provisions of the Act, and the ~~Commission's~~rules and regulations~~;~~ of the Commission;;

~~(iv~~(iv) There is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public, and (ii) that such activities will be conducted in compliance with the regulations in this chapter;

(~~v~~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 operating license;

(~~v~~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 Part 140 of this chapter have been satisfied; and

(viii) The findings required by subpart A of part 51 of this chapter have been made.

~~(2) The Commission may also find, at the time it issues the operating license, that certain acceptance criteria in one or more of the post-construction inspections, tests,~~

~~analyses verifications in a referenced early site permit 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 operating license, and findings under § 53.1378 with respect to those acceptance criteria are unnecessary.~~

(2) [Reserved]

(b) Fuel loading ~~or the installation of a fueled manufactured reactor module~~ may not begin until the operating license is issued.

(c) The operating license 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) ~~An~~The Commission will issue an operating license ~~may contain other terms~~in such form and containing such conditions and limitations, including technical specifications, as ~~the Commission~~ it deems ~~necessary and~~ appropriate and necessary.

§ 53.1390 Finality of operating licenses.

After issuance of an operating license, the Commission may not modify, add, or delete any term or condition of the operating license, the design of the facility, except in accordance with the provisions of § 53.1~~3~~590(c) of this part.

~~**§ 53.1393 Operation under an operating license.**~~

~~The license shall be subject to revocation, suspension, modification or amendment for cause as provided in the Atomic Energy Act, as amended (Act), and regulations, in accordance with the Act and regulations.~~

§ 53.1396 Duration of operating license.

An operating license is issued for a specified period not to exceed 40 years from the date of issuance. ~~Where the operation of a commercial nuclear plant is involved,~~ ~~the~~The Commission will issue the license for the term requested by the applicant 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 in accordance with § 53.1570 of this part

§ 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 for a facility that has permanently ceased operations, continues in effect beyond the expiration date to authorize ownership and possession of the ~~production or utilization~~ facility, until the Commission notifies the licensee in writing that the license is terminated. During this period of continued effectiveness, the licensee shall:

(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 operating license 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 ~~licensed~~ under this part.

§ 53.1413 Contents of applications for combined licenses; general information.

An application for a combined license must supplement the information required by § 53.1109 with 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 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 five years of operation of the facility. The applicant must also indicate the source(s) of funds to cover these costs. ~~[An applicant seeking to renew or extend the term of an operating license for a power reactor need not submit the financial information that is required in an application for an initial license.]~~

(3) Each application for a combined license 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 ~~it~~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; 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) 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 ~~in final safety analysis report~~.

~~(a)~~(a) *Final safety analysis report.* The application must contain a final safety analysis report (FSAR) that describes the facility~~, presents the design bases~~ and the limits on its operation, and presents a safety analysis of the structures, systems, and components of the facility as a whole. The Commission will require, before issuance of a combined license, that information supporting required siting, design, and analysis application content be completed and available for audit if the information is necessary

for the Commission to make its safety determination. The final safety analysis report 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 combined license:

~~(1) *Design information*. An application for a combined license for a commercial nuclear reactor must include the design information equivalent to that required for a standard design certification as defined in §§ 53.1239(a)(2)-(19).~~

~~(2) *Site information*.~~(1) *Site information*. An application for a combined license 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)-(~~viii).~~x).

(2) *Design information*. An application for a combined license 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)-(26).

(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) *Role of personnel*. (~~1~~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:

(~~i~~A) Human Factors Engineering Design Requirements

(~~ii~~B) Human System Interface Design Requirements

(~~iii~~C) Concept of Operations

(~~iv~~D) Functional Requirements Analysis and Function Allocation

(~~2~~ii) initial estimates of staffing plans and the anticipated operations staffing using the criteria in § 53.740.

(~~3) (i~~iii)(A) A description of the program for evaluating and applying operating experience.

(~~ii~~B) A description of a program for developing and maintaining plant procedures.

(8) Training and examination programs. A description of training and examination programs required by § 53.730(g).

(9) *Emergency plan*. Emergency plans complying with the requirements of § 53.855 of this part.

(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 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.

(10) *Organization.* A description of the applicant's organizational structure, allocations of responsibilities and authorities, and personnel qualifications requirements for operation.

(11) *Maintenance program*. A description of a maintenance program that meets the requirements in § 53.715.

(12) *Quality assurance*. A description of the quality assurance program that meets the requirements of § 53.865.

(13) *Radiation protection program*. A radiation protection program description that meets the requirements of § 53.850.

(14) *Security program*. A physical security plan that describes how the applicant will meet the requirements of § 53.860 of this part (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.

(15) *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 part 73 of this chapter, 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.[5] (Implementing procedures required for this plan need not be submitted for approval.)

(16) *Security training and qualification*. A training and qualification plan that describes how the applicant will meet the criteria set forth in 10 CFR 73.100 or appendix B to 10 CFR part 73.

(17) *Cyber security plan*. A cyber security plan in accordance with the criteria set forth in 10 ~~CR~~CFR 73.54 or 73.110.

(18) *Security plan implementation*. A description of the implementation of the 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 10 CFR 73.21 and 10 CFR 73.22.

(19) *Fire protection program*. A fire protection program description that meets the requirements of § 53.875.

(20) *Inservice inspection/inservice testing program*. An inservice inspection/inservice testing program description that meets the requirements of § 53.880.

(21) *Criticality safety program*. A criticality safety program description that meets the requirements of § 53.885.

(22) *Facility safety program*. A facility safety program plan that meets the requirements of § 53.900.

(23) *General employee training*. A description of the training program required to meet § 53.840 and its implementation.

(24) *Fitness-for-duty program*. A description of the fitness-for-duty program required by 10 CFR part 26 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 § 53.440(~~d~~a).

(d) If the combined license 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 §§ 53.1188(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 combined license. Any terms or conditions of the early site permit that could not be met by the time of issuance of the combined license, must be set forth as terms or conditions of the combined license.

(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 (~~14~~a)(9)(i) of this section are not required.

(e) If the combined license 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 must use the PRA 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 all terms and conditions that have been included in the design approval will be satisfied by the date of issuance of the combined license.

(f) If the combined license 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 must use the PRA 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 § 53.12~~03~~39(a)(~~21~~18) 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 combined license. 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 combined license, must be set forth as terms or conditions of the combined license.

(g) If the combined license application references the use of one or more manufactured ~~nuclear power~~ reactors licensed under § 53.1270 of this part, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the manufacturing license, provided, however, that the FSAR must either include or incorporate by reference the manufacturing license 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 manufacturing license. In addition, the plant-specific PRA

information must use the 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 manufacturing license will be satisfied by the date of issuance of the combined license. Any terms or conditions of the manufacturing license that could not be met by the time of issuance of the combined license, must be set forth as terms or conditions of the combined license.

(h) Each applicant for a combined license 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.

* * * * *

[5] A physical security plan that contains all the information required in both 10 CFR 73.55 or 10 CFR 73.100 and appendix C to 10 CFR part 73 satisfies the requirement for a contingency plan.

§ 53.1419 Contents of applications for combined licenses; other application content.

~~(a)~~ In addition to the FSAR, the application must also include the following:

(~~1~~a) *Environmental report.* (~~i~~1) An environmental report either in accordance with 10 CFR 51.50(c) if a limited work authorization under ~~in~~ § 53.1130 is not requested in conjunction with the combined license application, or in accordance with §§ 51.49 and 51.50(c) of this chapter if a limited work authorization is requested in conjunction with the combined license application.

(~~ii~~2) If the applicant wishes to request that a limited work authorization under § 53.1130 be issued before issuance of the combined license, the application must include the information otherwise required by § 53.1130, in accordance with either 10 CFR 2.101(a)(1) through (a)(4), or 10 CFR 2.101(a)(9).

~~(2) *Technical specifications*. Proposed technical specifications prepared in accordance with the requirements of § 53.710(a).~~

~~(3~~

(b) *Availability controls (if not included in the FSAR).* A description of the controls on plant operations, including availability controls, to provide reasonable assurance of safe operation and that the configurations and special treatments for NSRSS SSCs provide the capabilities and reliabilities required to satisfy the ~~-~~safety criteria of § 53.220, or more restrictive alternative criteria adopted under § 53.470 of this part, if not addressed by Technical Specifications ~~per (b)(2) above.~~under § 53.1416(a)(25).

(4c) *ITAAC.* The proposed inspections, tests, and analyses, including those applicable to emergency planning, that the licensee shall 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 combined license, the provisions of the Act, and the Commission's rules and regulations.

(~~i~~1) If the application references an early site permit with ITAAC, the early site permit ITAAC must apply to those aspects of the combined license which are approved in the early site permit.

(~~ii~~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 approved in the standard design certification.

(~~iii~~3) If the application references an early site permit with ITAAC or a standard design certification or both, 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 § 52.85 must indicate that the application includes this notification.

§ 53.1422 ~~Standards for review~~Review of applications.

(a) *Standards for review of applications.* Applications filed under this subpart will be reviewed according to the standards set out in 10 CFR parts 20, 51, 53, 73, and 140.

~~**§ 53.1425 Finality of referenced NRC approvals.**~~

~~If the application for a combined license 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 combined license issued are governed by the relevant provisions addressing finality, including §§ 53.1188, 53.1263, 53.1221, and 53.1288.~~

~~**§ 53.1428**~~(b) *Administrative review of applications; hearings*.

A proceeding on a combined license is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (10 CFR 2.101) and issuance of a notice of hearing (10 CFR 2.104). If an applicant requests a Commission finding on certain ITAAC with the issuance of the combined license, then those ITAAC will be identified in the notice of hearing. All hearings on combined licenses 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 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 combined license issued are governed by the relevant provisions addressing finality, including §§ 53.1188, 53.1263, 53.1221, and 53.1288.

§ 53.1431 Referral to the Advisory Committee on Reactor Safeguards.

The Commission shall refer a copy of the application to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS shall report on those portions of the application that concern safety and shall 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 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(c)(1)(ii) and (c)(1)(iv), and the Director of the Office of Nuclear Reactor Regulation makes the determination required by § 53.1130(c)(1)(iii).

(b) If, after an applicant has performed the activities permitted by paragraph (a) of this section, the application for the combined license is withdrawn or denied, then the applicant must implement the approved site redress plan.

§ 53.1437 Exemptions, departures, and variances.

(a) Applicants for a combined license under this subpart, or any amendment to a combined license, 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 combined license who has filed an application referencing an early site permit issued under § 53.1158 of this part 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 shall apply the same technically relevant criteria as were applicable to the application for the original or renewed site permit. Once a combined license referencing an early site permit is issued, variances from the early site permit will ~~be addressed under the provisions of Subpart I.~~not be granted for that construction permit or combined license.

(c) An applicant for a combined license who has filed an application referencing a nuclear power reactor manufactured under a manufacturing license issued under § 53.1270 of this part 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) or a departure under paragraph (c) of this section is subject to litigation during the combined license 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 § 53.1428 and receiving the report submitted by the ACRS, the Commission may issue a combined license 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 combined license;

(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 part 51 of this chapter have been made.

(2) The Commission may also find, at the time it issues the combined license, that certain acceptance criteria in one or more of the ITAAC in a referenced early site permit or standard design certification 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 combined license, and findings under § 53.1452(g) with respect to those acceptance criteria are unnecessary.

(b) The Commission shall identify within the combined license 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 combined license 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, the Commission may not modify, add, or delete any term or condition of the combined license, the design of the facility, the inspections, tests, analyses, and acceptance criteria contained in the license which are not derived from a referenced standard design certification or manufacturing license, except in accordance with the provisions of §§ 53.1452 or 53.1590.

(b) If the combined license does not reference a standard design certification or a reactor manufactured under § 53.1270 of this part, 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 I of this part.

(c) If the combined license 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 combined license references a reactor manufactured under § 53.1270, 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 combined license 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 § 53.1515.

(f) Any modification to, addition to, or deletion from the terms and conditions of a combined license, 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.

~~**§ 53.1446 Construction activities.**~~

~~A combined license holder must meet the requirements in § 53.610 prior to beginning construction activities. The licensee holder must notify the NRC at least 30 days prior to the beginning of construction that all requirements described in § 53.610 have been addressed.~~

§ 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 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 combined license 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 ITAAC activities 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 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 activities are complete.

(d) *Licensee determination of noncompliance with ITAAC*. (1) In the event that an activity is subject to a 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 I of this part.

(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 I of this part.

(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(g), the NRC shall publish notices in the *Federal Register* of the NRC staff's determination of the successful completion of inspections, tests, and analyses.

(2) The NRC shall make publicly available the licensee notifications under paragraph (c) of this section. The NRC shall, 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 seven (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. 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

combined license under this part, the Commission shall 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 combined license, except that a hearing shall not be granted for those ITAAC 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) One or more of the acceptance criteria of the ITAAC in the combined license 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, shall determine whether to grant or deny the request for hearing in accordance with the applicable requirements of 10 CFR 2.309. If the Commission grants the request, the Commission, acting as the presiding officer, shall 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 shall allow operation during an interim period under the combined license.

(d) The Commission, in its discretion, shall determine appropriate hearing procedures, whether informal or formal adjudicatory, for any hearing under paragraph (a) of this section, and shall state its reasons therefore.

(e) The Commission shall, 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 combined license will be processed as a request for action in accordance with 10 CFR 2.206. The petitioner shall 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 shall 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 combined license 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 combined license are met, except for those acceptance criteria that the Commission found were met under § 53.1440(a)(2). If the combined license is for a modular design, each reactor module 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 combined license, 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 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 combined license under § 53.1452(c).

§ 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 for a facility that has permanently ceased operations, continues in effect beyond the expiration date to authorize ownership and possession of the ~~production or utilization~~ facility, until the Commission notifies the licensee ~~inwriting~~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 combined license for the facility.

§ 53.1470 Standardization of commercial nuclear power plant designs: licenses to construct and operate nuclear power reactors of identical design at multiple sites.

The Commission's regulations in 10 CFR part 2 specifically provide for the holding of hearings on particular issues separately from other issues involved in

hearings in licensing proceedings, and for the consolidation of adjudicatory proceedings and of the presentations of parties in adjudicatory proceedings such as licensing proceedings (10 CFR 2.316 and 2.317). This section sets out the particular requirements and provisions applicable to situations in which applications for construction permits and subsequent operating licenses, or combined licenses, 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.[6]

(a) Except as otherwise specified in this section or as the context otherwise indicates, the provisions of this subpart apply to construction permit, operating license, and combined license applications under this subpart subject to this section.

(b) Each application for a construction permit, operating license, or combined license submitted pursuant to this section must be submitted as specified in §§ 53.1300, 53.1360, or 53.1410 and 10 CFR 2.101. Each application must state that the applicant wishes to have the application considered under this section and must 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 under this subpart, or the use of a reactor manufactured under this subpart. The final safety analysis report for each application must either incorporate by reference or include the final safety analysis of the common design, including, if applicable, the final safety analysis report for the referenced standard design certification or the manufactured reactor.[7]

(d) Each application submitted pursuant to this section must contain an environmental report as required by §§ 53.1312, 53.1372, or, 53.1419, 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 10 CFR 2.101, each application will be docketed and a notice of docketing for each application will be published in the *Federal Register*, in accordance with 10 CFR 2.104, *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 shall prepare draft and final environmental impact statements for each of the applications under 10 CFR part 51. Scoping under 10 CFR 51.28 and 51.29 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 shall 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 10 CFR 51.28 and 51.29 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 shall 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

shall 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 shall 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 construction permits, operating licenses, and combined licenses. The presiding officer shall 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.~~

* * * * *

[6] 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 part 2 of this chapter. 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.

[7] 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.

Each holder of ~~an early site permit, construction permit, operating license, or combined~~a license for a commercial nuclear plant licensed under this part shall maintain licensing basis information; evaluate changes to site characteristics, plant design features, and programmatic controls to determine needed approvals and revisions; and submit appropriate updates to the NRC in accordance with the requirements in this subpart. As used in this subpart, licensing basis information refers to that 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 information required to be maintained and submitted to the NRC in this part.

§ 53.1502 Specific terms and conditions of licenses.

(a) Each license issued under this part shall be subject to the provisions of the Act now or hereafter in effect and to all rules, regulations, and orders of the Commission. The terms and conditions of the license shall 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 shall be subject to all conditions deemed 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 licensee may take reasonable action that departs from a license condition or a technical specification (contained in a license issued under 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 meet national security objectives is immediately apparent.

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 paragraph (x) of this section, which remains in effect unless otherwise directed by the Commission during a national security emergency.

§ 53.1505 Changes to licensing basis information requiring ~~prior~~ NRC approval.

(a) Sections 53.1510 through 53.1520 define the process for a licensee to request and the NRC to issue amendments to licenses, ~~which include an early site permit, construction permit, operating license, or combined license and~~including any conditions contained therein, technical specifications or other attachments to a license, and any orders issued by the NRC modifying a license unless the order itself defines another method for controlling revisions to the requirements included in the order or the order is revised or superseded by another order issued by the NRC.

(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 ~~an early site permit, construction permit, operating license, or combined~~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 of this part, 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 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, and the analyses requirements of § 53.450, itsan analysis aboutof whether the issue ofamendment 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 early site permit, construction permit, operating license, or combined licensea 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 ~~on~~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 ~~power plant~~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 two 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)(2) 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;

(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;

(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)(2) 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 available to the State official designated to consult with it about its proposed determination the names of the Project Manager or other NRC personnel it designated to consult with the State. 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.

(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.

(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 power plants.

§ 53.1520 Issuance of amendment.

(a) In determining whether an amendment to a ~~permit or~~ license will be issued to the applicant, the Commission will be guided by the considerations which govern the

issuance of initial licenses ~~or permits~~ to the extent applicable and appropriate. If the application involves the material alteration of a licensed facility, a construction permit will be issued before the issuance of the amendment to the license, provided however, that if the application involves a material alteration to a nuclear power reactor manufactured under § 53.~~53.~~1285 before its installation at a site, or a combined license before the date that the Commission makes the finding under § 53.1452(g), no application for a construction permit 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 power plant).

(c) The Commission may make a final determination, under the procedures in § 53.1515, that a proposed amendment to an operating license or a combined license for a facility license under this part involves no significant hazards consideration, if operation of the facility in accordance with the proposed amendment would not:

(1) Involve a significant increase in the probability or consequences of an event sequence previously evaluated; or

(2) Create the possibility of a new or different kind of an event sequence 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.

(b) The request for an exemption will be included with the associated proposed changes to the license, which will be requested and processed in accordance with §§ 53.1510, 53.1515, and 53.1520.

(c) Licensees must evaluate changes to the facility as described in the final safety analysis 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 may not make changes to the design of the manufactured reactor or manufactured reactor module authorized to be manufactured without prior Commission approval. The request for a change to the design must be in the form of an application for a license amendment, and must meet the requirements of §§ 53.1510, 53.1515, and, as applicable, 53.1520.

(b) The holder of an operating or combined license under this part who references or uses a nuclear power reactor manufactured under a manufacturing license issued under this part must request approval for a 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 §§ 53.1510, 53.1515, and 53.1520. In those cases where a manufacturing license references a design certification rule, the amendment application must also request an exemption from the design certification rule in accordance with § 53.1525 if one or more elements of the certification information are adversely affected by the proposed change. Licensees must evaluate changes to the

facility as described in the final safety analysis report but outside of the scope of the referenced manufacturing license using the criteria in § 53.1550.

§ 53.1535 Amendments during construction.

(a) The holder of a construction permit or limited work authorization under this part may request an amendment to the construction permit or limited work authorization 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 construction permits or limited work authorizations under this part must be requested and processed in accordance with §§ 53.1510, 53.1515, 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 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 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 request will not be granted.

§ 53.1540 ~~Evaluating changes and updating~~ Updating licensing basis information ~~without NRC prior approval~~.

Sections 53.1545 through 53.1565 define the process for a licensee to modify licensing basis information and to evaluate potential changes to their facilities, procedures, programs, and organizations ~~and~~ to ~~modify licensing basis information without~~determine if NRC ~~prior~~ approval is required.

§ 53.1545 Updating final safety analysis reports.

(a) Each holder under this part of an operating license or combined license ~~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 biennially or more frequently to assure that the information included in the report contains the latest information developed. The submittal ~~shall~~must include the effects on the content of the FSAR of:

(1) changes made in the facility or procedures~~;~~ as described in the FSAR;

(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) updates related to the probabilistic risk assessments required under § 53.450;

(4) the cumulative effects of the changes to the facility or procedures ~~since the last update~~ on the margins to the safety criteria in §§ 53.210, 53.220, 53.450(e), and 53.470 since the last update.

(5) analyses of new safety issues performed by or on behalf of the licensee at Commission request.

(b)(1) The licensee shall submit revisions containing updated information to the Commission, as specified in § 53.040, identifying the location of revised or new information.

(2) The submittal shall 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) During the period from the docketing of an application for a combined license under subpart H until the Commission makes the finding under § 53.1452(g), the update to the FSAR providing the information required in (a)(1) through (a)(5) of this section and meeting the requirements of paragraph (b) of this section must be submitted annually.

(d) The updated FSAR shall be retained by the licensee until the Commission terminates their license.

§ 53.1550 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 and make changes in the procedures as described in the UFSAR without obtaining a license amendment pursuant to § 53.1510 only if:

(1) A change to the technical specifications incorporated in the license is not required and

(2) The change meets all of the following criteria:

(i) Does not result in ~~a change~~an increase to the frequency or consequences of an event sequence such that an event sequence previously deemed not risk significant becomes risk significant by the analyses performed in accordance with § 53.450(e).

(ii) Does not result in ~~a change~~an increase to the frequency or consequences of an event sequence such that an event sequence deemed risk significant in accordance with § 53.450(e) has a decrease of 10 percent or more in the calculated margins to the LBE evaluation criteria required to be established in accordance with § 53.450(e).

(iii) Does not result in ~~a change~~an increase to the frequency or consequences of 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) Does not involve a departure from a method of evaluation described in the UFSAR used in assessing margins in accordance with § 53.450(e) unless the results of the analysis under § 53.450(e) 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 in accordance with an NRC endorsed consensus code or standard.

(v) For commercial nuclear plants licensed under this part for which alternative evaluation criteria are ~~applicable~~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.

(vi) Does not result in the identification of a new design basis accident in accordance with § 53.450(f).

(vii) Does not result in a decrease by 10 percent or more in the margin between the consequence of any design basis accident and the safety criteria in § 53.210.

(viii) 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.

(3) In implementing this paragraph, the UFSAR is considered to include FSAR changes since submittal of the last update of the UFSAR pursuant to § 53.154~~0~~5.

(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 shall 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 will 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 Subpart G of this part are not required to retain records of departures from the design of the facility associated with structures, systems, and components that have been permanently removed from service using an NRC-approved change process.

(c)(1) The licensee shall 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 shall submit, as specified in § 53.040 of this part, a report containing a brief description of any changes, including a summary of the evaluation of each. A report must be submitted at intervals not to exceed 24 months. For combined licenses, the report must be submitted at intervals not to exceed 6 months during the period from the date of application for a combined license to the date the Commission makes its findings under 10 CFR 53.1452(g).

(3) The records of changes in the facility must be maintained until the termination of an operating license or combined license 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.

~~(d) [Reserved]~~

~~(e) [Reserved]~~

§ 53.1555 Control of licensing basis information in program descriptions.

Program documents ~~are~~must be included in licensing basis information to describe how programmatic ~~contributions~~controls contribute to meeting the requirements in Subpart B and to describe measures taken to ensure compliance with specific NRC regulations. §§ 53.1560 through 53.1565 define the process 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.

§ 53.1560 Updating program documents included in licensing basis information.

(a) Each ~~holder of an operating license or combined license~~licensee under this part must biennially or more frequently update the program documents submitted as part of the applications to obtain or maintain the license to assure that the information included in the documents contains the latest information developed. The submittals shall 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 § 53.154550;

(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 or other NRC regulations.

(b)(1) The licensee shall submit revisions containing updated information to the Commission, as specified in § 53.040, identifying the location of revised or new information.

(2) The submittal shall 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 § 53.1545~~4~~50 but not previously submitted to the Commission.

(c) The updated program documents shall 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) 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 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.

~~(4) reserved~~

(b) In implementing this paragraph, the program documents (as updated) are considered to include changes since submittal of the last updates of the program documents pursuant to § 53.1560.

(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 this part of an operating license or combined license, after the Commission makes the finding under § 53.1452(g), may make a change to a previously accepted quality assurance program 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 quality assurance program description that do not reduce the commitments must be submitted to the NRC in accordance with the requirements of § 53.1545. In addition to quality assurance program 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 QA program at the time of the change;

(B) The use of a quality assurance 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 quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the licensee is committed; and

(F)(i) Organizational revisions that ensure that persons and organizations performing quality assurance 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 quality assurance program 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 quality assurance program 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 quality assurance program 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 quality assurance program 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 three years.

(D) Changes to the quality assurance program 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 combined license, before the Commission makes the finding under § 53.1452(g) may make a change to a previously accepted quality assurance program 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 quality assurance program description that do not reduce the commitments must be submitted to NRC within 90 days. Changes to the quality assurance program 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 quality assurance topical report descriptions must be submitted as specified in § 53.040.

(ii) The submittal of a change to the safety analysis report quality assurance program 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 quality assurance program 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 three years.

(iv) Changes to the quality assurance program 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) 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 meet 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.

(ii) The licensee shall retain a record of each change to the emergency plan made without prior NRC approval for a period of three years from the date of the change and shall 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.

(iii) 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 meet the requirements of § 53.855.

(4) *Security programs.* (i) The licensee shall 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 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 shall 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 safeguards contingency plan without prior Commission approval if the changes do not decrease the safeguards effectiveness of the plan. The licensee shall 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 shall 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 shall 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 shall provide for the development, revision, implementation, and maintenance of its safeguards contingency plan. The licensee shall 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 ~~or permits~~.

(a) No commercial nuclear plant license ~~or permit~~ 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 ~~or permit~~ shall include:

(i) For a commercial nuclear plant license ~~or permit~~ issued under this part, as much of the information described in §§ 53.1109, 53.1306, 53.1366, and 53.1413 of this part 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 ~~or permit~~ is requested, the nature of the transaction necessitating or making desirable the transfer of the license ~~or permit~~, and an agreement to limit access to Restricted Data pursuant to § 53.1115. The Commission may require any person who submits an application for license ~~or permit~~ 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.

~~(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 or regulations or orders of the Commission, the Commission will approve an application for the transfer of a license ~~or permit~~, if the Commission determines:

(1) That the proposed transferee is qualified to be the holder of the license ~~or permit~~; and

(2) That transfer of the license ~~or permit~~ is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.

§ 53.1575 Termination of license.

(a) When ~~a licensee for a commercial nuclear plant licensed~~the holder of an operating license or combined license under this part has determined to permanently cease operations the licensee shall, within 30 days, submit a written certification to the NRC, consistent with the requirements of Subpart G.

(b) Once fuel has been permanently removed from the reactor system, the licensee shall submit a written certification to the NRC that meets the requirements of Subpart G.

(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 ~~10 CFR part 53~~ 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 G.

(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, 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

~~**§ 53.1580 Information requests.**~~

~~The~~ holder of ~~an early site permit,~~a construction permit~~, operating license,~~ or combined license under 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.

§ 53.1580 Information requests.

Any licensee under this part shall 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.

§ 53.1585 Revocation, suspension, modification of licenses~~, permits,~~ and approvals for cause.

A license~~, permit,~~ 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~~, permit,~~ 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 ~~permit or~~ license, provided, however, that failure to make timely completion of the proposed construction or alteration of a facility under a construction permit under this part shall be governed by the provisions of § 53.1342(b); or for violation of, or failure to observe, any of the terms and provisions of the act, regulations, license, ~~permit,~~ approval, or order of the Commission.

§ 53.1590 Backfitting.

(a)(1) Backfitting is defined as the modification of or addition to systems, structures, components, or design of 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 nuclear plant 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 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) Statement of the specific objectives that the proposed backfit is designed to achieve;

(2) General description of the activity that would be required by the licensee or applicant in order to complete the backfit;

(3) Potential change in the risk to the public from the accidental off-site release of radioactive material;

(4) Potential impact on radiological exposure of facility employees;

(5) 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.

§ 53.1595 Renewal. ~~(TBD)~~

Licenses may be renewed by the Commission upon expiration of the period of the license.

Subpart J—Reporting and Other Administrative Requirements

§ 53.1600 General information.

Each applicant and licensee under this part ~~will~~must ensure that NRC inspectors have unfettered access to sites and facilities licensed or proposed to be licensed in § 53.1610, ~~shall~~must maintain records and make reports to the NRC in accordance with requirements in §§ 53.1620 through 53.1650, ~~shall~~must meet financial qualification and reporting requirements in §§ 53.1670 through 53.1700, and ~~shall~~must obtain and maintain required financial protections in case of an accident in §§ 53.1720 and 53.1730.

§ 53.1610 Unfettered access for inspections.

(a) Each applicant for or holder of a manufacturing license, operating license, combined license, construction permit or an early site permit, must permit inspection by duly authorized representatives of the Commission of records, premises, activities, and of licensed materials in possession or use, related to the license or construction permit or early site permit as may be necessary to effectuate the purposes of the Act, as

amended, ~~including Section 105 of the Act,~~ and the Energy Reorganization Act of 1974, as amended.

(b)(1) Each holder of a manufacturing license, operating license, combined license ~~and~~, or construction permit 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 construction permit. The office must be convenient to and have full access to the facility and shall 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. A space of 250 square feet either within the site's office complex or in an office trailer or other onsite space is suggested as a guide. 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.

§ 53.1620 Maintenance of records, making of reports.

(a) Each holder of a manufacturing license~~e~~, operating license, combined license, construction permit 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~~, including Section 105 of the Act,~~ and the Energy Reorganization Act of 1974, as amended. 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, pursuant to § 53.080 of this part, has granted a specific exemption from the record retention requirements in the regulations in this part.

§ 53.1630 Immediate notification requirements for operating commercial nuclear plants.

(a) *General requirements**: (1) Each ~~commercial nuclear plant licensee holding~~ holder of an operating license under ~~[~~§~~§~~ 53.13~~60~~87 or a combined license under § 53.14~~1~~40~~]~~ of this part~~,~~ after the Commission makes the finding under ~~[~~§~~§~~ 53.~~1440]~~,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 three 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 one 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.

~~(5)~~ 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.

(~~6~~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 pursuant to § 53.755(j) 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 four 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 a safety-related standby cooling system or the unplanned sole reliance on a safety-related 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 eight 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 a condition not analyzed under § 53.450 that significantly degrades plant safety.

(ii) Any event or condition that at the time of discovery could have prevented the fulfilment of the safety functions 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.

(iii) Any event requiring the transport of a radioactively contaminated person to an offsite medical facility for treatment.

(iv) 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) *Followup 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.

~~**These Emergency Classes are addressed in [to be added].~~

~~***Requirements for ERDS/data links are addressed in [to be added].~~

§ 53.1640 Licensee event report system.

(a) *Reportable events*. (1) Each commercial nuclear plant licensee holding an operating license under § 53.1360 or a combined license under § 53.1410 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 pursuant to § 53.755(j) 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 a 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 of any SSC classified as SR for an identified safety function under § 53.460 of this part or the unplanned sole reliance on a 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 listed in § 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 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.

(viii)(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 § 53.230.

(B) Events covered in paragraph (a)(2)(viii)(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.

(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 Licensee Event Report shall 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 component or system classified as SR or NSRSS 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 ~~shutdown~~shut down, the availability of systems or components that are needed to ~~shutdown~~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 shall submit, as specified in § 53.040, the requested information as a supplement to the initial LER.

(d) *Submission of Reports*: Licensee event reports must be prepared on Form NRC 366 and submitted to the U.S. Nuclear Regulatory Commission, 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) *Reportable Occurrences*: The requirements contained in this section replace all existing requirements for licensees to report "Reportable Occurrences" as defined in individual plant Technical Specifications.

§ 53.1645 Periodic ~~R~~reports.

(a) *Effluents*. Each holder of an operating license, and each holder of a combined license after the Commission has made the finding under § 53.1452(g), shall 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, including any other information as may be required by the Commission to estimate maximum potential annual radiation doses to the public resulting from effluent releases. 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 quantities of radioactive materials released during the reporting period are significantly above design objectives, the report must cover this specifically. 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) [Reserved.]

§ 53.1650 Facility information and verification.

(a) In response to a written request by the Commission, each applicant for a construction permit or license and each recipient of a construction permit 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.

~~**§ 53.1655 Reporting of defects and noncompliance.**~~

~~[To be added.]~~

§ 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.

~~Applicants~~Except for an electric utility applicant for a license to operate a commercial nuclear plant, an applicant for a construction permit, operating license, or combined license under this part must possess or have reasonable assurance of obtaining the funds necessary for the activities for which the permit ~~of~~or license is sought. ~~Applicants that are electric utilities are assumed to have such reasonable assurance of funding the activities for which they seek a permit of license.~~

§ 53.1680 Annual financial reports.

With respect to any commercial nuclear plant ~~facility~~ of a type described in § 53.020, each licensee and each holder of a construction permit 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 construction permit who submit a Form 10-Q with the Securities and Exchange Commission or a Form 1 with the Federal Energy Regulatory Commission, need not submit the annual financial report or the certified financial statement under this paragraph.

§ 53.1690 Licensee's change of status; financial qualifications.

(a) An electric utility licensee holding an operating license or combined license (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 53.1458, must provide the NRC with the financial qualifications information that would be required for obtaining an initial operating license as specified in ~~§§§~~ 53.1366 or 53.1413. The financial qualifications information must address the first full five years of operation after the date the licensee ceases to be an electric utility.

(b)(1) Any holder of a license issued under this part shall 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 that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(iii) An affiliate (as that term is defined in 11 U.S.C. 101(2)) 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 Atomic Energy Act of 1954, as amended (AEA), the Commission consents, without individual application, to the creation of any mortgage, pledge, or other lien upon any commercial nuclear plant not owned by the United States which is the subject of a license or upon any leasehold or other interest in such facility; Pprovided:

(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 AEA, and regulations issued by the Commission pursuant to said Actthe AEA; 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 [§§§ 53.1399 or 53.1458].1570. The Commission will act upon such application pursuant to 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: (1) "*License*" includes any operating license, combined license, construction permit, and early site permit under part 53 of this chapterpart, which may be issued by the Commission with regard to a facility;

(2) “*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.

(3) “*Facility*” includes but is not limited to, a site which is the subject of an early site permit under § 53.1140, and a reactor manufactured under a manufacturing license under ~~[~~§§ 53.1270~~]~~ 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.

§ 53.1720 Insurance required to stabilize and decontaminate plant following an accident.

Each commercial nuclear plant licensee under this part shall take reasonable steps to obtain insurance available at reasonable costs and on reasonable terms from private sources or to demonstrate to the satisfaction of the NRC that it possesses an equivalent amount of protection covering the licensee's obligation, in the event of an accident at the licensee's reactor, to stabilize and decontaminate the plant and the plant site at which ~~the~~ such an accident may occur, provided that:

(a) The insurance required by this section must have a minimum coverage limit for each reactor station 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 (4) 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 shall 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), 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 of the 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)(~~iii~~3) and (d)(~~iv~~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 shall inform the Director of the 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 shall 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 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 for authority to decommission the reactor and to surrender the license voluntarily. The Director shall 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 ~~1~~ 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 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 shall 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.

Subpart K—Quality Assurance Criteria

§ 53.1800 General provisions.

Commercial nuclear power plants and manufactured reactors include structures, systems and components that prevent or mitigate the consequences of licensing basis events, including design basis accidents, as described in § 53.240, that could cause undue risk to the health and safety of the public. This subpart establishes quality assurance requirements for the design, manufacture, construction and operation of those structures, systems and components classified as safety related. The pertinent

requirements of this subpart apply to all activities affecting the safety-related functions of those ~~safety-related~~ structures, systems and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

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. Quality assurance includes quality control, which comprises those quality assurance 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[1] must~~applicant[1] must establish and execute the quality assurance program. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility for the quality assurance program. The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of (1) assuring that an appropriate quality assurance program is established and effectively executed; and (2) verifying, such as by checking, auditing, and inspecting, that activities affecting the safety-related functions have been correctly performed. The persons and organizations performing quality assurance

functions shall 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 quality assurance functions shall 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 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 quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance 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 quality assurance program at any location where activities subject to this subpart are being performed, shall have direct access to the levels of management necessary to perform this function.

* * * * *

[1] 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 power plant or manufacturing facility or has received an early site permit, design approval, design certification or manufacturing license, as applicable. These criteria will also be used for guidance in evaluating the adequacy of quality assurance programs in use by holders of construction permits, operating licenses, early site permits, design approvals, combined licenses and manufacturing licenses.

§ 53.1810 Quality ~~Assurance Program~~assurance program.

The applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this Subpart. The program shall be documented by written policies, procedures, or instructions and shall be carried out throughout the plant life in

accordance with those policies, procedures, or instructions. The applicant shall identify the structures, systems, and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations. The quality assurance program shall provide control over activities affecting the quality of the identified structures, systems, and components. Activities affecting quality shall 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 shall 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 shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. The applicant shall regularly review the status and adequacy of the quality assurance program. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.

§ 53.1815 Design ~~C~~control.

Measures shall be established to assure that applicable regulatory requirements and the functional design ~~basis~~criteria, as specified in the license application, for those structures, systems, and components to which this subpart 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.

Measures shall be established for the identification and control of design interfaces and for the coordination among participating design organizations. These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

The design control measures shall 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. The verifying or checking process shall 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 shall include suitable qualifications testing of a prototype unit under the most adverse design conditions. Design control measures shall be applied to items such as the following: reactor physics, stress, thermal hydraulic, and accident analysis; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; and delineation of acceptance criteria for inspections and tests.

Design changes, including field changes, shall 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~~document control.

Measures shall be established to assure that applicable regulatory requirements, functional design ~~basis~~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 subpart.

§ 53.1825 Instructions, ~~P~~procedures, and ~~D~~drawings.

Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative ~~and~~or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

§ 53.1830 Document ~~C~~control.

Measures shall 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 shall 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 shall 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~~purchased material, equipment, and ~~S~~services.

Measures shall 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 shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contactor 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 shall be available at the commercial nuclear power plant site or manufacturing facility prior to installation or use of such material and equipment. This documentary evidence shall be retained at the commercial nuclear power plant site or manufacturing facility and shall 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 shall 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 ~~C~~control of ~~Materials, Parts~~materials, parts, and ~~C~~components.

Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures shall 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 shall be designed to prevent the use of incorrect or defective material, parts, and components.

§ 53.1845 Control of ~~Special Processes~~special processes.

Measures shall 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 shall 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 shall be performed by individuals other than those who performed the activity being inspected. Examinations, measurements, or tests of material or products processed shall 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 shall be provided. Both inspection and process monitoring shall 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 shall not proceed without the consent of its designated representative are required, the specific hold points shall be designated in appropriate documents.

§ 53.1855 Test ~~C~~control.

A test program shall be established to assure that all testing required to demonstrate that structures, systems, and components 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 shall include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during commercial nuclear power plant and manufacturing facility operation, of structures, systems, and components. Test procedures shall 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 shall be documented and evaluated to assure that test requirements have been satisfied.

§ 53.1860 Control of ~~M~~measuring and ~~Test Equipment~~test equipment.

Measures shall 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, ~~S~~storage and ~~S~~shipping.

Measures shall 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, shall be specified and provided.

§ 53.1870 Inspection, ~~T~~test, and ~~Operating Status~~operating status.

Measures shall 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 power plant or manufactured reactor module. These measures shall 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 shall also be established for including the operating status of structures, systems, and components of the commercial nuclear power plant or manufactured reactor module, such as by tagging valves and switches, to prevent inadvertent operation.

§ 53.1875 Nonconforming ~~Materials, Parts~~materials, parts, or ~~C~~components.

Measures shall 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 shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

§ 53.1880 Corrective ~~A~~action.

Measures shall 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 shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

§ 53.1885 Quality ~~Assurance Records~~assurance records.

Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, 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 shall be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

§ 53.1890 Audits.

A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall 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 shall be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, shall be taken where indicated.

* * * * *

PART 73—PHYSICAL PROTECTION OF PLANTS AND MATERIALS

XX. The authority citation for part 73 continues to read as follows:

Authority: Secs. 53, 161, 68 Stat. 930, 948, as amended, sec. 147, 94 Stat. 780

(42 U.S.C. 2073, 2167, 2201); sec. 201, as amended, 204, 88 Stat. 1242, as amended, 1245, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 5841, 5844, 2297f); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 73.1 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 73.37(f) also issued under sec. 301, Pub. L. 96-295, 94 Stat. 789 (42 U.S.C. 5841 note). Section 73.57 is issued under sec. 606, Pub. L. 99-399, 100 Stat. 876 (42 U.S.C. 2169).

XX. Section 73.100 is added 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) AEach licensee that is licensed to operate a commercial nuclear plant licensee under 10 CFR part 53 thatand elects to implement the requirements of this section must do so through its Commission-approved 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 of this part.. 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.

(ii) Provide defense-in-depth in achieving performance requirements through the integration of engineered systems, administrative controls, and management measures to assure effectiveness of the physical protection program.

(3) The physical protection program must be designed and implemented to achieve and maintain the reliability and availability of security structures, systems, and components. The physical protection program must achieve and maintain at all times the capabilities for meeting the following performance requirements:

(i) *Intrusion detection*. The licensee must be capable of detecting attempted and actual unauthorized access to interior and exterior areas containing equipment needed to implement safety and security functions.

(ii) *Intrusion assessment*. The licensee must be capable of rapid assessment 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 licensee must be capable of 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 for timely security responses to adversary attacks with adequate defense-in-depth.

(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 meeting 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 in 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 in 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 described in § 73.56;

(B) The fitness-for-duty program described in part 26 of this chapter;

(C) The cyber security program described in §§ 73.54 or 73.110; and

(D) The physical protection program described 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 ~~operations and~~ plans and associated procedures must be coordinated with ~~plant operations~~other onsite plans and ~~plans~~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 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.

(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, in accordance with § 73.70, all analyses, assessments, calculations and descriptions of the technical basis for meeting 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 security 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 establish 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 ~~protecting~~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, verifications, and assessments based on the importance, security significance, reliability, and availability of physical protection functions and implementation of programs and requirements in this section.

(2) The licensee must document processes and procedures for implementing the performance evaluations, verifications, and assessments. 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 systems and equipment, including supporting systems, are inspected, tested, and~~/or~~ calibrated for operability and performance at intervals necessary and sufficient to meet the requirements in this section.

(2) The licensee must implement corrective actions to ensure resolution of identified vulnerabilities and deficiencies to meet the requirements in this section.

(3) The licensee must establish and implement timely compensatory measures for degraded or inoperable security systems, equipment, 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 systems, equipment, 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 equipment.

(i) *Suspension of security measures*. (1) The licensee may suspend

implementation of affected requirements of this section in accordance with § 53.740(j) and (k) under the following conditions:

(~~A~~i) In an emergency, when action is immediately needed to protect the public health and safety; and

(~~B~~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 § 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.

XX. Section 73.110 is added to read as follows:

§ 73.110 Technology neutral requirements for protection of digital computer and communication systems and networks

(a) Each licensee ~~of~~that is licensed to operate a commercial nuclear reactor under 10 CFR part 53 shall establish, implement, and maintain a cyber security program that is commensurate with the potential consequences resulting from cyber attacks, 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 cyber attacks that are capable of causing the following consequences:

(1) Adversely impacting the functions performed by digital assets that would prevent a postulated ~~radiological~~fission product release resulting in offsite doses exceeding the ~~offsite dose~~ values in §§§ 53.210~~(a) and (b)~~ 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 shall:

(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 satisfy paragraph (a) of this section.

(2) Implement the cyber security program in accordance with paragraph (d) of this section.

(c) The licensee shall meet the ~~confidentiality, integrity, and availability~~ 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 cyber attacks.

(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 cyber attacks 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 shall 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 meet 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 ~~in accordance with the 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;

~~(A)~~(B) Maintain the capability for timely detection and response to cyber attacks;

~~(B)~~(C) Mitigate the consequences of cyber attacks;

~~(C)~~(D) Correct exploited vulnerabilities; and

(~~D~~E) Restore affected systems, networks, and/or equipment affected by cyber attacks.

(3) The licensee shall develop and maintain written policies and implementing procedures to implement the cyber security plan. Policies, implementing procedures, ~~site-specific analysis,~~ 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 shall review the cyber security program in accordance with the requirements in § 73.100(f)(3).

(5) The licensee shall retain all records and supporting technical documentation required to satisfy the requirements of this section as a record until the Commission terminates the license for which the records were developed~~,~~ and shall maintain superseded portions of these records for at least three (3) years after the record is superseded, unless otherwise specified by the Commission.

XX. Section 73.120 is added to read as follows:

§ 73.120 Access Authorization

(a) *Introduction and scope*. Each applicant for an operating license or a holder of a combined ~~operating~~ license under 10 CFR part 53 must establish, maintain, and implement an access authorization program before initial fuel load into the reactor. ~~For licensees who meet the criterion in 10 CFR 53.210(a)(2)(i), this access authorization program must be in accordance with the requirements of this section or 10 CFR 73.56. For licensees not meeting the criterion in 10 CFR 53.210(a)(2)(i), this access authorization program must be in accordance with the requirements of 10 CFR 73.56.~~

(b) *Applicability*. (1) The following individuals shall 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 power 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 meets the requirements of this section.

(c) *General performance objectives and requirements*. Each licensee's or

applicant's access authorization program under this section must provide reasonable assurance 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 shall maintain the capabilities for meeting the following performance requirements:

(1) *Background investigation*. (i)(A) Licensees and applicants shall ensure that any individual seeking initial unescorted access or to maintain unescorted access is subject to a background investigation.

(B) Background investigations shall 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 may not initiate a background investigation without the informed and signed consent of the subject individual. 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 shall 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*. ~~(i)~~ Licensees, applicants, and contractors or vendors

shall ensure the access authorization program includes provisions that the individuals specified in paragraph (b) of this section are subject to behavioral observation.

(~~A~~i) Each person subject to behavioral observation shall be responsible for communicating 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.

(~~B~~ii) Behavioral observation shall 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.

(~~ii)(A)~~3) *Self-reporting of legal actions.* Licensees or applicants shall~~.~~

~~(B) Behavioral observation shall include~~ inform personnel who are granted and who maintain unescorted access of their responsibilities to self-report~~ing~~ to plant supervision ~~of~~ 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.

(~~3~~4) *Unescorted access*. Licensees or applicants shall 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 shall be reviewed annually by the reviewing official. Licensees and applicants shall conduct an FBI criminal history record check update, and ~~they~~it shall be completed within 10 years of the last review.

(45) *Termination of unescorted access.* Licensees and applicants shall 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.

(56) *Determination basis for access*. (i) The licensee's or applicant's reviewing official shall 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 meet the requirements of this section.

(ii) Licensees and applicants shall provide individuals subject to this ~~subpart~~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 shall name one or more individuals to be reviewing officials pursuant to the requirements of § 37.23(b)(2) of this chapter.

(67) *Review procedures*. Review procedures shall 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.

(78) *Protection of information*. Licensees, applicants, contractors, or vendors shall 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.

(89) *Access ~~Authorization Reviews~~authorization reviews and corrective action*. Licensees and applicants shall 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 shall 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.

(~~9~~10) *Records.* Licensees, applicants, and contractors or vendors shall 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 shall:

(~~1~~i) retain documentation regarding the trustworthiness and reliability of individual employees for 3 years from the date the individual no longer requires unescorted access.

(~~2~~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.

(~~3~~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.