[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50, 52, and 72

[NRC-2015-0225]

RIN 3150-AJ68

Emergency Preparedness for Small Modular Reactors and Other New Technologies

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule and guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to include new alternative emergency preparedness requirements for small modular reactors and other new technologies. This final rule acknowledges technological advancements and other differences from large light-water reactors that are inherent in small modular reactors and other new technologies. The NRC is concurrently issuing Regulatory Guide 1.242, "Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities."

DATES: This final rule is effective on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

ADDRESSES: Please refer to Docket ID NRC-2015-0225 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Website:** Go to https://www.regulations.gov and search for Docket ID NRC-2015-0225. Address questions about NRC dockets to Dawn Forder; telephone: 301-415-3407; email: Dawn.Forder@nrc.gov. For technical questions, contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at https://www.nrc.gov/reading-rm/adams.html. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to pdr.resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section.

- **NRC's PDR:** You may examine and purchase copies of public documents, by appointment, at the NRC's Public Document Room (PDR), Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

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SUPPLEMENTARY INFORMATION:

EXECUTIVE SUMMARY:

A. Need for the Regulatory Action

Certain existing requirements and guidance are focused on large light-water reactors (LWRs) and currently operating non-power reactors (also referred to as research and test reactors), as defined in part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), "Domestic Licensing of Production and Utilization Facilities." Through this final rule, the NRC is amending its regulations to create an alternative emergency preparedness (EP) framework for small modular reactors (SMRs) and other new technologies (ONTs). These new alternative EP requirements and implementing guidance in Regulatory Guide 1.242 adopt a performance-based, technology-inclusive, risk-informed, and consequence-oriented approach. The new alternative EP requirements 1) continue to provide reasonable assurance that adequate protective measures can and will be implemented by an SMR or ONT licensee; 2) promote regulatory stability, predictability, and clarity; 3) reduce the need for requests for exemptions from EP requirements; 4) recognize advances in design and technological advancements embedded in design features; 5) credit safety enhancements in evolutionary and passive systems; and 6) credit the potential benefits of smaller sized reactors and non-LWRs associated with postulated accidents, including slower transient response times, and relatively small and slow release of fission products. This final rule and guidance could affect existing SMR and non-LWR applicants and licensees as well as SMRs, non-LWRs, and non-power production or utilization facilities that would be

licensed after the effective date of this final rule. Those applicants and licensees have the option to develop a performance-based EP program as an alternative to using the existing, deterministic EP requirements in 10 CFR part 50. This final rule does not include within its scope emergency planning, preparation, or response for large LWRs, fuel cycle facilities,[1] or currently operating non-power reactors. For the purposes of this final rule, large LWRs are reactors that are licensed to produce greater than 1,000 megawatts thermal power.

B. Major Provisions

Major provisions of this final rule and guidance include the addition of:

- A new alternative performance-based EP framework, including requirements for demonstrating effective response in drills and exercises for emergency and accident conditions;
- A requirement for a hazard analysis of any facility contiguous to or near an SMR or ONT, that considers any hazard that would adversely impact the implementation of emergency plans developed under this framework;
- A scalable approach for determining the size of the plume exposure pathway emergency planning zone; and
- A requirement to describe ingestion response planning in the emergency plan, including the offsite capabilities and resources available to prevent contaminated food and water from entering the ingestion pathway.

C. Costs and Benefits

[1] Emergency planning requirements for facilities licensed under 10 CFR part 70, "Domestic Licensing of Special Nuclear Material," are set forth in § 70.22(i).

The NRC prepared a final regulatory analysis of the expected quantitative costs and benefits of this final rule and associated guidance as well as the qualitative factors considered in the NRC's rulemaking decision. The conclusion from the analysis is that this final rule and associated guidance result in net averted costs to the industry and the NRC ranging from $7.98 million using a 7-percent discount rate to $14.9 million using a 3-percent discount rate.

The regulatory analysis considered qualitative aspects, such as greater regulatory stability, predictability, and clarity to the licensing process. These benefits result from applicants and licensees not needing to use the exemption process to establish EP criteria commensurate with design- and site-specific considerations. Another qualitative consideration is promoting a performance-based regulatory framework that specifies requirements to be met and provides flexibility to an applicant or licensee regarding the information or approach needed to satisfy those requirements.

For more information, the final regulatory analysis is available as indicated in the "Availability of Documents" section of this document.

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XVII. Availability of Documents

I. Background

In December 2016, the NRC developed and published "NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness," with a goal to further develop the NRC's non-light-water reactor (non-LWR) regulatory, technical, and policy infrastructure to be ready to review potential licensing applications for non-LWR technologies. This final rule contributes to the NRC's efforts to optimize non-LWR regulatory readiness. In particular, the NRC's objective for this final rule is to create alternative emergency preparedness (EP) requirements that: 1) continue to provide reasonable assurance that adequate protective measures can and will be implemented by a small modular reactor (SMR) or other new technology (ONT) licensee; 2) promote regulatory stability, predictability, and clarity; 3) reduce the need for requests for exemptions from EP requirements; 4) recognize advances in design and technology advancements embedded in design features; 5) credit safety enhancements in evolutionary and passive systems; and 6) credit the potential benefits of smaller sized reactors and non-LWRs associated with postulated accidents, including slower transient response times, and relatively small and slow release of fission products.

Within the "Supplementary Information" section of this document, the NRC uses the term "ONTs" to refer to new technologies, such as non-LWRs and medical radioisotope facilities licensed under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR). Further, within this document, the NRC uses the term "existing" or "current" in the context of the NRC's regulations to mean the requirements in § 50.47, "Emergency plans," and appendix E to 10 CFR part 50, "Emergency Planning and Preparedness for Production and Utilization Facilities," before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** and, when referring

to applicants or licensees for an SMR or ONT facility, to mean applicants or licensees for an SMR or ONT facility as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

This final rule also defines "non-power production or utilization facility" (NPUF) to clarify the applicability of the performance-based EP framework. The definition includes production or utilization facilities, licensed under § 50.21(a), § 50.21(c), or § 50.22, as applicable, that are not nuclear power reactors or production facilities as defined under paragraphs (1) and (2) of the definition of *Production facility* in § 50.2. In the context of this final rule, medical radioisotope facilities licensed under 10 CFR part 50 are included within this definition of NPUF. The term "non-power production or utilization facility" is used in this final rule to distinguish between those medical radioisotope facilities licensed as production or utilization facilities under 10 CFR part 50 and other facilities to be used for the production of medical radioisotopes licensed under the regulations in 10 CFR parts 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," 40, "Domestic Licensing of Source Material," and 70, "Domestic Licensing of Special Nuclear Material." Those facilities licensed under 10 CFR parts 30, 40, or 70 are subject to existing emergency planning requirements in those parts. Relevant 10 CFR part 70 fuel facility emergency planning considerations (e.g., inadvertent criticality accidents and hazardous chemical exposures) applicable to 10 CFR part 50 production facilities have been incorporated into this final rule and associated guidance. As such, the scope of this final rule is limited to those ONT facilities (e.g., non-LWRs licensed as power reactors, new non-power reactors, and medical radioisotope facilities) for which the NRC expects to receive license applications under 10 CFR parts 50 or 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." Those NPUFs that are not considered ONTs (i.e., currently operating non-power reactors) are not within the scope

of this final rule. Currently operating non-power reactors continue to implement existing emergency planning requirements and guidance.

A. Existing Emergency Preparedness Framework for Nuclear Power Reactors

Appendix E to 10 CFR part 50 identifies the specific items currently required to be included in emergency plans. Additionally, § 50.47 provides EP requirements for nuclear power reactors, including planning standards for onsite and offsite emergency response plans. Other relevant regulations include paragraphs (q), (s), and (t) of § 50.54, "Conditions of licenses."

For large LWRs, the most notable guidance documents for the development and maintenance of emergency plans are: NUREG-0654/FEMA-REP-1, Revision 1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," dated November 1980, which provides guidance and evaluation criteria for the development and evaluation of operating power reactors' and offsite response organizations' (OROs) radiological emergency response plans; NUREG-0654/FEMA-REP-1, Revision 2, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," dated December 2019, which reflects changes to NRC regulations, guidance, and policies, as well as advances in technology and best practices that occurred since issuance of the 1980 version; Regulatory Guide (RG) 1.219, Revision 1, "Guidance on Making Changes to Emergency Plans for Nuclear Power Reactors," dated July 2016, which provides guidance for operating power reactor licensees implementing requirements in § 50.54(q) for evaluating and making changes to emergency plans; NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 13.3, "Emergency Planning," dated March 2007, which provides the criteria that

the NRC uses in reviewing applicants' emergency plans as described in the applications' safety analysis reports; and NUREG-0800, Section 14.3.10, "Emergency Planning - Inspections, Tests, Analyses, and Acceptance Criteria," dated March 2007, which provides the criteria that the NRC uses in reviewing 10 CFR part 52 applicants' proposed inspections, tests, and analyses applicable to emergency planning that the licensee performs, and the associated acceptance criteria. This regulatory framework has defined the EP programs for the current operating fleet of power reactors for several decades. These standards have been effectively used in practice and provided a basis to draw from in developing this EP regulatory framework for SMRs and ONTs.

Currently, applicants for SMR LWR licenses can use the guidance used by large LWRs described in the preceding paragraph. Applicants for non-LWR licenses can use NUREG-0654/FEMA-REP-1, Revision 1 or 2; RG 1.219, Revision 1; and RG 1.233, Revision 0, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors," which provides guidance on the selection of licensing-basis events; classification and special treatments of structures, systems, and components; and assessment of defense in depth.

B. Existing Emergency Preparedness Framework for Non-power Production or Utilization Facilities

The EP requirements applicable to a particular applicant or licensee can vary depending on the type of facility. In the August 19, 1980, final rule, "Emergency Planning" (45 FR 55402) (referred to herein as the "1980 Final Rule"), the NRC established in appendix E to 10 CFR part 50 emergency planning requirements for research and test reactors (RTRs) that reflected the lower potential radiological hazards associated with these facilities. The RTRs and other NPUFs must meet the emergency

planning requirements of §§ 50.34(a)(10), 50.34(b)(6)(v), and 50.54(q) and appendix E to 10 CFR part 50. The requirements of § 50.47 do not apply to RTRs and other NPUFs. Additionally, in section I.3. of appendix E to 10 CFR part 50, the NRC differentiates between emergency planning requirements for nuclear power reactors and those for other facilities, stating that the size of emergency planning zones (EPZs) and the degree to which compliance with sections I through V of appendix E to 10 CFR part 50 is necessary are determined on a case-by-case basis for facilities other than power reactors.

Further, footnote 2 of appendix E to 10 CFR part 50 provides that RG 2.6, "Emergency Planning for Research and Test Reactors," is used as guidance for the acceptability of RTR emergency response plans. Regulatory Guide 2.6 was initially issued in January 1979 and most recently updated to Revision 2, "Emergency Planning for Research and Test Reactors and Other Non-power Production and Utilization Facilities," in September 2017. Consistent with the radiological risks associated with operating power levels between 5 watts thermal and 20 megawatts thermal (MWt) for currently operating RTRs, RG 2.6, Revision 2 endorses the use of the emergency planning guidance based on source term and power level contained in American National Standards Institute (ANSI) and American Nuclear Society (ANS) standard ANSI/ANS-15.16-2015, "Emergency Planning for Research Reactors." Similarly, RG 2.6, Revision 2 endorses the use of ANSI/ANS-15.16-2015 for other NPUFs. The ANSI/ANS-15.16, originally developed in 1982, and updated in 2008 and 2015, provides specific criteria and guidance for RTRs to comply with the applicable requirements set forth in §§ 50.34, "Contents of applications; technical information," and 50.54, and appendix E to 10 CFR part 50.

In October 1983, the NRC issued NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors."

Consistent with ANSI/ANS-15.16, NUREG-0849 provides areas of review, planning standards, and evaluation items for the NRC to evaluate compliance with the applicable emergency planning requirements, previously described. Notably, the guidance contained in both ANSI/ANI-15.16 and NUREG-0849 addresses EPZs for RTRs ranging from the operations boundary[2] to 800 meters from the operations boundary for facilities up to 50 MWt. Both guidance documents state that the EPZs for facilities operating above 50 MWt are to be considered on a case-by-case basis. Section 12.7, "Emergency Planning," of the non-power reactor standard review plan, NUREG-1537, Parts 1 and 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-power Reactors" and the Interim Staff Guidance augmenting NUREG-1537, Parts 1 and 2, for the licensing of radioisotope production facilities and aqueous homogeneous reactors provide additional emergency planning considerations for NPUFs. For example, this additional guidance includes relevant radioisotope production facility emergency planning considerations (e.g., hazardous chemicals) contained in the Interim Staff Guidance augmenting NUREG-1537 based on NUREG-1520, Revision 1, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility."

These criteria and guidance provide a basis for NPUF applicants and licensees to develop acceptable emergency response plans for their facilities. This existing regulatory framework for EP at NPUFs provides the planning necessary to reflect the lower potential radiological hazards associated with the operation of these facilities compared to large LWRs. These EP standards provide additional information for developing the consequence-oriented approach to establishing EPZs and the planning commensurate with the radiological risk for SMRs and ONTs.

[2] As defined in ANSI/ANS-15.16-2015, "operations boundary" refers to the area within the site boundary such as the reactor building (or the nearest physical personnel barrier in cases where the reactor building is not a principal physical personnel barrier) where the reactor chief administrator has direct authority over all activities.

C. Evolution of the Emergency Preparedness Regulatory Framework for Small Modular Reactors and Other New Technologies

The use and regulation of small reactors and other advanced reactor designs have been active topics of discussion between the NRC and the nuclear reactor industry for more than 30 years. The NRC has worked with stakeholders to develop an initial framework for the implementation of performance-based EP regulations and licensing of non-LWR designs, culminating in the current EP rulemaking activities. This section describes the history of small and advanced reactor designs that led to this final rule.

1. Emerging Interest in Advanced Nuclear Reactor Technology

Concurrent with large LWR deployment and design evolution, the United States and other countries have developed and promoted several different reactor designs that are either light-water SMRs with passive safety features or reactors that do not use light-water as a coolant. This latter category is commonly referred to as non-LWR technology. Advanced designs using non-LWR technology include liquid-metal-cooled reactors, gas-cooled reactors, and molten-salt-cooled reactors. These advanced designs could have a rated thermal power ranging from low to very high and may apply modular construction concepts.

As advanced reactor technology evolved in the 1980s and early 1990s, the NRC considered the prospect of a regulatory regime for these emerging technologies. On July 8, 1986, the Commission issued a policy statement, “Regulation of Advanced Nuclear Power Plants, Statement of Policy” (51 FR 24643), outlining the Commission’s early thoughts on the regulation of advanced reactor designs. In the policy statement, the Commission provided a high-level framework for the review and consideration of advanced reactor designs. Following issuance of the policy statement, the NRC published NUREG-1226, “Development and Utilization of the NRC Policy Statement on

the Regulation of Advanced Nuclear Power Plants" in June 1988 to provide guidance on implementing and utilizing the policy statement. With the issuance of this initial guidance came questions concerning EP requirements for such designs.

In response, the NRC staff proposed in SECY-93-092, "Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and Their Relationship to Current Regulatory Requirements,"[3] dated April 8, 1993, that no change to existing EP regulations for advanced reactors was then needed. The NRC staff noted that regulatory direction would be given at or before the start of the design certification phase of advanced reactors so that design implications for EP could be addressed in the licensing process.

The Commission agreed and stated in the Staff Requirements Memorandum (SRM) for SECY-93-092, dated July 30, 1993, that it was premature to reach a conclusion on EP for advanced reactors and that existing regulatory requirements should be used for ongoing review processes. However, the Commission directed that:

> [T]he staff should remain open to suggestions to simplify the emergency planning requirements for reactors that are designed with greater safety margins. To that end, the staff should submit to the Commission recommendations for proposed technical criteria and methods to use to justify simplification of existing emergency planning requirements.

In response to the Commission's direction, the NRC performed an evaluation to develop technical criteria and methods for EP for evolutionary and advanced reactor designs. The evaluation focused on evolutionary and passive advanced LWR designs due to the availability of design and risk assessment data and because applicants were pursuing certification of these designs. In SECY-97-020, "Results of Evaluation of Emergency Planning for Evolutionary and Advanced Reactors," dated January 27, 1997,

[3] "PRISM," "MHTGR," "PIUS," and "CANDU" are abbreviations for Power Reactor Innovative Small Module, Modular High-Temperature Gas-Cooled Reactor, Process Inherent Ultimate Safety, and CANadian Deuterium-Uranium, respectively.

the staff determined that the rationale upon which EP for current reactor designs is based, that is, potential consequences from a spectrum of accidents, is appropriate for use as the basis for EP for evolutionary and passive advanced LWR designs and is consistent with the Commission's defense-in-depth safety philosophy.

In the early 2000s, performance-based EP became an important component of LWR licensing and relicensing discussions. As part of an EP exemption request review, in SECY-04-0236, "Southern Nuclear Operating Company's Proposal to Establish a Common Emergency Operating Facility at its Corporate Headquarters," dated December 23, 2004, the staff noted the following:

> [A]s part of the top-down review of Emergency Preparedness, the staff has identified 10 CFR 50 Appendix E section E.8 and 10 CFR 50.47(b)(3) as opportunities to enhance the emergency preparedness regulatory structure. The staff will propose rulemaking to remove "near-site" from the regulations, as a more performance-based requirement is appropriate….

The Commission agreed, highlighting the potential value of performance-based EP for LWRs in the SRM for SECY-04-0236, dated February 23, 2005, as follows:

> The staff should consider revising 10 CFR Part 50 to make the requirements for EOFs [emergency operations facilities] more performance-based to allow other multi-plant licensees to consolidate their EOFs, if those licensees can demonstrate their emergency response strategies will adequately cope with an emergency at any of the associated plants.

In this decision, the Commission allowed for the development of a performance-based EP requirement.

In SECY-06-0200, "Results of the Review of Emergency Preparedness Regulations and Guidance," dated September 20, 2006, the staff sought Commission approval to explore the feasibility of a voluntary, performance-based EP regulatory regimen. Specifically, the staff stated:

> [A]s the EP program has matured and industry performance has improved, the staff recognized the benefits of a performance-based regulatory structure. Thus, the staff is proposing a new voluntary

> performance-based regulatory regimen. The staff has conceptualized the basis for a voluntary performance-based EP regulatory regimen…. This regimen could be adopted in lieu of the existing EP regulations contained in 10 CFR Part 50. The current regimen tends to emphasize compliance with, and control over, emergency plans and facilities. The performance-based regimen would focus licensee efforts on actual performance competencies, rather than control of emergency plans and procedures. Regulatory oversight would focus on licensee performance, instead of licensee processes and procedures. Creating a performance-based EP regulatory regimen could achieve a higher level of preparedness, as the regimen would focus on results and abilities rather than on means. The performance-based regimen would provide the NRC with enhanced oversight of the actual competencies important to protection of public health and safety while allowing licensees increased flexibility.

In SECY-06-0200, the staff also outlined several high-level performance-based concepts for large LWRs related to performance goals, staffing, and performance indicators (PIs). In the SRM for SECY-06-0200, dated January 8, 2007, the Commission approved several staff recommendations, including the staff's request to begin activities to explore a voluntary performance-based EP regulatory concept.

During the early development of a performance-based EP regulatory concept, the NRC published a "Policy Statement on the Regulation of Advanced Reactors," dated October 14, 2008 (73 FR 60612). The policy statement expressed the Commission's expectation that advanced reactor designers would ensure that security and emergency response are considered alongside safety during the early stages of plant design.

By 2014, the NRC had finalized its study and review of the potential to enhance the oversight of performance-based nuclear power plant EP programs as directed in the SRM for SECY-06-0200. In SECY-14-0038, "Performance-Based Framework for Nuclear Power Plant Emergency Preparedness Oversight," dated April 4, 2014, the staff stated:

> A systematic review and revision of EP requirements to employ a more performance-based oversight regimen (regulation, inspection, and enforcement) has the potential to enhance many aspects of emergency response and oversight. A performance-based oversight regimen could simplify EP regulations and focus inspection more fully on response-

> related performance rather than the current focus on plan maintenance and compliance.

Although the staff asserted that the performance-based framework would simplify EP regulations and focus inspections more on response-related performance, the staff recommended that the existing framework continue to be used with operating plants because changing the EP approach for those plants would require significant resources and could introduce regulatory uncertainty. Additionally, the staff recognized that existing EP programs provided reasonable assurance of adequate protection of public health and safety and therefore recommended maintaining the current EP regimen.

In the SRM to SECY-14-0038, dated September 16, 2014, the Commission directed that:

> The staff should be vigilant in continuing to assess the NRC's emergency preparedness program and should not rule out the possibility of moving to a performance-based framework in the future. The Commission notes the potential benefit of a performance-based emergency preparedness regimen for small modular reactors, and the staff should return to the Commission if it finds that conditions warrant rulemaking.

2. Approach to Emergency Preparedness for Small Modular Reactors and Other New Technologies

In the late 2000s, the discussion of modernizing EP and developing alternative performance-based requirements for LWRs merged with the NRC's ongoing discussions of advanced reactor designs. By this time, several advanced reactor designs were under discussion in the U.S., including the U.S. Department of Energy's (DOE's) Next Generation Nuclear Plant and SMR programs, and by private sector companies seeking to introduce an alternative to large LWRs. By 2010, the NRC began considering the possibility of developing a performance-based approach to EP for SMRs and ONTs. In SECY-10-0034, "Potential Policy, Licensing, and Key Technical Issues for Small Modular Nuclear Reactor Designs," issued on March 28, 2010, the staff identified EP as a key technical issue for the licensing of SMRs and other advanced reactor designs.

The enclosure to the SECY stated that resolution of offsite EP requirements would be of interest to the Federal Emergency Management Agency (FEMA) and the public, as well as to applicants trying to support their business case at the design certification stage.

Contemporaneous with the issuance of SECY-10-0034, the NRC held a series of public meetings with other Federal agencies, industry leaders, and key stakeholders to discuss potential policy, licensing, and technical issues associated with advanced reactor designs. Summaries of the October 8-9, 2009, and July 28, 2010, meetings are available in ADAMS, as provided in the "Availability of Documents" section of this document. Discussions included the proposed framework of potential EP requirements. Emergency preparedness was a significant policy issue for SMR designers because SMR designs may have reduced accident consequences offsite per reactor module, potentially forming the basis for smaller EPZs relative to large LWRs.

The staff discussed the public's input from those meetings in SECY-11-0152, "Development of an Emergency Planning and Preparedness Framework for Small Modular Reactors" on October 28, 2011. The paper informed the Commission of the staff's proposed actions to develop an emergency planning and preparedness framework for SMR facilities. In the document, the staff stated its intent to develop a technology-neutral (now technology-inclusive), dose-based, consequence-oriented EP framework for SMR sites that would take into account the various designs, modularity, and co-location of these facilities with other NRC-licensed facilities and industrial facilities not licensed by the NRC, as well as the size of the EPZs. The staff also stated that "[t]he staff will work with stakeholders to develop general guidance on calculating the offsite dose, and is anticipating that the industry will develop and implement the detailed calculation method for review and approval by the staff."

In response to SECY-11-0152, the Nuclear Energy Institute (NEI) prepared a white paper to provide perspective to the NRC and SMR developers in establishing

EPZs for SMRs. In the "White Paper on Proposed Methodology and Criteria for Establishing the Technical Basis for Small Modular Reactor Emergency Planning Zone," submitted in December 2013, NEI noted the NRC expectation in SECY-11-0152 that SMR license applicants will provide a well-justified technical basis for NRC's review and consideration. The 2013 White Paper was designed to "discuss a generic methodology and criteria that can be adopted and used by the SMR developers and plant operating license applicants for establishing the design-specific and site-specific technical basis for SMR-appropriate EPZs." In the paper, NEI stated that the intent of the paper was to "serve as a vehicle to support the continuing dialogue with the staff that should result in a mutually agreeable methodology and criteria, and thus provide the SMR developers and applicants sufficient guidance as they proceed to develop their design-specific and site-specific technical basis." As stated in the paper, NEI's approach was rooted in the following:

> (1) the expectation of enhanced safety inherent in the design of SMRs (e.g., increased safety margin, reduced risk, smaller and slower fission product accident release, and reduced potential for dose consequences to population in the vicinity of the plant); (2) the applicable SECY-11-0152 concepts including utilization of existing emergency preparedness regulatory framework and dose savings criteria of NUREG-0396; and (3) the significant body of risk information available to inform the technical basis for SMR-appropriate EPZ, including severe accident information developed since NUREG-0396 was published in 1978, and information from the design-specific and plant-specific probabilistic risk assessments (PRAs) which will support SMR design and licensing.

The NEI 2013 White Paper addressed only SMRs with light-water-cooled and moderated designs and the plume exposure pathway EPZ. It did not address other designs or the ingestion pathway EPZ (IPZ). The NRC reviewed the White Paper and discussed the development of the regulatory framework with NEI and stakeholders; however, the NRC did not endorse the paper.

In the enclosure to SECY-10-0034, the staff stated, "Should it be necessary, the staff will propose changes to existing regulatory requirements and guidance or develop

new guidance concerning reduction of offsite emergency preparedness for SMRs in a timeframe consistent with the licensing schedule." In 2015, the NRC determined that SMR EP issues were a key concern for potential SMR and ONT applicants, and that addressing those issues would enhance regulatory predictability for both applicants and the NRC. In May 2015, the staff sought Commission approval to initiate rulemaking to revise the EP regulations and guidance for SMRs and ONTs. In SECY-15-0077, "Options for Emergency Preparedness for Small Modular Reactors and Other New Technologies," dated May 29, 2015, the staff proposed a consequence-oriented approach to establishing EP requirements commensurate with the potential consequences to public health and safety and the common defense and security at SMR and ONT facilities. The staff stated that the need for EP is based on the projected offsite dose in the unlikely occurrence of a severe accident. In SRM-SECY-15-0077, the Commission approved the staff's recommendation to proceed with rulemaking, keeping a performance-based framework in mind as previously directed in SRM-SECY-14-0038. The Commission further directed that, for any SMR reviews conducted prior to the establishment of a regulation, the staff should be prepared to adapt an approach to EPZs for SMRs under the exemption process.

In June 2015, NEI issued a White Paper supporting the NRC proposal in SECY-15-0077 and recommending the revision of EP regulations and guidance for SMR facilities. In "White Paper: Proposed Emergency Preparedness Regulations and Guidance for Small Modular Reactors Facilities," dated July 2015, NEI provided proposed revisions to the planning standards set forth in § 50.47 and appendix E to 10 CFR part 50 as well as associated EP guidance. The proposed revisions were developed by NEI to "constructively inform the staff's deliberations concerning the development of an SMR EP framework, and serve as a basis for future public meeting

engagement." The NRC has considered NEI's recommendations in the development of this final rule.

In addition to the NEI white papers, the NRC has had several interactions with the public concerning licensing issues related to SMRs and ONTs, including joint DOE-NRC Workshops on Advanced Non-Light-Water Reactors held on September 1-2, 2015, and June 7-8, 2016. The NRC held these workshops to obtain stakeholder feedback regarding the proposed rule and inform the public on the proposed approach. Additional information on these workshops may be found in their summaries.

3. Rulemaking Activity

In response to SRM-SECY-15-0077, on May 31, 2016, the staff submitted a rulemaking plan to the Commission (SECY-16-0069, "Rulemaking Plan on Emergency Preparedness for Small Modular Reactors and Other New Technologies") to propose rulemaking to address EP for SMRs and ONTs. In SECY-16-0069, the staff provided a proposed rulemaking schedule, outlining the need to develop EP requirements for SMRs and ONTs commensurate with the potential consequences to public health and safety posed by these facilities. On June 22, 2016, the Commission issued SRM-SECY-16-0069 approving the staff's rulemaking plan.

On August 22, 2016, the NRC held a public meeting to request feedback from stakeholders on a potential performance-based approach for EP for SMRs and ONTs. The participants supported a performance-based approach for EP, indicating that it would be more effective because it would focus on achieving desired outcomes. Participants also favored the performance-based approach because it would allow for innovation and flexibility in addressing the EP requirements. The potential need for an entire new suite of guidance documents, including the process by which licensees make changes to their emergency plans (i.e., change process), was the only disadvantage identified by participants as it would require additional up-front work to reflect the new

approach. A summary of this public meeting is available in ADAMS, as provided in the "Availability of Documents" section of this document. After considering the feedback received from the stakeholders in support of the performance-based approach to EP, the NRC developed a draft regulatory basis that included an option to proceed with rulemaking to implement this approach.

On April 13, 2017, the NRC issued a draft regulatory basis for a 75-day public comment period (82 FR 17768). In the draft regulatory basis, the NRC requested feedback from the public on questions related to the scope of the draft regulatory basis, performance-based approach, regulatory impacts, and cumulative effects of regulation (CER). In addition, the NRC held a public meeting on May 10, 2017, to discuss the draft regulatory basis with interested stakeholders. A summary of this public meeting is available in ADAMS, as provided in the "Availability of Documents" section of this document.

The NRC received comment submissions from 57 individuals and organizations on the draft regulatory basis and the associated regulatory analysis, including223 individual comments related to EP. The commenters included individuals, environmental groups, industry groups, a Tribal government, States, and FEMA. The NRC reviewed all comments submitted on the draft regulatory basis, grouped the comments into categories by comment topic, and developed a resolution for each topic. Comments included topics such as: consequence-based approach, co-location, dose assessment, EPZ and offsite EP, general rulemaking approach, siting of multi-module facilities, performance-based approach, regulatory analysis, scope of the draft regulatory basis, safety, and technology-inclusive approach. The NRC considered those comments and discussions from the public meeting as it finalized the regulatory basis. The NRC published a notification in the *Federal Register* announcing the public availability of the regulatory basis on November 15, 2017 (82 FR 52862).

On May 12, 2020, the NRC published the proposed rule, “Emergency Preparedness for Small Modular Reactors and Other New Technologies,” for a 75-day public comment period (85 FR 28436). On May 25, 2020, the NRC published a notification to correct the definition of “Non-power production or utilization facility” (85 FR 32308). The NRC held a public meeting on June 24, 2020, to engage with external stakeholders on the proposed rule and associated draft guidance document. Additional information about this public meeting is detailed in the meeting summary. The NRC received several requests to extend the comment period by 6 months or more due to the Coronavirus Disease public health emergency. On July 21, 2020, the NRC extended the comment period by 60 days with a closing date of September 25, 2020 (85 FR 44025). The NRC received comment submissions from 2,212 individuals and organizations, including 2,087 form letters and form letters with non-substantive additional text. The staff’s analysis identified 649 unique comments on the proposed rule and associated guidance, the regulatory analysis, and the environmental assessment. The commenters included State and local governments, Tribal governments and Tribal organizations, Federal agencies, members of the nuclear power industry, non-governmental organizations, and private citizens. A summary of the comments and the NRC’s responses to the comments are available as indicated in the “Availability of Documents” section of this document. The NRC used these comments to develop this final rule.

II. Discussion

A. Objective and Applicability

This final rule creates alternative EP requirements that: 1) continue to provide reasonable assurance that adequate protective measures can and will be implemented by an SMR or ONT licensee; 2) promote regulatory stability, predictability, and clarity; 3)

reduce the need for requests for exemptions from EP requirements; 4) recognize advances in design and technology advancements embedded in design features; 5) credit safety enhancements in evolutionary and passive systems; and 6) credit the potential benefits of smaller sized reactors and non-LWRs associated with postulated accidents, including slower transient response times, and relatively small and slow release of fission products. This final rule applies to existing and future SMR and ONT facilities. These applicants and licensees have the option to develop a performance-based EP program designed for SMRs and ONTs, as an alternative to complying with the existing, deterministic EP requirements in 10 CFR part 50.

This final rule does not include within its scope emergency planning, preparation, and response for large LWRs, which for the purposes of this final rule are those LWRs that are licensed to produce greater than 1,000 MWt power; fuel cycle facilities; or currently operating non-power reactors. The current operating fleet of power reactors has an established EP regulatory framework under § 50.47 and appendix E to 10 CFR part 50. Emergency planning requirements for facilities licensed under 10 CFR part 70 are set forth in § 70.22(i). The NRC established in appendix E to 10 CFR part 50 emergency planning requirements for RTRs that reflect the lower potential radiological hazards associated with these facilities.

The plume exposure pathway EPZ for the current operating fleet of nuclear power reactors consists of an area about 10 miles (16 km) in radius and the IPZ for such facilities consists of an area about 50 miles (80 km) in radius. See current §§ 50.33(g) and 50.47(c). As discussed in the “Background” section of this document, in the early 2000s, the NRC anticipated that future SMR and ONT applications would reflect a wide range of potential designs that have smaller source terms and incorporate EP considerations as part of the design. In its Statement on the Regulation of Advanced Reactors (73 FR 60612), the Commission stated that it “expects that advanced reactors

will provide enhanced margins of safety and/or use simplified, inherent, passive, or other innovative means to accomplish their safety and security functions." Under the current EP framework, §§ 50.33(g) and 50.47(c)(2) provide that the size of plume exposure pathway EPZs and IPZs for gas-cooled nuclear reactors and for reactors with an authorized power level less than 250 MWt may be determined on a case-by-case basis. Section I.3 of appendix E to 10 CFR part 50 states that the EPZs for facilities other than power reactors may also be determined on a case-by-case basis. In addition, applicants and licensees for power reactors may also request that the size of the EPZs and IPZs for their facilities be determined on a case-by-case basis by seeking an exemption under § 50.12, "Specific exemptions," from the requirements in §§ 50.33(g) and 50.47(c)(2) regardless of authorized power level. Furthermore, appendix E to 10 CFR part 50, provides the flexibility to determine other emergency planning considerations, such as organization, assessment actions, activation of emergency organization, emergency facilities, and equipment, on a case-by-case basis for certain facilities.

The NRC initiated this rule to seek a wide-range of public views and increase regulatory predictability and flexibility in the development of an alternative, generic approach that designers, vendors, and applicants may use to determine the appropriate EP requirements for SMRs and ONTs, for which emergency planning may otherwise be addressed on a case-by-case basis. In particular, this final rule provides additional predictability and flexibility for advanced reactor developers that use simplified or other innovative means to accomplish their safety functions and provide enhanced margins of safety. Large LWRs were not included by the NRC in the scope of this final rule because an EP licensing framework already exists for those reactors, and licensees for those plants have not expressed a clear interest in changing that framework.

For clarity, this final rule defines the different types of affected facilities. The NRC amends § 50.2 to include the terms "small modular reactor," "non-light-water

reactor," and "non-power production or utilization facility." The NRC has included a definition of "non-light-water reactor" to address ONTs, including liquid-metal-cooled reactors, gas-cooled reactors, and molten-salt-cooled reactors. Having a separate definition for these non-LWR technologies clarifies the applicability of the existing EP standards and requirements in 10 CFR part 50, which are specific to LWRs, and maintains consistency between this final rule and the "Variable Annual Fee Structure for Small Modular Reactors" final rule (81 FR 32617; May 24, 2016).

The NRC evaluated the suitability of using the existing definition of "small modular reactor" in § 171.5, "Definitions" for the purposes of this EP final rule. The § 171.5 definition of "small modular reactor" means, for the purpose of calculating fees, the class of light-water power reactors having a licensed thermal power rating less than or equal to 1,000 MWt per module. This rating is based on the thermal power equivalent of a light-water SMR with an electrical power generating capacity of 300 megawatts electric or less per module. Although similar, this final rule's definition of "small modular reactor" does not include reference to electrical power generating capacity. For the fee-related regulations in 10 CFR part 171, "Annual Fees For Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC," the NRC determined that using the thermal power equivalent of electric power generating capacity would be equitable because SMRs should pay annual fees that are commensurate with the economic benefit received from their license (81 FR 32617). However, because electric power generating capacity is not a criterion the NRC uses to determine EP requirements, this final rule's definition focuses on thermal power rating.

The NRC received a public comment on the proposed rule that the definition of "small modular reactor" should indicate that an SMR can have a licensed thermal power

up to 1,000 MWt, and that this limit applies to each module in a facility rather than the total thermal power of all modules in a facility. The proposed rule's definition of "small modular reactor" provided that an SMR was a power reactor licensed to produce heat energy up to 1,000 MWt, which may be of modular design as defined in § 52.1, "Definitions." The NRC agreed that this definition could be subject to more than one interpretation and revised the definition of "small modular reactor" to read: "a power reactor, which may be of modular design as defined in § 52.1 of this chapter, licensed under § 50.21 or § 50.22 to produce heat energy up to 1,000 megawatts thermal per module." The "per module" language is also consistent with the definition of "small modular reactor" in § 171.5.

B. Need for Changes to Existing Regulatory Framework

As mentioned in the "Background" section of this document, in SECY-10-0034, the NRC identified potential policy and licensing issues for SMRs based on the preliminary design information supplied in pre-application interactions and discussions with SMR designers and the DOE. In general, these issues result from the key differences between the new designs and the current-generation large LWRs, such as rated thermal power, moderator, coolant, and fuel design. In SECY-10-0034, the NRC described designs discussed in pre-application interactions with DOE and SMR designers. The rated thermal power of these designs ranged from 30 MWt to 1,000 MWt. The designs included the use of helium gas, sodium, and light-water as coolants. While some SMR designs employ conventional LWR radiological barrier designs, some designs may employ a non-traditional containment approach.

In addition to licensing issues associated with differences in designs, some of the licensing issues resulted from industry-proposed review approaches and industry-proposed modifications to current policies and practices, including standard review plans

and design-specific review standards. The potential for smaller reactor core sizes, lower power densities, lower probability of severe accidents, slower accident progression, and smaller accident offsite consequences per module that characterize some SMR designs have led DOE, SMR designers, and potential operators to revisit the determination of the size of the EPZs, the extent of onsite and offsite emergency planning, and the number of onsite response staff needed.

Historically, licensees of small reactors have requested exemptions from EP regulations because those EP requirements would have imposed a regulatory burden on the applicants that was not necessary to protect the public health and safety due to the facilities' designs. The NRC anticipates that existing or future SMR and ONT applicants could also have designs that differ substantially from the existing fleet of large LWRs. These applicants could also request exemptions from EP requirements that are potentially unnecessary to protect the public health and safety. Although the exemption process provides the flexibility to address these existing or future applicants, regulating by exemption generally provides little opportunity for public engagement in the exemption process and can lead to undue burden and lack of predictability for applicants, licensees, and the NRC stemming from the applicant or licensee specific nature of exemption requests.

This final rule creates a transparent alternative EP regulatory framework for SMR and ONT applicants and licensees that continues to provide reasonable assurance that adequate protective measures can and will be implemented in a radiological emergency. The final alternative EP requirements consider a wide range of views, acknowledge technological advancements and other differences from large LWRs inherent in SMRs and ONTs, and reduce regulatory burden by precluding the need for exemptions from EP requirements as applicants request permits and licenses. This final rule also supports the principles of good regulation, including openness, clarity, and reliability.

1. Technical Basis

This final rule is a performance-based, technology-inclusive, risk-informed, and consequence-oriented alternative approach to EP for SMRs and ONTs. These approaches form the basis for the NRC's final rule, and the following discussion addresses the technical basis for each.

a. Performance-Based Approach to Emergency Planning

The NRC's current regulatory framework for EP in 10 CFR part 50 requires that site-specific emergency plans be developed and maintained in compliance with 16 planning standards for nuclear power reactors. This deterministic structure does not provide performance standards, but the regulations and guidance for emergency response organizations (EROs) emphasize requirements for emergency plans and facilities. The existing EP requirements for large LWRs are based on decades of research on the risks posed by these facilities. The risks for these facilities are well understood, and, as such, a deterministic approach to regulating EP is an effective method for providing reasonable assurance that protective measures can and will be taken in a radiological emergency.

The NRC anticipates that existing and future SMR and ONT applications will use a wide range of potential designs and source terms. Advances in designs could enhance the EP for these facilities. At the same time, EP itself is improving through technological innovations like FEMA's Integrated Public Alert & Warning System. Because the technology for EP and certain SMR and ONT designs are still evolving, a performance-based approach could allow for more regulatory flexibility, provide a basis for appropriate EP through review of design- and site-specific accident scenarios, and minimize the need for exemption requests that would otherwise be anticipated under a prescriptive regulatory framework. In this context, a performance-based approach bases the adequacy of EP upon the NRC's identification of emergency response functions that

affect the protection of public health and safety and the licensee's successful execution of those functions. The NRC's performance-based framework, inspection and enforcement program, and design-specific review process provide reasonable assurance that protective measures can and will be taken in the event of an emergency at an SMR or ONT facility. The NRC has previously explored the idea of a performance-based EP framework, as discussed in the "Performance-Based Emergency Preparedness" section of this document, and the Commission noted that a performance-based approach was a potential benefit to regulating EP for SMRs. The performance-based approach could simplify EP regulations and focus inspections more fully on response-related performance.

The NRC also considered a graded approach to EP that would take into account the magnitude of any credible hazard involved, the particular characteristics and status of a facility, and the balance between radiological and non-radiological hazards. A graded approach to EP has a longstanding regulatory history. The 16 EP planning standards for nuclear power reactors, outlined in § 50.47(b), and the associated evaluation criteria in NUREG-0654/FEMA-REP-1, Revision 1 and NUREG-0654/FEMA-REP-1, Revision 2, are part of a continuum of planning standards for radiological EP. The existing regulations in § 50.47(c)(2) for EPZ size determinations for gas-cooled reactors and reactors with power levels less than 250 MWt, the EP regulations for production and utilization facilities other than nuclear power reactors in appendix E to 10 CFR part 50, and the EP regulations for fuel cycle facilities in § 70.22(i) and independent spent fuel storage installations (ISFSIs) in § 72.32, "Emergency plan," are also part of a graded approach to EP that is commensurate with the relative radiological risk, source term, and potential hazards, among other considerations.

b. Technology-Inclusive Approach to Emergency Planning

As previously mentioned, the NRC has licensed, reviewed, or had pre-application discussions with stakeholders supporting a range of technology types that are included in the scope of this final rule. Based on the information currently available to the NRC, unique design considerations (e.g., passive safety characteristics, advanced fuel types, and chemical processes) and the potential for multi-module facilities and siting contiguous to, or near, NRC-licensed facilities or facilities not licensed by the NRC could lead to a variety of accident frequencies, progression times, and potential consequences for SMRs or ONTs. To incorporate recent and potential technology advancements and reduce the need for future EP rulemaking, this final rule offers a technology-inclusive approach to EP for SMRs and ONTs. In this context, technology-inclusive means the establishment of performance requirements for any SMR or ONT applicant or licensee to use in its emergency plan, developed using methods of evaluation that are flexible and practicable for application to a variety of reactor technologies.

As described further in the "Performance-Based Framework" section of this document, the NRC's final alternative framework for SMRs and ONTs consists of two major elements – an EPZ size determination process and a set of performance-based requirements. The size of an EPZ determined by this process is scalable based on factors such as accident source term, fission product release, and associated dose characteristics, and the same process can be applied to all SMR and ONT designs. Further, the performance-based requirements in § 50.160, "Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities," do not contain any technology specific language. Rather, applicants and licensees demonstrate how they meet the EP performance-based framework based on their design- and site-specific considerations through the implementation of a performance objective scheme and the conduct of drills and exercises.

c. Consequence-Oriented and Risk-Informed Approaches to Emergency Planning

This final rule offers a consequence-oriented approach to establish EP requirements for SMRs and ONTs. In this context, consequence-oriented means the principle of basing decisions regarding the scope of EP upon the potential consequences from a spectrum of accidents, including those that could result in an offsite radiological release. The decisions regarding EP should be based upon projected offsite dose from such accidents and the pre-determined plume exposure pathway EPZ for pre-planned protective measures.

The NRC reviewed the current EP requirements associated with various nuclear facilities, including large and small operating reactors, material facilities, fuel facilities, ISFSIs, NPUFs, and decommissioning large LWRs (including SECY-18-0055, "Proposed Rule: Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning," dated May 22, 2018). In this review, the NRC identified that all of the existing types of NRC-licensed nuclear facilities use a consequence-oriented approach and take into account other considerations, such as the likelihood of the accident, to establish the boundary of the plume exposure pathway EPZ (or other planning area). The consequence or dose considerations are based on the U.S. Environmental Protection Agency (EPA) early-phase Protective Action Guides (PAGs) (EPA-520/1-75-001), issued in September 1975. The PAGs were revised and republished as EPA-400-R-92-001 in May 1992, and a subsequent revision, EPA400/R-17/001, was issued in January 2017.

The general considerations from the existing planning basis for EP, established 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," introduced the concept of generic EPZs as the basis for preplanned response actions. These planning distance considerations were intended to result in dose savings to members of the public in the environs of a nuclear facility when

the EPA PAGs were used as the threshold to trigger the preplanned protective measures in the event of a reactor accident that would result in offsite dose consequences. Planning should also be based upon knowledge of the potential consequences, timing, and radiological release characteristics from a spectrum of accidents, including severe accidents. The joint NRC-EPA task force that developed NUREG-0396 considered several possible rationales for establishing the size of the EPZs, including risk, cost effectiveness, and the accident consequence spectrum (e.g., dose and significant health effects). After reviewing these alternatives, the NRC-EPA task force concluded that the objective of emergency response plans should be to provide dose savings for a spectrum of accidents that could produce offsite doses in excess of the EPA PAGs for those members of the public who would most likely receive exposure as a result of a significant release.

In the 1980 Final Rule, based on the guidance in NUREG-0396, the NRC established plume exposure pathway and ingestion pathway EPZ requirements for large LWRs of about 10 miles (16 km) and 50 miles (80 km), respectively. The NRC also clarified that the size of the EPZ could be determined on a case-by-case basis for gas-cooled nuclear reactors and for reactors with an authorized power level less than 250 MWt. The NRC stated that this requirement was based on the lower potential hazard from these facilities (i.e., lower radionuclide inventory and longer times to release significant amounts of activity in many scenarios) and clarified that the radionuclides to be considered in planning for large LWR accident scenarios were set forth in NUREG-0396. Similarly, the NRC established in the 1980 Final Rule that the degree to which compliance with sections I through V of appendix E to 10 CFR part 50 would apply to RTRs and fuel cycle facilities would be determined on a case-by-case basis because the radiological hazards to the public associated with the operation of RTRs and fuel

cycle facilities involve considerations different than those associated with nuclear power reactors.

This final rule for SMRs and ONTs continues this consequence-oriented approach for determining the size of the plume exposure pathway EPZ. The primary purpose of the plume exposure pathway EPZ is to define the area where predetermined, prompt protective measures are necessary, which results in dose savings and a reduction in early health effects. In this final rule, the NRC establishes in § 50.33(g)(2)(i) two criteria for determining a plume exposure pathway EPZ size. The first criterion is that the plume exposure pathway EPZ is the area within which public dose, as defined in § 20.1003, "Definitions," is projected to exceed 10 millisieverts (mSv) (1 rem) total effective dose equivalent (TEDE) over 96 hours from the release of radioactive materials from the facility considering accident likelihood and source term, timing of the accident sequence, and meteorology. The second criterion is that the plume exposure pathway EPZ is the area where predetermined, prompt protective measures are necessary.

The principle of using dose versus distance to determine EPZ size has been used in the past when the NRC licensed several small reactors with a reduced EPZ size of 5 miles (8 km). These reactors include the Fort St. Vrain high-temperature gas-cooled reactor (HTGR) (842 MWt), the Big Rock Point boiling water reactor (BWR) (240 MWt), and the La Crosse BWR (165 MWt). Pre-application discussions between the NRC and SMR designers have indicated that SMRs also could have reduced offsite dose consequences in the unlikely event of an accident. With the expected safety enhancements in SMR designs and the potential for reduced accident source terms and fission product releases from SMRs and ONTs, this final rule provides an alternative EP framework that allows SMR and ONT applicants to develop EPZ sizes commensurate with their accident source terms, fission product releases, and accident dose characteristics considering site-specific meteorology.

To support this final rule, the NRC conducted research on EPZ size determinations for SMRs and ONTs. Because of the potential variations in SMR or ONT designs, the NRC cannot conduct a comprehensive evaluation of source terms and spectra of accidents as part of this final rule. Instead, the research study, "Generalized Dose Assessment Methodology for Informing Emergency Planning Zone Size Determinations," dated June 2018, reviewed the dose assessment methodologies that informed the EPZ size determinations in NUREG-0396 and developed a general methodology for determining plume exposure pathway EPZ size based on NUREG-0396. Information from that review and a subsequent set of recommended analyses documented in "Required Analyses for Informing Emergency Planning Zone Size Determinations," dated June 2018, was used to develop the methodology described in Appendix A, "General Methodology for Establishing Plume Exposure Pathway EPZ Size," of RG 1.242.

This final rule requires applicants that choose to comply with § 50.160 to submit an analysis under § 50.33(g)(2) to provide the technical basis justifying the proposed plume exposure pathway EPZ size. The NRC evaluates each application on a case-specific basis. The "Emergency Planning Zones" section in this document contains additional discussion on the NRC's consequence-oriented approach to EPZ size determinations for an SMR or ONT facility.

The proposed rule included a plume exposure pathway EPZ in which public dose is projected to be above 10 mSv (1 rem) TEDE over 96 hours from the release of radioactive materials, resulting from a spectrum of credible accidents for the facility. The NRC received public comments concerning the need for clarification on the plume exposure pathway EPZ determination requirements, including the 10 mSv (1 rem) TEDE over 96 hours from the release of radioactive materials and the definition of "spectrum of credible accidents." The NRC removed the phrase "spectrum of credible accidents" in

this final rule. The determination of whether accidents are credible for a facility is a part of the applicant's safety analysis required for its application. As part of the NRC's safety review of the application, the NRC reviews the applicant's assessment of licensing basis events, event likelihood, and public dose consequences. The NRC's determination of the acceptability of the applicant's assessment supports the agency's separate review of the applicant's emergency plan.

As a result of these comments on the proposed rule, the NRC revised the requirements by listing in § 50.33(g)(2)(i)(A) the major considerations for the radiological consequence analysis to be used in determining the plume exposure pathway EPZ size for the facility: accident likelihood and source term, timing of the accident sequence, and meteorology. Consideration of accident likelihood in combination with event sequences makes it possible to arrive at the spectrum of accidents taken from the licensing basis events to develop the basis for the applicant's site-specific plume exposure pathway EPZ. Source terms are used to determine dose consequences. Timing of the accident sequence facilitates determining if prompt protective measures are warranted. Meteorology input is essential in determining the weather conditions that impact dose consequences due to atmospheric transport and dispersion of the radioactive plume. Meteorological inputs should consider, but not be limited to, wind speeds, wind directions, atmospheric stability, precipitation, and mixing height, for temporal and geographical representativeness. Regulatory Guide 1.242 provides guidance on these considerations and developing the dose-consequence analysis.

The NRC also added a second criterion to the plume exposure pathway EPZ size determination in § 50.33(g)(2)(i)(B): the plume exposure pathway EPZ is the area in which predetermined, prompt protective measures are necessary. This rule provision adds a functional criterion to the EPZ to be consistent with the planning basis approach in NUREG-0396 and Federal guidance contained in the EPA PAG Manual.

The risk-informed planning basis for EP, established in NUREG-0396, was endorsed in the Commission policy statement, “Planning Basis for Emergency Responses to Nuclear Power Reactor Accidents,” dated October 23, 1979 (44 FR 61123), and incorporated in the 1980 Final Rule. In the policy statement, the Commission said, “Predetermined protective action plans are needed for the EPZs.” As described in NUREG-0396, for very serious accidents, predetermined, prompt protective actions would be taken if projected doses, at any place and time during an actual accident, appeared to be at or above the applicable proposed PAGs, based on information readily available in the reactor control room (i.e., at predetermined emergency action levels).

The planning basis established in NUREG-0396 determined that the scope of the planning effort needs to include: 1) the distance to which detailed planning for predetermined protective actions is warranted, 2) the time dependent characteristics of potential releases and exposures, and 3) the radioactive materials potentially released. The specified planning distance ensures that the locations of at-risk populations are identified, the responsible authorities who would carry out these actions will be notified, and the means of communication to these authorities are included in the detailed planning. The time available between recognition of the initiation of a serious accident and the beginning of the radioactive release to the environment is critical in determining what predetermined protective actions would be appropriate.

The planning basis in NUREG-0396 used the accident analyses and assumptions of NUREG-75/014, “Reactor Safety Study – An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants,” (WASH-1400), Appendices III and IV; Appendix V; Appendix VI; and Appendices VII-X, dated October 1975. These analyses assume that the range of times for the onset of radiological accident conditions and the start of a major radiological release could be from less than an hour to several

hours. The potential for a major atmospheric release would necessitate consideration of predetermined, prompt protective measures. The length of time from the initiation of an event to the time of release in relation to the ability for OROs to determine and initiate protective measures is key to reducing dose and providing for public health and safety. If OROs have sufficient time to determine what protective measures, if any, are necessary to take for releases occurring after a delay from the initiating event (e.g., several hours), then predetermined, prompt protective measures may not be necessary. As an example of an analysis of timing considerations, the Low-Power Rule ("Emergency Planning and Preparedness Requirements for Nuclear Power Plant Fuel Loading and Low-Power Testing," Final Rule, 53 FR 36955; September 23, 1988) included an analysis on the need for predetermined, prompt protective measures. Due to the substantial reduction in the likelihood of an accident and potential accident consequences for low power testing as compared to continuous full power operation, the analysis for this example identified a time period of 10 hours from the start time of the initiating event to the start time of a potential major release as a reasonable amount of time for OROs to take appropriate response actions that provide for public health and safety without the need for predetermined, prompt protective measures.

This timing of a potential major release is the basis for requiring predetermined, prompt protective measures triggered by plant conditions or dose projections in response to a General Emergency declaration. Because SMRs and ONTs are expected to have accident timing characteristics different from large light-water reactor technologies considered in NUREG-0396, and because technology important to emergency planning and response continues to improve, the NRC added a functional criterion to this final rule to ensure that the need for predetermined, prompt protective measures is evaluated in the planning considerations.

This final rule requires applicants and licensees choosing to comply with § 50.160 to describe in their emergency plan the information that demonstrates compliance with the elements set forth in § 50.160(b). This includes the capability to assess and classify emergency events, establish and maintain effective communications, assess radiological conditions in and around the facility, and recommend protective measures to offsite authorities as conditions warrant. If an applicant or licensee determines under § 50.33(g)(2)(i)(B) that pre-determined, prompt protective measures are warranted, which would occur only if § 50.33(g)(2)(i)(A) is also met, then an EPZ is required. The need for pre-determined, prompt protective measures is assumed to exist unless an applicant can demonstrate that the timing of accidents in relation to the proposed capabilities for assessment and notification are such that predetermined, prompt protective measures are not warranted. That is, the applicant must demonstrate that plant condition-based, predetermined, prompt protective measures are not required because sufficient time is available, and the capability exists, to initiate appropriate response actions offsite as conditions warrant. RG 1.242 provides guidance for the EPZ functional criterion.

The capability for taking protective measures is not dependent upon an established EPZ. The EPZ is a planning tool to ensure predetermined, prompt protective measures can and will be taken if accident conditions warrant. If both § 50.33(g)(2)(i) criteria are met, then an EPZ is required. However, if there is no need for predetermined, prompt protective measures, then the final rule still requires licensees to develop and maintain capabilities to assess, classify, notify, and recommend protective measures as conditions warrant. In all cases, the NRC will not issue an initial operating license (OL) or combined license (COL) unless the NRC finds that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

This final rule does not provide for a specific IPZ. This final rule includes ingestion response planning requirements instead of an IPZ at a set distance as part of the performance-based framework. Ingestion response planning focuses planning efforts on identification of major exposure pathways for ingestion of contaminated food and water. This final rule requires applicants and licensees who comply with § 50.160 to describe in their emergency plan the licensee, Federal, State, and local resources for ingestion emergency response capabilities available to sample, assess, and implement a quarantine or embargo of food and water to protect against contaminated food and water entering the ingestion pathway. For those applicants and licensees using § 50.47(b) and appendix E to 10 CFR part 50, the IPZ requirements remain unchanged.

These ingestion emergency response capabilities are implemented either by the licensee within the site boundary or by Federal, State, and local authorities in the intermediate or later-stage response to an accident involving the release of radioactive material. The sampling, assessing, and imposing of a quarantine or embargo are longer-term issues. Federal and State authorities frequently issue precautionary actions or implement quarantines or embargos for non-radiological contamination of foods. Further, Federal resources are available upon request to State, local, and Tribal response to any nuclear or radiological incident. Current State and local plans include sampling, assessing, and implementing precautionary actions prior to exceeding dose thresholds or PAGs.

2. Performance-Based Framework

This final rule creates a new section, § 50.160, that provides a performance-based EP framework for SMRs and ONTs as an alternative to the current regulations. Under § 50.54(q)(2)(ii) in this final rule, licensees are required to follow and maintain either an emergency plan that meets the requirements in § 50.160 or an emergency plan that meets the requirements in appendix E to 10 CFR part 50 and, for nuclear power

reactor licensees, the planning standards of § 50.47(b). Sections 50.34 and 52.79, "Contents of applications; technical information in final safety analysis report," stipulate that SMR and ONT applicants have the option to choose either approach.
Section 50.160 includes: 1) emergency response functions that must be demonstrated through the regular development and maintenance of performance objectives and periodic drills and exercises, 2) onsite and offsite planning activities to be met by applicants and licensees to which the provision applies, 3) requirements for considering credible hazards associated with contiguous or nearby NRC-licensed facilities and industrial facilities not licensed by the NRC, and 4) a requirement for applicants and licensees to determine and describe in the emergency plan the boundary and physical characteristics of the plume exposure pathway EPZ and ingestion response planning capabilities. Licensees complying with § 50.160 are required under § 50.160(b)(1) to demonstrate effective response in drills and exercises and describe in their emergency plans how they will maintain preparedness. To comply, emergency plans must include a description of how the emergency response functions in § 50.160(b)(1)(iii) and the planning activities in § 50.160(b)(1)(iv), if applicable, will be met.

The NRC has a long history of successful implementation of performance-based EP requirements (e.g., performance-based requirements for emergency facilities and staffing, and the Reactor Oversight Process).[4] Under this final rule's performance-based approach to EP, performance and results are the primary basis for regulatory decisionmaking, and the applicant or licensee has the flexibility to determine how to meet the established performance criteria for an effective EP program. The performance-based regimen focuses on actual performance competencies, rather than control of emergency plans and procedures. Regulatory oversight focuses on

[4] For further information on the Reactor Oversight Process, see: https://www.nrc.gov/reactors/operating/oversight.html.

performance, instead of processes and procedures. The performance-based regimen provides the NRC with enhanced oversight of the actual competencies important to the protection of public health and safety while allowing applicants and licensees increased flexibility.

The performance-based requirements in § 50.160 address the most risk-significant aspects of EP (e.g., classification, notification, protective action recommendation, mitigation), as well as several planning activities currently required under appendix E to 10 CFR part 50. Compliance with § 50.160 is demonstrated by performance during drills or exercises and the NRC's review of performance objectives and corrective actions. The NRC, in consultation with FEMA when an EPZ extends beyond the site boundary, ensures that reasonable assurance is maintained based on demonstrations of required emergency response functions through drills and exercises and NRC inspections. Between drills and exercises, licensees maintain a set of performance objectives to measure emergency response performance. See the "Reasonable Assurance" section of this document for a discussion of how this final rule maintains reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

In responding to a public comment related to risks associated with the loading and storage of irradiated fuel, the NRC determined that a conforming change is needed to 10 CFR part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater that Class C Waste." A 10 CFR part 72 specific license ISFSI must comply with the EP requirements in § 72.32. Most power reactor licensees have 10 CFR part 72 general licenses for their ISFSIs. For these ISFSIs, § 72.32(c) provides that the emergency plan required by § 50.47 satisfies the EP requirements of § 72.32. This provision means that an emergency plan that meets the requirements of § 50.47 satisfies the EP requirements of

§ 72.32. This same policy applies to an ISFSI on the site of a power reactor whose licensee is complying with § 50.160. To allow for this, the NRC revised § 72.32(c) to clarify that the emergency plan that meets either the requirements in § 50.160 or the requirements in appendix E to part 50 and § 50.47(b) satisfies the EP requirements of § 72.32.

a. Application Process

Current applicants for a construction permit (CP), early site permit (ESP), OL, or COL are required to provide emergency planning information as described in § 50.33, § 50.34, § 52.17, "Contents of applications; technical information," and § 52.79. In particular, § 50.34(a)(10) requires applicants for CPs to describe within the preliminary safety analysis report (PSAR) their preliminary plans for coping with emergencies. Under § 52.17(b), ESP applicants must identify within their site safety analysis report physical characteristics of the proposed site that could pose a significant impediment to the development of emergency plans and, as applicable, measures for mitigating or eliminating the significant impediments. Within the site safety analysis report, ESP applicants also have the option of proposing either major features of emergency plans (under § 52.17(b)(2)(i)) or complete and integrated emergency plans (under § 52.17(b)(2)(ii)) for NRC review and approval. Applicants for OLs and COLs, as well as ESP applicants choosing to provide emergency plans under § 52.17(b)(2)(ii), must submit radiological emergency response plans of State and local governments wholly or partially within the plume exposure pathway EPZ and State governments wholly or partially within the IPZ under § 50.33(g). Under §§ 50.34(b)(6)(v) and 52.79, OL and COL applicants also must include in their final safety analysis report (FSAR) their plans for coping with emergencies.

Because SMR and ONT licensees are given a choice between complying with either § 50.160 or complying with the requirements in appendix E to 10 CFR part 50 and,

for nuclear power reactor licensees, the planning standards in § 50.47, this final rule includes a number of conforming changes to clarify application requirements for applicants choosing the performance-based requirements.

- Construction permit and OL applicants must include emergency planning information in their PSARs and FSARs, respectively, and § 50.34(a)(10) and (b)(6)(v) require that the information describe how the applicant complies with either appendix E to 10 CFR part 50 or § 50.160.

- In order to maintain applicability to applicants and licensees choosing to comply with § 50.160, the NRC has added references to § 50.160 in § 50.47(c)(1), § 50.47(c)(1)(i), and § 50.47(e).

- Combined license and ESP applicants must continue to include emergency planning information in their site safety analysis report and FSAR; §§ 52.17(b)(2), 52.18, and 52.79(a)(21) require that the information describe how the applicant complies with either the applicable requirements in § 50.47 and appendix E to 10 CFR part 50, or the requirements in § 50.160.

- Applicants choosing to comply with § 50.160 must describe how their emergency plans meet the requirements in § 50.160(b). A revision to § 52.1 clarifies that, for applicants choosing the performance-based approach, the definition for “major feature of the emergency plans” includes aspects of plans necessary to address the requirements of § 50.160(b).

- Section 50.33(g)(2)(ii)(A) clarifies requirements to submit State, local, and participating Tribal emergency response plans for SMR, non-LWR, and NPUF applicants. Namely, if the application is for an OL or COL, or for an ESP that contains plans for coping with emergencies, and the plume exposure pathway EPZ extends beyond the site boundary (as defined in § 20.1003), the applicant must submit State,

local, and participating Tribal emergency response plans. For purposes of this final rule, the term "participating Tribal" government means a Federally recognized Tribal government that has decided to participate in FEMA's offsite radiological emergency preparedness (REP) program and act as an independent entity with its own radiological emergency plan. The NRC included participating Tribal emergency response plans in this requirement to reflect the Commission's January 9, 2017 "Tribal Policy Statement" (82 FR 2402) and the 2019 issuance of NUREG-0654/FEMA-REP-1, Revision 2, which encourages the involvement of Tribal governments in NRC activities, and to reflect that Tribes have the option to participate in emergency planning in the communities where they are located. A Tribal government that has its own radiological emergency response plan can participate in State or local emergency response planning as an independent entity. A Tribe also has the option of being part of a State or local emergency response plan without participating in exercises or other community emergency response planning. To the extent that the Tribe elects to be included in State and local plans or does not participate in community emergency planning, FEMA will evaluate the adequacy of the State or local emergency response plan to provide for adequate protection of the members of the Tribal nation.

The requirements in § 50.33(g)(2) also include submission of an analysis for determining the plume exposure pathway EPZ, which is discussed in the "Emergency Planning Zones" section of this document.

b. Performance Objectives

Applicants and licensees adopting the alternative performance-based regulations must describe how they intend to maintain the effectiveness of their emergency plans to meet the performance-based requirements, which includes the implementation of a performance objective scheme that reflects the emergency response functions under § 50.160(b)(1)(iii). The NRC anticipates that performance objectives needed to

demonstrate compliance with performance-based requirements will vary by design. Therefore, the NRC or industry may develop additional guidance related to performance objectives for specific designs or classes of designs.

Section 50.160(b)(1)(ii) requires applicants and licensees using § 50.160 to describe in the emergency plan an approach to develop and maintain at the beginning of each calendar quarter a list of performance objectives for that calendar quarter. Each licensee also must maintain records showing the implemented performance objectives and associated metrics during each calendar quarter for the previous eight calendar quarters. The NRC monitors the performance objectives and metrics to ensure that licensees are maintaining adequate emergency planning and preparedness. During evaluated exercises, the NRC assesses the performance of the licensee and reviews the ability of the licensee to take corrective actions in a timely manner.

c. Drills and Exercises

A key feature of this final rule is the use of drills and exercises to demonstrate that the applicant or licensee can implement the emergency plan to carry out an effective response to emergency and accident conditions. Current regulations in appendix E to 10 CFR part 50, section IV.F include a requirement for periodic drills and exercises for nuclear power reactor licensees to be conducted during an eight-year drill and exercise cycle. The eight-year cycle requirement affords sufficient time for a licensee to vary exercise scenario content to provide ERO members the opportunity to demonstrate proficiency in the key skills necessary to respond to several specific scenario elements. Similarly, § 50.160(b)(1)(iii) requires the use of drills and exercises to demonstrate the licensee's capabilities in the enumerated emergency response functions listed in § 50.160(b)(1)(iii)(A)-(H). Additionally, maintenance of these capabilities is demonstrated through continued drills and exercises. And, unlike the exercise cycle requirements in appendix E to 10 CFR part 50, this final rule's performance-based

requirements do not define the required frequency of drills and exercises or their scenarios. However, the exercise cycle frequency adopted by applicants and licensees should afford sufficient time during which ERO members will be provided ample opportunities to demonstrate their emergency response function capabilities listed in § 50.160(b)(1)(iii)(A)-(H). Applicants and licensees are required to describe exercise scenario elements necessary to demonstrate the emergency response functions in their emergency plans.

For facilities with EPZs that do not extend beyond the site boundary, OROs are not required to participate in radiological drills and exercises. Participation is not required because State, local, and Tribal government organizations do not need to provide for predetermined, prompt protective measures or take specialized actions in response to an event, other than providing onsite firefighting, law enforcement, and ambulance/medical services. Applicants and licensees may consider allowing State, local, or Tribal government organizations to participate in drills when requested by the offsite authorities. The "Offsite Radiological Emergency Preparedness Planning Activities" section of this document addresses ORO participation for facilities with EPZs that extend beyond the site boundary.

Under § 50.160(b)(1)(iii), the applicant's or licensee's emergency response team needs to have sufficient capability to demonstrate the following emergency response functions:

- Event classification and mitigation. The applicant or licensee needs to establish an emergency classification and action level scheme with established criteria for determining the need for notification of State, local, and Tribal governments, and participation of those governments in emergency response such that demonstration of the scheme can be achieved through the performance of drills or exercises within a performance-based framework. Applicants and licensees need to demonstrate the

ability to assess, classify, monitor, and repair facility malfunctions and return the facility to safe conditions. The term “safe conditions” means that the facility has been restored to a radiologically safe and stable condition.

- Protective actions. The drill and exercise program needs to demonstrate the capability to implement and maintain protective actions for onsite personnel, as warranted. Applicants and licensees need to demonstrate the ability to recommend protective actions to offsite authorities as conditions warrant.

- Communications. The drill and exercise program needs to demonstrate that control room staff are capable of making effective communications to the ERO, including personnel and organizations who may have responsibilities for responding during emergencies. Control room staff and the emergency response team must have a means for maintaining communication with the NRC as needed, and with OROs based on prior arrangements. For example, the applicant or licensee may need to notify and maintain communications with the onsite fire brigade; offsite fire departments, rescue squad, or medical dispatch; and local law enforcement according to established agreements. As EP programs are developed, applicants and licensees need to determine if notification to OROs is appropriate. If notification to OROs is necessary, then drills and exercises need to demonstrate notifying the appropriate Federal, State, local, and Tribal officials of an emergency.

- Command and control. The drill or exercise needs to demonstrate continuity of operations through one or more shift changes of emergency response personnel, including the augmentation of the ERO. The supporting organizational structure needs to have defined roles, responsibilities, and authorities, and the drill or exercise needs to show how key ERO functions (e.g., communications, command and control of operations, notification of OROs, accident/incident assessment, information

dissemination to OROs and media, radiological monitoring, protective response, security) will be maintained around the clock throughout the emergency.

- Staffing and operations. The drills or exercises need to demonstrate effective emergency response with the level of staffing at the SMR or ONT as described in the emergency plan. There needs to be sufficient on-shift staff to perform all necessary tasks until augmenting staff arrive to provide assistance. This is of particular interest to the NRC because of the potential for reduced staffing levels at SMRs and ONTs, as compared to large LWRs. For example, some SMR and ONT designs may use multiple modules at one site with a single, centralized control room. Designers have indicated that they are considering designs that can operate with a staffing complement that is less than what is currently required of large LWRs by § 50.54(m), which sets forth the minimum licensed operator staffing requirements. Under this final rule, drills and exercises provide the NRC the opportunity to consider the sufficiency of emergency response staffing to implement the roles and responsibilities described in the emergency plan. The performance opportunities allow applicant and licensee staff to develop, maintain, or demonstrate key skills and provide applicants, licensees, and the NRC the opportunity to identify and correct any weaknesses or deficiencies.

- Radiological Assessment. During the drills or exercises, control room staff, on-shift personnel, and the emergency response team need to demonstrate the ability to assess radiological conditions, including the ability to: monitor and assess dose to personnel resulting from radiological releases and inadvertent criticality accidents; conduct radiological surveys; assess and report information to the ERO such as early indications of loss of adequate core cooling and radiological releases, including the release of hazardous chemicals produced from licensed material; and use protective equipment to implement protective action strategies. The NRC received a public comment suggesting a revision to § 50.160(b)(1)(iii)(F)(*1*), “Radiological conditions,”

§ 50.160(b)(1)(iii)(F)(*3*), "Core or vessel damage," and § 50.160(b)(1)(iii)(F)(*4*), "Releases." The commenter recommended the NRC change the phrase "and report radiological conditions to the response organization" to read "and report radiological conditions to the onsite and offsite response organizations." In the proposed rule, the NRC explained that the information to be reported under § 50.160(b)(1)(iii)(F)(*1*), (F)(*3*) and (F)(*4*) (i.e., radiological conditions; the extent and magnitude of damage to the core or other vessel containing irradiated special nuclear material; and the extent and magnitude of all radiological releases, including releases of hazardous chemicals produced from licensed material, respectively) would be reported to the ERO. However, considering the public comment, the NRC determined that that information would need to be reported to only certain personnel within the ERO. Therefore, the NRC changed these rule provisions, so the information is reported to the "applicable response personnel."

- Reentry. Reentry is the temporary movement of people into an area of actual or potential hazard. The applicant or licensee also needs to demonstrate general plans for reentry after an emergency through drills or exercises. The applicant or licensee needs to demonstrate reentry plans for the site boundary, including determining when facility conditions are acceptable to justify reentry (e.g., based on air and soil sampling and analysis to determine levels of radiological contamination and projected dose). Certain individuals who have been evacuated or relocated from a restricted area may be allowed to reenter under controlled conditions to perform specified activities.

- Critique and corrective actions. The performance of emergency response functions in drills and exercises (or responses to actual emergencies) is evaluated to identify weaknesses or deficiencies in ERO performance and the EP program. The applicant or licensee needs to use a corrective action program to evaluate, track, and correct EP weaknesses and deficiencies identified in drills and exercises (or responses

to actual emergencies). Weaknesses and deficiencies may include items such as errors in the emergency plan or implementing procedures, ERO performance weaknesses, or degraded conditions in emergency response facilities, systems, and equipment resulting in a performance objective not being met. Corrective actions include remedial exercises to demonstrate that the deficiencies have been fully addressed.

d. Planning Activities

In addition to an applicant's or licensee's performance demonstrations through drills and exercises, this final rule includes a set of required planning activities in § 50.160(b)(1)(iv) to account for certain EP-related activities that are not readily observable or effectively measured through drills and exercises. This final rule includes two sets of planning activities: § 50.160(b)(1)(iv)(A) establishes planning activities for all applicants and licensees complying with § 50.160; and § 50.160(b)(1)(iv)(B) establishes planning activities that apply to applicants and licensees with a plume exposure pathway EPZ that extends beyond the site boundary.

Currently, § 50.47(b) requires licensees to be capable of maintaining prompt communication among the response organizations and the public. In § 50.160(b)(1)(iv)(A)(*1*), SMR and ONT applicants and licensees are required to be capable of preparing and issuing information to the public during emergencies to protect public health and safety. The NRC is establishing in § 50.160(b)(1)(iv)(A)(*2*) that applicants and licensees also must be capable of implementing the NRC-approved emergency response plan in conjunction with the Licensee Safeguards Contingency Plan. In implementing the emergency response plan, licensees should coordinate security-related and emergency response activities to ensure an adequate and efficient response to a radiological event. The regulations in § 50.160(b)(1)(iv)(A)(*3*) require the capability to establish voice and data communications with the NRC for use during emergencies. Voice communication through the Emergency Notification System (ENS)

and data communication through an electronic data link provide timely updates to the NRC on the implementation of the emergency plan during and after an emergency. Section 50.160(b)(1)(iv)(A)(*4*) requires the capability to establish emergency response facilities to support the emergency response functions required in § 50.160(b). Applicants and licensees need to establish a facility from which effective direction can be given and effective control can be executed for the duration of an emergency. Depending on design- and site-specific considerations, applicants and licensees may need to establish multiple emergency response facilities to demonstrate the capability to support emergency response functions. Emergency plans need to include descriptions of the facilities' functional capabilities, activation times, staffing, and communication systems.

In this final rule, the NRC moved the proposed requirement in § 50.160(b)(1)(iv)(B)(*4*) to new § 50.160(b)(1)(iv)(A)(*5*). This provision requires applicants and licensees to provide site familiarization training to individuals whose assistance may be needed in the event of a radiological emergency, including personnel from offsite response organizations. The NRC moved this provision to ensure that all applicants and licensees complying with § 50.160 provide this offsite organization training, notwithstanding whether an applicant's or licensee's plume exposure pathway EPZ extends beyond the site boundary.

Finally, the NRC moved the proposed requirement in § 50.160(b)(1)(iv)(B)(*11*) to new § 50.160(b)(1)(iv)(A)(*6*). This provision requires applicants and licensees to maintain up to date the emergency plan, contacts and arrangements with OROs, procedures, and evacuation time estimates (ETEs). Emergency plans need to include a description of the periodic coordination with OROs. The NRC moved this provision to ensure that all applicants and licensees complying with § 50.160 maintain their

emergency plans, notwithstanding whether the plume exposure pathway EPZ extends beyond the site boundary.

e. Offsite Radiological Emergency Preparedness Planning Activities

Current requirements for offsite radiological emergency response plans are included in § 50.47 and appendix E to 10 CFR part 50. In select cases, the NRC has granted exemptions from these requirements to licensees based partially on a demonstration that an offsite radiological release would not exceed the EPA PAGs at the site boundary. For SMR and ONT applicants and licensees complying with § 50.160 that have no plume exposure pathway EPZ or establish a plume exposure pathway EPZ at the site boundary, the NRC does not mandate offsite radiological emergency planning activities. Section 50.160(b)(1)(iv)(B) establishes offsite planning activities that must be described in the emergency plan for applicants and licensees with plume exposure pathway EPZs extending beyond the site boundary. These activities include:

- Contacts/arrangements with governmental agencies. Applicants and licensees need to describe in emergency plans their contacts and arrangements with OROs for offsite radiological emergency response. Applicants and licensees need to ensure regular coordination with these organizations, including review of emergency plan changes.

- Notification of OROs. Applicants and licensees need to establish primary and backup means of notifying OROs and a message authentication scheme. The emergency plan needs to include the proposed time period within which notifications to OROs would be made.

- Protective measures. Applicants and licensees need to maintain the capability to issue offsite protective action recommendations to OROs (e.g., evacuation, sheltering). The emergency plan needs to describe the procedures by which protective measures are implemented, maintained, and discontinued in their emergency plans.

• Evacuation time estimate study. Applicants and licensees need to conduct an evacuation time estimate (ETE) study and maintain the ETE up to date. The ETE is primarily used in the development of protective action strategies and to inform offsite protective action decisionmaking. In the proposed rule, § 50.160(b)(1)(iv)(B)(*5*) would have required an ETE "of the areas beyond the site boundary and within the EPZ." The NRC received comments that the phrase, "areas beyond the site boundary" could be interpreted to exclude, rather than include, the area within the site boundary. As a result, in this final rule, the NRC removed the phrase "beyond the site boundary and" to clarify that an ETE is intended to estimate the time to evacuate various sectors and distances within a licensee's plume exposure pathway EPZ, which includes the area within the plant site boundary. However, for a site boundary EPZ, the NRC is not requiring an ETE because predetermined, prompt offsite protective actions are not required. In addition, in this final rule § 50.160(b)(1)(iv)(B)(*5*) is renumbered to § 50.160(b)(1)(iv)(B)(*4*)

• Emergency response facilities. Applicants and licensees need to describe in their emergency plans an offsite facility and any backup facilities for coordination of the response with OROs.

• Offsite dose projections. Applicants and licensees need to be capable of making offsite dose assessments and communicating their results to OROs. The emergency plan needs to describe the methods and instruments available for conducting these assessments.

• Dissemination of public information. Applicants and licensees need to describe in their emergency plans the means of providing initial and updated information to the public during an emergency (e.g., communication with the news media, coordination with OROs). Applicants and licensees need to describe the public alert and notification system.

- Reentry. Applicants and licensees need to describe in their emergency plans coordination with OROs on offsite reentry plans including the conditions necessary to allow reentry into the EPZ during and after an emergency. Some conditions may include: 1) use of access control points to issue dosimetry and train reentering individuals on its use; 2) use of stay times (as used here, the amount of time a person can safely stay in a restricted zone without exceeding their exposure limit), depending on the location of the reentry destination; 3) use of a health physicist escort or other personnel escort trained in the use of dosimetry; and 4) provision of monitoring and decontamination for exiting individuals. Reentry plans cover private citizens. For example, reentry plans may cover scenarios such as farmers being permitted to reenter the affected area to provide essential care for livestock.

- Offsite drills and exercises. Applicants and licensees need to describe in their emergency plans how offsite radiological emergency response is incorporated into their drills and exercises without mandatory public participation. Drill and exercise programs need to incorporate offsite response, and applicants and licensees need to coordinate with offsite response organizations, including FEMA, for their participation in drills and exercises and implementation of corrective actions.

In carrying out its responsibility under the Atomic Energy Act of 1954, as amended (AEA), the NRC establishes regulatory standards for onsite and offsite radiological emergency planning. If an applicant's or licensee's emergency plan meets the NRC's regulations, then the NRC has reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. In the case of existing EP regulations for NPUFs, fuel cycle facilities, and ISFSIs, there are no regulatory requirements for dedicated offsite radiological emergency plans as part of the NRC license. Accordingly, NRC guidance for such facilities states that FEMA findings and determinations are not needed to support NRC licensing decisions.

Similarly, for SMRs and ONTs within the scope of this final rule, FEMA findings and determinations regarding reasonable assurance under § 50.54(s)(3) are only needed for a facility where a plume exposure pathway EPZ extends beyond the site boundary requiring dedicated offsite radiological EP plans for the facility.

This final rule, which does not require offsite planning activities for facilities without plume exposure pathway EPZs or with plume exposure pathway EPZs at the site boundary, does not affect the authority that FEMA has under its regulations in Chapter I, "Federal Emergency Management Agency, Department of Homeland Security," of 44 CFR, "Emergency Management and Assistance," for overall emergency management and assistance to State and local response organizations, nor does it affect the responsibilities of State and local governments to establish and maintain comprehensive emergency management plans. Under its role as described in the National Response Framework, the NRC remains ready to provide FEMA and State, local, and Tribal governments with technical advice related to the safety and security of any proposed SMR or ONT facility.

In cases where a plume exposure pathway EPZ does not extend beyond the site boundary, even in the absence of NRC requirements for offsite radiological emergency planning, the responsible OROs would continue to take actions to protect the health and safety of the public. Each of the States has established an emergency management organization to facilitate the safeguarding of the life and property of its citizens.[5]

The NRC has confidence in the ability of OROs to implement appropriate response actions when necessary, using comprehensive "all-hazards" emergency planning. The OROs' general emergency response capabilities are not unique to

[5] See FEMA's Emergency Management Agencies website https://www.fema.gov/emergency-management-agencies.

radiological emergency response. The NRC's confidence is expressed in the NRC's regulations in § 50.47(c)(1)(iii) and further strengthened by the NRC's recognition of national-level efforts (e.g., National Incident Management System,[6] National Preparedness Goal,[7] Core Capabilities,[8] National Preparedness System,[9] National Planning Frameworks[10]), in which the NRC participates, to improve the state of emergency planning at all levels of government and within the whole community.[11] Consequently, for SMR and ONT facilities without plume exposure pathway EPZs or with plume exposure pathway EPZs at the site boundary, there is reasonable assurance that appropriate response actions can and will be taken in the event of a radiological emergency, without the need for regulatory standards for offsite radiological emergency response plans and the associated FEMA findings and determinations that offsite plans are adequate and can be implemented.

f. Changes to Emergency Plans

Section 50.54(q) currently establishes the process for evaluation, submission, and review of changes to emergency plans. The NRC is establishing that SMRs and ONTs continue to follow the existing process for changes to emergency plans, whether the facilities are following the performance-based approach to EP under § 50.160 or the approach to EP under § 50.47(b) and appendix E to 10 CFR part 50. This final rule includes conforming changes to § 50.54(q).

[6] For further information on the National Incident Management System, see: https://www.fema.gov/pdf/emergency/nims/nimsfaqs.pdf.
[7] For further information on the National Preparedness Goal, see: https://www.fema.gov/national-preparedness-goal.
[8] For further information on Core Capabilities, see: https://www.fema.gov/core-capabilities.
[9] For further information on the National Preparedness System, see: https://www.fema.gov/national-preparedness-system.
[10] For further information on the National Planning Frameworks, see: https://www.fema.gov/national-planning-frameworks.
[11] For more information on the definition of "whole community," see: https://www.fema.gov/whole-community#.

Existing § 50.54(q)(2) requires licensees to follow and maintain the effectiveness of an emergency plan that meets the requirements in appendix E to 10 CFR part 50 and, for power reactor licensees, the planning standards in § 50.47(b), and existing § 50.54(q)(3) and (4) describe the process for analyzing, submitting, and making changes to emergency plans. The NRC is revising § 50.54(q)(2) through (4) to include cross-references to the requirements under § 50.160 for licensees choosing the performance-based approach and to clarify that licensees must follow and maintain an emergency plan that meets either the applicable requirements of § 50.160 or the requirements of appendix E to 10 CFR part 50 and, for nuclear power reactor licensees, the planning standards of § 50.47(b). The NRC is not making any changes to the emergency plan change process. Licensees choosing the performance-based approach to EP must evaluate changes to their emergency plans against the performance-based requirements under § 50.160 using the same reduction in effectiveness criteria as current licensees and submit changes that reduce the effectiveness of the plan to the NRC for approval prior to implementation. The NRC is revising the definition of "emergency planning function" under § 50.54(q)(1) to remove references to appendix E to 10 CFR part 50 and § 50.47(b) because emergency planning functions are addressed under both these sections and under § 50.160, and the NRC does not consider the references essential to the definition.

For any existing or future holder of an OL or COL for an SMR or non-LWR, or any future holder of an OL for an NPUF, § 50.54(q)(7) stipulates that a licensee desiring to change its emergency plan to comply with the performance-based approach to EP needs to submit a license amendment request with the proposed changes to its emergency plan. The request needs to include an explanation of the schedule and analyses supporting the implementation of a performance-based EP program.

g. Emergency Response Data System

Appendix E to 10 CFR part 50, section VI, “Emergency Response Data System,” outlines a set of system, testing, and implementation requirements for the emergency response data system (ERDS) for operating nuclear power reactor licensees, and § 50.72, “Immediate notification requirements for operating nuclear power reactors,” includes requirements for activation of ERDS. In contrast, the 10 CFR part 50, appendix E ERDS requirement and § 50.72 ERDS activation requirement are not applicable to applicants and licensees choosing to comply with § 50.160. Applicants and licensees choosing § 50.160 need to describe in their emergency plans the data links with the NRC for use in emergencies. Specific parameters to be reported are determined for the specific technology during the license application process under 10 CFR part 50 or part 52. The NRC must review each applicant’s data transmission capabilities on a case-specific basis. The NRC is not making any changes to its ERDS regulations.

3. Hazard Analysis of Contiguous or Nearby Facilities

The NRC anticipates that SMRs and ONTs may be located on the same site or close to large LWRs or other types of reactors; industrial, military, or transportation facilities; or a combination of these or other facilities. The presence of such facilities requires additional EP considerations relative to an independently sited facility. For example, SMRs or ONTs may need to be prepared for events associated with contiguous or nearby facilities’ hazards.

Although the NRC’s regulations do not extend to the licensing, operations, or oversight of non-nuclear facilities, the NRC has authority over the activities of NRC applicants and licensees that are located on or close to an industrial site or other facility not licensed by the NRC. For example, a nuclear power facility could be sited contiguous to or near an industrial facility to supply process heat or electrical power, or an SMR could be used to power a desalination facility located on the same site. There are many potential examples of licensees that may be located contiguous to or near a

facility not licensed by the NRC; under each scenario, the hazards of the facility not licensed by the NRC must be factored into the EP program of the nuclear facility to ensure the protection of public health and safety.

For SMR or ONT applicants and licensees located contiguous to or near another facility, § 50.160(b)(2) requires the applicant or licensee to perform a hazard analysis to assess any credible hazards that would adversely impact the implementation of emergency plans at the SMR or ONT facility. The analysis needs to identify site-specific, credible hazards from other, non-nuclear facilities that require the applicant's or licensee's emergency plan to include arrangements that would otherwise not be needed in the absence of the facility. For example, these arrangements might include notifying contiguous or nearby facilities regarding emergencies, classifying a hazard from another facility that may negatively impact the safe operation of the nuclear facility, and providing for protective actions for the other facility's personnel or other on-site individuals, such as visitors. A credible hazard could include any event at another facility's site that would lead to an emergency response at the SMR or ONT facility. It may be appropriate for SMRs or ONTs with contiguous or nearby facilities to consider a quantitative or qualitative assessment of all postulated accident scenarios at the other facilities. The applicant's or licensee's EP program must reflect these credible hazards and the planning activities needed to address the hazards. For example, the location of facilities on the same site or close to an SMR or ONT may affect the applicant's or licensee's determinations about the EPZ size. Looking across all facilities, the applicant or licensee must assess the combined radiological and industrial hazards at the site.

The NRC is issuing RG 1.242 with this final rule, which includes guidance on hazard analyses for contiguous or nearby facilities.

4. Emergency Planning Zones

The NRC is establishing a consequence-oriented, technology-inclusive approach to EPZ size determinations for SMRs and ONTs. This approach is similar to the dose/distance rationale historically used by the NRC, in part, to determine EPZ size for production or utilization facilities. Under the existing regulations, SMRs or ONTs, depending on their capacity and technology, are either required to establish a 10-mile (16-km) plume exposure pathway EPZ and a 50-mile (80-km) IPZ or follow the case-by-case EPZ size determination process under §§ 50.33(g), 50.47(c)(2), and section I.3. of appendix E to 10 CFR part 50. Preapplication discussions and previous applications for EP exemption requests from SMRs and ONTs have indicated that these technologies could have reduced offsite dose consequences in the unlikely event of an accident, and the standard 10-mile (16-km) EPZ and 50-mile (80-km) IPZ may not be necessary to ensure public health and safety for these facilities. Because of the range of potential source terms and designs for SMRs or ONTs, the NRC is establishing an alternative scalable methodology for determining EPZ size on a case-specific basis. This methodology is established in guidance (RG 1.242) generically without design- or site-specific information regarding source term, fission products, or projected offsite dose. Applicants must provide the design- and site-specific information regarding source term, fission products, or projected offsite dose for NRC review in an application.

As mentioned in the “Technical Basis” section of this document, NUREG-0396 established the planning basis for EP and established EPZs for large LWRs based on the conclusion that the objective of emergency response plans should be to provide dose savings for a spectrum of accidents that could produce offsite doses in excess of the EPA PAGs. This final rule is offering an EPZ size determination process that is consistent with this philosophy. Section 50.33(g)(2) establishes EPZ size determination requirements for SMR, non-LWR, and NPUF applicants complying with § 50.160. Small modular reactor and non-LWR applicants for an OL, COL, CP, or ESP and NPUF

applicants for a CP or OL must submit the analysis used to establish their proposed plume exposure pathway EPZ size. Applicants need to establish their EPZ as the area within which public dose, as defined in § 20.1003, is projected to exceed 10 mSv (or 1 rem) TEDE over 96 hours from the release of radioactive materials from the facility considering accident likelihood and source term, timing of the accident sequence, and meteorology. In addition, applicants need to show that the plume exposure pathway EPZ is the area in which predetermined, prompt protective measures are necessary. If the plume exposure pathway EPZ extends beyond the site boundary and if the application is for an SMR or non-LWR OL, COL, an ESP that contains plans for coping with emergencies under § 52.17(b)(2)(ii), or an ESP that proposes major features of the emergency plans and describes the EPZ, then § 50.33(g)(2) requires that the exact configuration of the plume exposure pathway EPZ be determined in relation to local emergency response needs and capabilities, as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. Section 50.160(b)(3) requires applicants to describe in their emergency plans the boundary and physical characteristics of the EPZ.

Upon receiving an OL, COL, ESP, or CP applicant's technical basis for proposed site-specific plume exposure pathway EPZ size, the NRC must review the design and licensing information to ensure that the information that the applicant provides on the offsite dose consequences is commensurate with the requested EPZ size and that the applicable performance-based requirements are met to ensure adequate protection of public health and safety. Some of this information may have already been provided as part of a certified design referenced in an application or in a topical report related to the design. The NRC also must assess the need to provide site-specific guidance concerning the accident scenarios being considered.

The plume exposure pathway EPZ determination requirements could result in an applicant having no plume exposure pathway EPZ. For this result to occur, the applicant's analysis required by § 50.33(g)(2) would need to show that one or both of the criteria in § 50.33(g)(2)(i) are not met. For purposes of complying with § 50.160, this applicant would be similar to an applicant with a site boundary plume exposure pathway EPZ. Both applicants would need to have an emergency plan that meets the requirements of § 50.160(a), (b)(1)(i)-(iv)(A), (b)(2), (b)(4) and (c). An applicant with a site boundary plume exposure pathway EPZ would also need to comply with § 50.160(b)(3), which requires the applicant to determine and describe in its emergency plan the boundary and physical characteristics of the EPZ.

In addition to the plume exposure pathway EPZ size determination process, the NRC is including ingestion response planning requirements under § 50.160(b)(4). Applicants and licensees complying with § 50.160 are required to describe in their emergency plans the capabilities to prevent contaminated food and water from entering the ingestion pathway. The proposed rule would have required applicants and licensees to describe in their emergency plans the capabilities to protect contaminated food and water from entering the ingestion pathway. Although the goal is to protect the public from contaminated food and water, this goal can be achieved by preventing contaminated food and water from entering the ingestion pathway. Therefore, in the final rule, the NRC revised § 50.160(b)(4) to require applicants and licensees to describe in their emergency plans the capabilities to prevent contaminated food and water from entering the ingestion pathway.

The capabilities described in the emergency plan need to address major exposure pathways associated with the ingestion of contaminated food and water. The duration of any exposure to contaminated food or water could range from weeks to months and represents a long-term response need. Even in cases where the facility's

plume exposure pathway EPZ is bounded by the site boundary, the applicant or licensee must reference capabilities of Federal, State, and local authorities.

Examples of demonstrated capabilities in response to ingestion of contaminated food or water include three notable large-scale quarantines documented by the Centers for Disease Control and Prevention: the multi-state outbreaks of E. Coli O157:H7 infections from spinach (September-October 2006); the multi-state outbreak of human *salmonella enteritis* infections associated with shell eggs (July-December 2010); and, the multi-state outbreak of fungal meningitis and other infections (October 2012). In each case, the successful quarantine and removal from public access of contaminated food and water products in response to biological contamination demonstrates that a response to prevent ingestion of contaminated foods and water could be performed in an expeditious manner without a predetermined ingestion planning zone.

5. Implementation

This final rule includes implementation schedules for existing and future applicants and licensees of facilities choosing to comply with § 50.160. The NRC received public comments on the proposed requirement for applicants to conduct an initial exercise to demonstrate effectiveness of the EP program no later than 18 months before the issuance of an OL or the scheduled date for initial loading of fuel for a part 52 COL holder. The comments suggested that an initial exercise “no later than 18 months before” the issuance of an OL for a part 50 applicant or the scheduled date for initial loading of fuel for a part 52 COL holder is not the appropriate time frame. In reviewing these comments, the NRC determined that the wording in the proposed rule needed revision. Specifically, in § 50.160(c)(1), the NRC is revising the rule language to require an applicant for an OL issued under 10 CFR part 50 after the effective date of this final rule that desires to comply with the performance-based approach to EP to establish, implement, and maintain an EP program that meets the requirements of § 50.160(b), as

described in the emergency plan and license, and conduct an initial exercise to demonstrate this compliance within 2 years before the issuance of an OL for the first unit described in the license application. Similarly, in § 50.160(c)(2), a holder of a COL issued under 10 CFR part 52 desiring to comply with the performance-based approach to EP before the Commission has made the finding under § 52.103(g) is required to establish, implement, and maintain an EP program that meets the requirements of § 50.160(b), as described in the emergency plan and license, and conduct an initial exercise to demonstrate this compliance within 2 years before the scheduled date for initial loading of fuel. These changes allow greater flexibility in demonstrating regulatory compliance and ensure consistency with appendix E to 10 CFR part 50, which requires an applicant to conduct a full-participation emergency planning exercise within 2 years before the issuance of an OL for a part 50 applicant or the scheduled date for initial loading of fuel for a part 52 COL holder.

As discussed in the "Changes to Emergency Plans" section of this document, for existing or future SMRs or ONTs that hold OLs or COLs, § 50.54(q)(7) stipulates that facilities desiring to change their emergency plans to comply with the performance-based approach to EP, shall submit a license amendment request with these final changes.

a. Reasonable Assurance

The NRC's authority to regulate the use of radioactive materials is set forth in the AEA. The AEA confers broad regulatory powers to the Commission and specifically authorizes it to issue regulations it deems necessary to fulfill its responsibilities under that statute. Section 161.b of the AEA authorizes the Commission to establish by rule, regulation, or order such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable to promote the common defense and security or to

protect health or to minimize danger to life or property. Under Section 161.i of the AEA, the Commission may prescribe such regulations or orders, as it may deem necessary, to protect health and to minimize danger to life or property.

The NRC's regulations include standards for both onsite and offsite emergency response plans. The Commission, based on its authority under the AEA, determined that these standards are necessary for operating power reactors to provide for public health and safety. The regulations in §§ 50.47 and 50.54 prescribe how the NRC makes licensing decisions or takes appropriate enforcement action by using findings of reasonable assurance that adequate protective measures can and will be taken to protect public health and safety in the event of a radiological emergency. The NRC bases reasonable assurance findings on: 1) the NRC's assessment of the adequacy of the applicant's or licensee's onsite emergency plan and whether there is reasonable assurance the plan can be implemented, and 2) the NRC's review of FEMA findings and determinations as to whether State and local emergency plans are adequate and whether there is reasonable assurance that they can be implemented.

The performance-based approach to EP under § 50.160 provides an adequate basis for an acceptable state of EP and ensures that coordination and applicable arrangements with offsite agencies are maintained (e.g., notification and assistance resources). Reasonable assurance is maintained under the performance-based approach through: 1) submission and case-specific review of design- and site-specific analyses to support the proposed plume exposure pathway EPZ size; 2) review of site-specific emergency plans to ensure compliance with the performance-based requirements; 3) demonstration of emergency response functions through drills and exercises; 4) regular tracking of performance objective information; 5) analysis of potential hazards associated with contiguous or nearby NRC-licensed facilities or

facilities not licensed by the NRC; and 6) the NRC's inspection and enforcement program.

For applicants and licensees with plume exposure pathway EPZs beyond the site boundary, the NRC, in consultation with FEMA, continues to ensure that reasonable assurance is maintained based on the performance-based requirements, as demonstrated through drills and exercises. As described in the "Offsite Radiological Emergency Preparedness Planning Activities" section of this document, FEMA findings and determinations regarding reasonable assurance under § 50.54(s)(3) are not needed for SMRs or ONTs without plume exposure pathway EPZs or with plume exposure pathway EPZs that do not extend beyond the site boundary. The NRC makes reasonable assurance determinations regarding onsite EP requirements for these facilities, and every licensee must follow and maintain the effectiveness of its emergency plan if the NRC is to continue to find, under § 50.54(s)(2)(ii), that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at that site.

In this final rule, the NRC revised § 50.160(b) from the proposed rule to state that the reasonable assurance finding made under § 50.47(a)(1) necessary to issue an OL, COL, or ESP to an applicant complying with § 50.47 and appendix E to part 50 is also necessary to issue an OL, COL, or ESP to a power reactor applicant complying with § 50.160. The NRC also revised § 50.47(a)(1)(iv) to reflect that an applicant for an ESP that proposes major features of the emergency plan under § 52.17(b)(2)(i) can choose to comply with § 50.160.

b. Administrative and Clarifying Changes to the Regulations

The NRC is making clarifying changes to the following paragraphs.

1. Section 50.54(q)(4), which required after February 21, 2012, any changes to a licensee's emergency plan that reduce the effectiveness of the plan as defined in

paragraph (q)(1)(iv) to be submitted to the NRC for approval before implementation. As the date of the provision has expired, the NRC is deleting “after February 21, 2012” and retaining the remainder of the provision.

2. Section 50.54(q)(5), which required licensees to submit a report of each change made without prior NRC approval, as allowed under § 50.54(q)(3), after February 21, 2012, including a summary of its analysis, within 30 days after the change is put into effect. The NRC is deleting “after February 21, 2012” from this provision, as the date has expired, and retaining the remainder of the provision.

3. Section 50.54(s)(2)(ii), which allows the NRC to take enforcement action to shut down power reactors that do not provide reasonable assurance that adequate protective measures would be taken in the event of a radiological emergency after April 1, 1981. There is no longer a need for the date requirement of this provision because any future determinations made under § 50.54(s) will occur after April 1, 1981. The NRC is deleting “after April 1, 1981” and retaining the remainder of the provision.

The NRC is revising these requirements in the interest of regulatory clarity. Eliminating or revising these requirements does not relax currently effective regulatory requirements or cause any regulatory burden for existing or future licensees.

III. Opportunities for Public Participation

The NRC published the proposed rule on May 12, 2020 (85 FR 28436), and the comment period was open until July 27, 2020. On July 21, 2020 (85 FRN 44025), the NRC extended the public comment period by an additional 60 days to September 25, 2020, to allow more time for members of the public and other stakeholders to develop and submit their comments.

The NRC hosted one public meeting to engage with external stakeholders on the proposed rule and associated draft guidance document during the public comment period. This public meeting was held on June 24, 2020. A summary of the public meeting is available in ADAMS, as provided in the "Availability of Documents" section. The feedback from this public meeting informed the development of this final rule.

IV. Public Comment Analysis

The NRC prepared a summary and analysis of public comments received on the 2020 proposed rule and draft regulatory guide, as referenced in the "Availability of Documents" section. In response to the proposed rule and draft regulatory guide, the NRC received 2,212 comment submissions.

The public comment submittals are available from the Federal e-Rulemaking Web site at https://www.regulations.gov under Docket ID NRC-2015-0225. Responses to the public comments, including a summary of how this final rule or the guidance changed as a result of the public comments, can be found in the public comment analysis document as indicated in the "Availability of Documents" section of this document.

For more information about the associated guidance document, see the "Availability of Guidance" section of this document.

V. Section-by-Section Analysis

The following paragraphs describe the specific changes within this final rule.

Section 50.2 Definitions

In § 50.2, this final rule adds the definitions for *Non-light-water reactor*, *Non-power production or utilization facility,* and *Small modular reactor*.

Section 50.8 Information collection requirements; OMB approval

In § 50.8, this final rule adds new § 50.160 to the list of approved information collection requirements contained in 10 CFR part 50.

Section 50.10 License required; limited work authorization

In § 50.10, this final rule revises paragraph (a)(1)(vii) to include onsite emergency facilities necessary to comply with new § 50.160 requirements within the scope of items for which a CP or limited work authorization is necessary to commence construction.

Section 50.33 Contents of applications; general information

In § 50.33, this final rule revises paragraph (g) to create new subparagraphs (g)(1) and (2). Paragraph (g)(1) contains the original text of paragraph (g) and adds the qualifier "Except as provided in paragraph (g)(2) of this section."

Paragraph (g)(2) establishes EPZ size determination requirements for SMR, non-LWR, and NPUF applicants complying with § 50.160.

Section 50.34 Contents of applications; technical information

In § 50.34, this final rule revises paragraph (a)(10) to require SMR, non-LWR, or NPUF CP applicants to describe in their PSARs the preliminary plans for coping with emergencies based on the requirements in either § 50.160 or appendix E to 10 CFR part 50.

This final rule also revises paragraph (b)(6)(v) to require SMR, non-LWR, and NPUF applicants for an OL to include in their FSARs their plans for coping with

emergencies based on the requirements in either § 50.160 or appendix E to 10 CFR part 50.

Section 50.47 Emergency plans

In § 50.47, this final rule makes conforming changes to paragraphs (a)(1)(iv), (b) introductory text, (c)(1) introductory text, (c)(1)(i), and (e) and adds new paragraph (f) denoting when the offsite emergency response plan requirements in § 50.47(a)(2), (b), and (c)(2) do not apply.

Section 50.54 Conditions of licenses

In § 50.54, this final rule revises paragraph (q)(1)(iii) to remove the references to appendix E to 10 CFR part 50 and § 50.47(b).

This final rule revises paragraph (q)(2) to include new subparagraphs (q)(2)(i) and (ii). Paragraph (q)(2)(i) contains the original text of paragraph (q)(2) and adds the qualifier "except as provided in paragraph (q)(2)(ii) of this section," and paragraph (q)(2)(ii) allows SMR, non-LWR, and NPUF licensees to follow and maintain the effectiveness of an emergency plan that meets the requirements of § 50.160 or appendix E to 10 CFR part 50 and, for nuclear power reactor licensees, § 50.47(b).

This final rule also revises paragraph (q)(3) to include new subparagraphs (q)(3)(i) and (ii). Paragraph (q)(3)(i) contains the original text of paragraph (q)(3) and adds the qualifier "except as provided in paragraph (q)(3)(ii) of this section" and paragraph (q)(3)(ii) specifies when an SMR, non-LWR, or NPUF licensee choosing to comply with the performance-based EP regulations could make changes to its emergency plan without prior NRC approval.

Paragraphs (q)(4) and (5) are amended to remove the date February 21, 2012, and paragraph (q)(4) is further revised to specify that licensees that choose to comply

with the new requirements of § 50.160, when making an emergency plan change that reduces plan effectiveness, need to specify the basis for concluding how their revised emergency plans continue to meet the requirements of that section.

This final rule adds new paragraph (q)(7) that contains the details for submitting license amendment requests for SMR, non-LWR, or NPUF licensees implementing EP programs with the associated plan modifications necessary to meet the requirements of new § 50.160.

Paragraph (s)(2)(ii) is amended to remove the date April 1, 1981, and to replace the word “reactor” with the word “facility.”

This final rule revises paragraph (s)(3) by adding clarification at the beginning of the sentence that if the standards apply to offsite emergency response plans, or if the planning activities in new § 50.160(b)(1)(iv)(B) apply, then the NRC bases its findings on a review of FEMA’s findings and determinations.

This final rule also revises paragraph (gg)(1) introductory text to include the option for SMR, non-LWR, or NPUF applicants to use new § 50.160, as applicable.

Section 50.160 Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities

This final rule adds a new subpart, “Small Modular Reactors, Non-Light-Water Reactors, and Non-power Production or Utilization Facilities,” after § 50.155 and new § 50.160, which contains alternative EP requirements for SMRs, non-LWRs, and NPUFs.

Appendix E to Part 50 – Emergency Planning and Preparedness for Production and Utilization Facilities

This final rule revises paragraph I.3 and footnote 2 to clarify that the potential radiological hazards to the public associated with the operation of NPUFs and fuel facilities involve considerations different than those associated with power reactors. This paragraph is also amended to replace “as necessary” with “is necessary,”.

Section 52.1 Definitions

This final rule revises the definition of *Major feature of the emergency plans* to include new § 50.160, as applicable.

Section 52.17 Contents of applications; technical information

This final rule revises paragraphs (b)(2)(i) and (ii) to include new § 50.160, as applicable.

Section 52.18 Standards for review of applications

This final rule revises § 52.18 to make editorial changes and to include references to new § 50.160, as applicable.

Section 52.79 Contents of applications; technical information in final safety analysis report

This final rule revises paragraph (a)(21) to require applicants for SMRs or non-LWRs to comply with either the requirements in § 50.160 or the requirements in appendix E to 10 CFR part 50 and § 50.47(b).

Section 72.32 Emergency plans

In § 72.32, this final rule revises paragraph (c)(2) to replace the words “required by” with “that meets either the requirements in” and to add a reference to new § 50.160.

VI. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. This final rule affects only the licensing and operation of nuclear power facilities and NPUFs. The companies, universities, and government agencies that own these facilities do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810).

VII. Regulatory Analysis

The NRC has prepared a final regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The conclusion from the analysis is that this final rule and associated guidance results in net savings to the industry and the NRC of $7.98 million using a 7-percent discount rate and $14.9 million using a 3-percent discount rate. The final regulatory analysis is available as indicated in the "Availability of Documents" section of this document.

VIII. Backfitting and Issue Finality

This final rule contains new alternative requirements for SMR and ONT applicants and licensees. Because these alternative requirements are not imposed upon applicants and licensees and do not prohibit applicants and licensees from following existing requirements, the requirements do not constitute backfitting under

10 CFR part 50 or part 72 or affect the issue finality of any approval issued under 10 CFR part 52.

As described in Section XVI, “Availability of Guidance,” in this document, the NRC is issuing RG 1.242, which provides guidance on methods acceptable to the NRC for complying with this final rule. Issuance of the RG does not constitute backfitting under §§ 50.109 and 72.62 and does not affect the issue finality of any approval issued under 10 CFR part 52. As discussed in the “Implementation” section of the RG, the NRC has no current intention to impose the RG on holders of an OL, ESP, or COL. If, in the future, the NRC seeks to impose positions stated in the RG in a manner that would constitute backfitting or affect the issue finality of an approval under 10 CFR part 52, the NRC would need to make the showing as set forth in § 50.109 or address the regulatory criteria set forth in the applicable issue finality provision, as applicable, that would allow the NRC to impose the position.

IX. Cumulative Effects of Regulation

Cumulative Effects of Regulation (CER) consists of the challenges licensees may face in addressing the implementation of new regulatory positions, programs, and requirements (e.g., rulemaking, guidance, generic letters, backfits, inspections). The CER may manifest in several ways, including the total burden imposed on licensees by the NRC from simultaneous or consecutive regulatory actions that can adversely affect the licensee’s capability to implement those requirements, while continuing to operate or construct its facility in a safe and secure manner.

The goals of the NRC’s CER effort were met throughout the development of this final rule. The NRC engaged external stakeholders at public meetings and by soliciting public comments on the proposed rule and associated draft guidance document. The

NRC held a public meeting on June 24, 2020, to discuss the proposed rule. A summary of the public meeting is available in ADAMS, as provided in the "Availability of Documents" section of this document.

Although the new alternative EP requirements for SMRs and ONT are voluntary, the NRC included in the *Federal Register* notice for the proposed rule a request for feedback related to CER. Specifically, the NRC requested feedback on the implementation and potential unintended consequences of the proposed rule. The NRC received two comments in response to the CER questions in the proposed rule, but neither required a change to the rule.

X. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998 (63 FR 31885).

XI. Environmental Assessment and Final Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this final rule is not a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The basis of this determination reads as follows: The majority of the provisions in this

final rule are administrative or procedural in nature and either do not affect the physical environment or would have no noticeable effects. Further, the NRC has evaluated the final requirements of interest to stakeholders based on interactions described in section 6, “Environmental Impacts of the Proposed Action,” of this environmental assessment that have the potential to affect the human environment, including the scalable approach for determining the size of the plume exposure pathway EPZ under § 50.33(g) and the ingestion response planning requirements under § 50.160(b)(4), and determined that this final rule does not have a significant environmental impact for the following reasons. Under the existing EP requirements and these final alternative EP requirements, the dose criteria under which predetermined protective measures would be taken (e.g., evacuation, sheltering) would be similar under both rules, and therefore, the dose consequence to the public is similar. The ingestion response planning requirements under § 50.160(b)(4), while not requiring SMR and ONT applicants and licensees to establish an IPZ, provide the same capabilities available to identify and interdict contaminated food and water in the event of a radiological emergency as required under existing EP regulations. The environmental effects of the final ingestion response planning requirements are similar to that of the existing EP requirements. For these reasons, the NRC concludes that the EPZ requirement under § 50.33(g) and ingestion response planning requirement under § 50.160(b)(4) do not have a significant impact on the physical environment. Therefore, this rulemaking does not warrant preparation of an environmental impact statement. Accordingly, the NRC has determined that a Finding of No Significant Impact is appropriate.

The determination of this environmental assessment is that there is no significant offsite impact to the public from this action. The environmental assessment is available as indicated under the “Availability of Documents” section.

XII. Paperwork Reduction Act

This final rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The collections of information were approved by the Office of Management and Budget (OMB), approval numbers 3150-0011 and 3150-0151.

The burden to the public for the information collections is estimated to average a reduction of 548 hours per response for 10 CFR part 50 and a reduction of 200 hours per response for 10 CFR part 52, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection.

The information collections create a transparent alternative EP regulatory framework that allows SMR and ONT applicants and licensees to submit for NRC approval a performance-based EP program, to include a scalable plume exposure pathway EPZ and licensee-defined performance objectives and metrics, while continuing to provide reasonable assurance that adequate protective measures can and will be implemented in a radiological emergency. Applicants or licensees requesting approval to construct or operate utilization or production facilities are required by the AEA to provide information and data that the NRC may determine necessary to ensure the adequate protection of health and safety of the public. The submission of emergency plans to the NRC is required in order to allow the NRC to determine that the emergency plans and EP programs provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. Information is used by the NRC to evaluate the adequacy of the alternative EP program for approval, assess ongoing adequacy once implemented, determine whether to take actions, such as to conduct inspections or to alert other licensees to prevent similar events that may

have generic implications, and to update information in the NRC Emergency Operation Center used in support of an NRC response to an actual emergency, drill, or exercise. Responses to these collections of information are required for applicants and licensees choosing to comply with 10 CFR 50.160. Confidential and proprietary information submitted to the NRC is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b).

You may submit comments on any aspect of the information collections, including suggestions for reducing the burden, by the following methods:

- **Federal Rulemaking Website:** Go to http://www.regulations.gov and search for Docket ID NRC-2015-0225.
- **Mail comments to:** FOIA, Library, and Information Collections Branch, Office of Information Services, Mail Stop: T6-A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0011 and 3150-0151), Attn: Desk Officer for the Nuclear Regulatory Commissio[n,] 725 17th Street, NW Washington, DC 20503; email: oira_submission@omb.eop.gov.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XIII. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act (CRA) (5 U.S.C. 801-808). However, OMB has not found it to be a major rule as defined in the CRA.

XIV. Criminal Penalties

For the purposes of Section 223 of the AEA, the NRC is issuing this final rule that will amend §§ 50.10, 50.34, 50.47, 50.54, 50.160, and appendix E to 10 CFR part 50 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement. Criminal penalties as they apply to regulations in 10 CFR part 50 are discussed in § 50.111.

XV. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC revises regulations associated with EP in 10 CFR parts 50, 52, and 72. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XVI. Availability of Guidance

The NRC is issuing new guidance, RG 1.242, “Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities,” that support implementation of the requirements in this final rule. The guidance is available in ADAMS, as provided in the “Availability of

Documents" section of this document. You may access information and comment submissions related to the guidance by searching on https://www.regulations.gov under Docket ID NRC-2015-0225.

The guidance document is intended for use by applicants, licensees, and NRC staff, and describes an approach and method acceptable for implementing the requirements of this final rule. As a guidance document, RG 1.242 does not establish additional requirements, and applicants and licensees are able to propose alternative ways for demonstrating compliance with the requirements in § 50.160.

XVII. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

DOCUMENT	ADAMS ACCESSION NO. / WEB LINK / *FEDERAL REGISTER* CITATION
EPA 520/1-75-001, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," September 1975.	https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=9101AK8V.PDF
NUREG-75/014, "Reactor Safety Study – An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants," (WASH-1400), October 1975 (Appendices III-IV, Appendix V, Appendix VI, Appendices VII-X).	ML070610293 ML070530533 ML070600389 ML070600376
NUREG-0396, "Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants," December 1978.	ML051390356
RG 2.6, "Emergency Planning for Research Reactors," January 1979.	ML12184A008
"10 CFR Parts 50 and 70, Emergency Planning," Final Rule, August 19, 1980.	45 FR 55402

NUREG-0654/FEMA-REP-1, Revision 1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," November 1980.	ML040420012
"Emergency Planning and Preparedness," Final Rule, July 13, 1982.	47 FR 30232
NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors," October 1983.	ML062190191
"Specific Exemptions; Clarification of Standards," Final Rule, December 12, 1985.	50 FR 50764
"Regulation of Advanced Nuclear Power Plants, Statement of Policy," July 8, 1986.	51 FR 24643
NUREG-1226, "Development and Utilization of the NRC Policy Statement on the Regulation of Advanced Nuclear Power Plants," June 1988.	ML13253A431
"Emergency Planning and Preparedness Requirements for Nuclear Power Plant Fuel Loading and Low-Power Testing," Final Rule, September 23, 1988.	53 FR 36955
"Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants," Final Rule, April 18, 1989.	54 FR 15372
EPA-400-R-92-001, "Manual of Protection Action Guides and Protective Actions for Nuclear Incidents," May 1992.	https://www.epa.gov/sites/production/files/2016-03/documents/pags.pdf
SECY-93-092, "Issues Pertaining to the Advanced Reactor (RISM, MHTGR, and PIUS) and CANDU 3 Designs and Their Relationship to Current Regulatory Requirements," April 8, 1993.	ML040210725
SRM-SECY-93-092, "Staff Requirements—SECY-93-092—Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and Their Relationship to Current Regulatory Requirements," July 30, 1993.	ML003760774
NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," February 1996.	ML042430055
NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," February 1996.	ML042430048

SECY-97-020, “Results of Evaluation of Emergency Planning for Evolutionary and Advanced Reactors,” January 27, 1997.	ML992920024
Homeland Security Presidential Directive 5, “Management of Domestic Incidents,” February 28, 2003.	https://www.dhs.gov/publication/homeland-security-presidential-directive-5
SECY-04-0236, “Southern Nuclear Operation Company’s Proposal to Establish a Common Emergency Operating Facility at its Corporate Headquarters,” December 23, 2004.	ML042590576
SRM-SECY-04-0236, “Staff Requirements—SECY-04-0236—Southern Nuclear Operating Company’s Proposal to Establish a Common Emergency Operating Facility at its Corporate Headquarters,” February 23, 2005.	ML050550131
SECY-06-0200, “Results of the Review of Emergency Preparedness Regulations and Guidance,” September 20, 2006.	ML061910707
SRM-SECY-06-0200, “Staff Requirements—SECY-06-0200—Results of the Review of Emergency Preparedness Regulations and Guidance,” January 8, 2007.	ML070080411
NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,” Section 13.3, “Emergency Planning,” March 2007.	ML063410307
NUREG-0800, Section 14.3.10, “Emergency Planning - Inspections, Tests, Analyses, and Acceptance Criteria,” March 2007.	ML070730206
“Policy Statement on Regulation of Advanced Reactors,” October 14, 2008.	73 FR 60612
“Summary of Workshop on Small and Medium-Sized Nuclear Reactors (SMRs),” October 22, 2009.	ML092940138
SECY-10-0034, “Potential Policy, Licensing, and Key Technical Issues for Small Modular Reactor Designs,” March 28, 2010.	ML093290268
NUREG-1520, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility,” Revision 1, May 1, 2010.	ML101390110
“Summary of July 28, 2010, Category 2 Meeting with Small Modular Reactor Design Representatives to Discuss Small Modular Reactor Key Licensing Issues (TAC NO. Q00269),” August 26, 2010.	ML102380209
Presidential Policy Directive/PPD-8, “National Preparedness,” March 30, 2011.	https://www.dhs.gov/presidential-policy-directive-8-national-preparedness

SECY-11-0152, “Development of an Emergency Planning and Preparedness Framework for Small Module Reactors,” October 28, 2011.	ML112570439
“Enhancements to Emergency Preparedness Regulations,” Final Rule, November 23, 2011.	76 FR 72559
Interim Staff Guidance for NUREG-1537, “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content’ for Licensing Radioisotope Production Facilities and Aqueous Homogenous Reactors,” October 12, 2012.	ML12156A069
Final Interim Guidance for NUREG-1537, “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria’ for Licensing Radioisotope Production Facilities and Aqueous Homogenous Reactors,” October 17, 2012.	ML12156A075
NEI 99-02, “Regulatory Assessment Performance Indicator Guideline,” Revision 7, August 13, 2013.	ML13261A116
NEI White Paper, “White Paper: Proposed Methodology and Criteria Establishing the Technical Basis for Small Modular Reactor Emergency Planning Zone,” December 23, 2013.	ML13364A345
SECY-14-0038, “Performance-Based Framework for Nuclear Power Plant Emergency Preparedness Oversight,” April 4, 2014.	ML13238A018
SECY-14-0066, “Request by Dominion Energy Kewaunee Inc., for Exemptions from Certain Emergency Planning Requirements,” June 27, 2014.	ML14072A257
SRM-SECY-14-0038, “Staff Requirements—SECY-14-0038—Performance-Based Framework for Nuclear Power Plant Emergency Preparedness Oversight,” September 16, 2014.	ML14259A589
SECY-14-0118, “Request by Duke Energy Florida, Inc., for Exemptions from Certain Emergency Planning Requirements,” October 29, 2014.	ML14219A444

American National Standards Institute/American Society Standard (ANSI/ANS) 15.16 – 2015. "Emergency Planning for Research Reactors," American Nuclear Society, La Grange Park, IL, February 2015.	https://webstore.ansi.org/standards/ansi/ansians15162015
SECY-15-0077, "Options for Emergency Preparedness for Small Module Reactors and Other New Technologies," May 29, 2015.	ML15037A176
"Summary of June 7-8, 2015, Department of Energy and Nuclear Regulatory Commission Co-Hosted Workshop on Advanced Non-Light Water Reactors," July 7, 2015.	ML16188A226
NEI White Paper, "Proposed Emergency Preparedness Regulations and Guidance for Small Modular Reactor Facilities," July 2015.	ML15194A275
SRM-SECY-15-0077, "Staff Requirements—SECY-15-0077—Options for Emergency Preparedness for Small Module Reactors and Other New Technologies," August 4, 2015.	ML15216A492
"Summary of September 1-2, 2015, Nuclear Regulatory Commission and Department of Energy Co-Hosted Workshop on Advanced Non-Light Water Reactors," October 1, 2015.	ML15265A165
"Variable Annual Fee Structure for Small Modular Reactors," Proposed Rule, November 4, 2015.	80 FR 68268
"Memorandum of Understanding Between the Department of Homeland Security/Federal Emergency Management Agency and Nuclear Regulatory Commission Regarding Radiological Emergency Response, Planning, and Preparedness," December 7, 2015.	ML15344A371
"Variable Annual Fee Structure for Small Modular Reactors," Final Rule, May 24, 2016.	81 FR 32617
SECY-16-0069, "Rulemaking Plan on Emergency Preparedness for Small Module Reactors and Other New Technologies," May 31, 2016.	ML16020A388
Nuclear Innovation Alliance, "Enabling Nuclear Innovation: Strategies for Advanced Reactor Licensing," June 7, 2016.	https://docs.wixstatic.com/ugd/5b05b3_71d4011545234838aa27005ab7d757f1.pdf
SRM-SECY-16-0069, "Staff Requirements—SECY-16-0069—Rulemaking Plan on Emergency Preparedness for Small Module Reactors and Other New Technologies," June 22, 2016.	ML16174A166
RG 1.219, Revision 1, "Guidance on Making Changes to Emergency Plans for Nuclear Power Reactors," July 2016.	ML16061A104

"Summary of August 22, 2016, Public Meeting to Discuss a Performance-Based Approach to Emergency Preparedness for Small Modular Reactors and Other New Technologies," September 15, 2016.	ML16257A510
"NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness," December 2016.	ML16356A670
EPA-400/R-17/001, "PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents," January 2017.	https://www.epa.gov/sites/production/files/2017-01/documents/epa_pag_manual_final_revisions_01-11-2017_cover_disclaimer_8.pdf
"Tribal Policy Statement," January 9, 2017.	82 FR 2402
"Emergency Preparedness for Small Modular Reactors and Other New Technologies," Draft Regulatory Basis, April 13, 2017.	82 FR 17768
"Summary of May 10, 2017, Public Meeting on the Draft Regulatory Basis for the Rulemaking for Emergency Preparedness for Small Modular Reactors and Other New Technologies," May 24, 2017.	ML17139C860
RG 2.6, "Emergency Planning for Research and Test Reactors and Other Non-Power Production and Utilization Facilities," September 2017.	ML17263A472
"Emergency Preparedness for Small Modular Reactors and Other New Technologies," Regulatory Basis, November 15, 2017.	82 FR 52862
"Regulatory Improvements for Power Reactors Transitioning to Decommissioning Rulemaking," Regulatory Basis, November 27, 2017.	82 FR 55954
SECY-18-0055, "Proposed Rule: Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning," May 22, 2018.	ML18012A019
"Generalized Dose Assessment Methodology for Informing Emergency Planning Zone Size Determinations," June 2018.	ML18064A317
"Required Analyses for Informing Emergency Planning Zone Size Determinations," June 2018.	ML18114A176
SRM-SECY-18-0103, "Staff Requirements—SECY-18-0103—Proposed Rule: Emergency Preparedness for Small Modular Reactors and Other New Technologies (RIN 3150 AJ68; NRC-2015-0225)," December 17, 2019.	ML19351C729

NUREG-0654/FEMA-REP-1, Revision 2, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," December 2019.	ML19347D139
RG 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light Water Reactors," June 2020.	ML20091L698
Summary of June 24, 2020, Public Meeting to Discuss the Proposed Emergency Preparedness for Small Modular Reactors and Other New Technologies Rule, July 14, 2020	ML20196L775
"Regulatory Analysis for the Final Rule: Emergency Preparedness for Small Modular Reactors and Other New Technologies," December 2021.	ML21200A079
"Environmental Assessment for the Final Rule—Emergency Preparedness for Small Modular Reactors and Other New Technologies," December 2021.	ML21200A080
"Supporting Statement for Information Collections Contained in the Emergency Preparedness for Small Modular Reactors and Other New Technologies Final Rule; 10 CFR Part 50, Domestic Licensing of Production and Utilization Facilities," December 2021.	ML21200A185
"Supporting Statement for Information Collections Contained in the Emergency Preparedness for Small Modular Reactors and Other New Technologies Final Rule; 10 CFR Part 52, Licensing, Certifications, and Approvals for Nuclear Power Plants," December 2021.	ML21200A190
RG 1.242, "Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities," December 2021.	ML20345A345
"NRC Response to Public Comments; Emergency Preparedness for Small Modular Reactors and Other New Technologies."	ML21200A077
SECY-21-XXXX, "Final Rule: Emergency Preparedness for Small Modular Reactors and Other New Technologies," December XX, 2021.	MLXXXXXXXXX

SRM-SECY-21-XXXX, “Final Rule: Emergency Preparedness for Small Modular Reactors and Other New Technologies,” MONTH XX, 202X.	MLXXXXXXXXX

List of Subjects

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 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

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, as amended; and

5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 50, 52, and 72:

PART 50 – DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for part 50 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 101, 102, 103, 104, 105, 108, 122, 147, 149, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note; Sec. 109, Pub. L. 96-295, 94 Stat. 783.

2. In § 50.2, add in alphabetical order the definitions for *Non-light-water reactor, Non-power production or utilization facility,* and *Small modular reactor* to read as follows:

§ 50.2 Definitions.

* * * * *

Non-light-water reactor means a nuclear power reactor using a coolant other than light water.

Non-power production or utilization facility means a production or utilization facility, licensed under § 50.21(a) or (c), or § 50.22, as applicable, that is not a nuclear power reactor or a production facility as defined under paragraphs (1) and (2) of the definition of *Production facility* in this section.

* * * * *

Small modular reactor means a power reactor, which may be of modular design as defined in § 52.1 of this chapter, licensed under § 50.21 or § 50.22 to produce heat energy up to 1,000 megawatts thermal per module.

* * * * *

§ 50.8 [Amended]

3. In § 50.8(b), add the citation “50.160,” after the citation “50.155,”.

4. In § 50.10, revise paragraph (a)(1)(vii) to read as follows:

§ 50.10 License required; limited work authorization.

(a) * * *

(1) * * *

(vii) Onsite emergency facilities necessary to comply with either § 50.160 or § 50.47 and appendix E to this part, as applicable.

* * * * *

5. In § 50.33, revise paragraph (g) to read as follows:

§ 50.33 Contents of applications; general information.

* * * * *

(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 nuclear power reactor, or if the application is for an early site permit and contains plans for coping with emergencies under § 52.17(b)(2)(ii) of this chapter, the applicant shall submit the 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),[4] as well as the plans of State governments wholly or partially within the ingestion pathway EPZ.[5] If the application is for an early site permit that, under 10 CFR

52.17(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, the plume exposure pathway EPZ for nuclear power reactors 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 nuclear power reactor 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.

* * * * *

[4] 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.

[5] 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.

(2) Small modular reactor, non-light-water reactor, or non-power production or utilization facility applicants complying with § 50.160 who apply for a construction permit or an operating license under this part, or small modular reactor or non-light-water reactor applicants complying with § 50.160 who apply for a combined license or an early site permit under part 52 of this chapter, must submit as part of the application the analysis used to determine whether the criteria in § 50.33(g)(2)(i)(A) and (B) are met and, if they are met, the size of the plume exposure pathway EPZ.

(i) The plume exposure pathway EPZ is the area within which:

(A) Public dose, as defined in § 20.1003 of this chapter, is projected to exceed 10 mSv (1 rem) total effective dose equivalent over 96 hours from the release of radioactive materials from the facility considering accident likelihood and source term, timing of the accident sequence, and meteorology; and

(B) Pre-determined, prompt protective measures are necessary.

(ii) If the application is for an operating license or combined license or if the application is for an early site permit and contains plans for coping with emergencies under § 52.17(b)(2)(ii) of this chapter, and if the plume exposure pathway EPZ extends beyond the site boundary:

(A) The applicant shall submit radiological emergency response plans of State, local, and participating Tribal governmental entities in the United States that are wholly or partially within the plume exposure pathway EPZ.

(B) The exact configuration of the plume exposure pathway EPZ surrounding the facility 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.

(iii) If the application is for an early site permit that, under § 52.17(b)(2)(i) of this chapter, proposes major features of the emergency plans and describes the EPZ, and if the EPZ extends beyond the site boundary, then the exact configuration of the plume exposure pathway EPZ surrounding the facility 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.

* * * * *

6. In § 50.34, revise paragraphs (a)(10) and (b)(6)(v) to read as follows:

§ 50.34 Contents of applications; technical information.

(a) * * *

(10) A discussion of the applicant's preliminary plans for coping with emergencies based on:

(i) Except as provided in paragraph (a)(10)(ii) of this section, the requirements in appendix E to this part.

(ii) For a small modular reactor, a non-light-water reactor, or non-power production or utilization facility construction permit applicant, the requirements in either § 50.160 or appendix E to this part.

* * * * *

(b) * * *

(6) * * *

(v) Plans for coping with emergencies based on:

(A) Except as provided in paragraph (b)(6)(v)(B) of this section, the requirements in appendix E to this part.

(B) For a small modular reactor, a non-light-water reactor, or a non-power production or utilization facility operating license applicant, the requirements in either § 50.160 or appendix E to this part.

* * * * *

7. In § 50.47, revise paragraphs (a)(1)(iv), (b) introductory text, (c)(1) introductory text, (c)(1)(i), and (e) and add paragraph (f) to read as follows:

§ 50.47 Emergency plans.

* * * * *

(a) * * *

(1) * * *

(iv) If an application for an early site permit proposes major features of the emergency plans under 10 CFR 52.17(b)(2)(i), no early site permit will be issued unless a finding is made by the NRC that the major features are acceptable in accordance with the applicable standards of either § 50.47 and appendix E to this part, or the applicable requirements of § 50.160, within the scope of emergency preparedness matters addressed in the major features.

* * * * *

(b) The onsite and, except as provided in paragraphs (d) and (f) of this section, offsite emergency response plans for nuclear power reactors must meet the following standards:

* * * * *

(c)(1) Failure to meet the applicable standards set forth in either § 50.160 or § 50.47(b) may result in the Commission declining to issue an operating license; however, the applicant will have an opportunity to demonstrate to the satisfaction of the Commission that deficiencies in the plans are not significant for the plant in question, that adequate interim compensating actions have been or will be taken promptly, or that there are other compelling reasons to permit plant operations. Where an applicant for an operating license asserts that its inability to demonstrate compliance with the requirements in either § 50.160 or § 50.47(b) results wholly or substantially from the decision of State and/or local governments not to participate further in emergency planning, an operating license may be issued if the applicant demonstrates to the Commission's satisfaction that:

(i) The applicant’s inability to comply with the requirements in either § 50.160 or § 50.47(b) is wholly or substantially the result of the non-participation of State and/or

local governments.

* * * * *

(e) Notwithstanding the requirements of paragraph (b) of this section and the provisions of § 52.103 of this chapter, a holder of a combined license under part 52 of this chapter that is complying with the requirements of § 50.47(b) and appendix E to this part may not load fuel or operate except as provided in accordance with appendix E to this part and § 50.54(gg), and a holder of a combined license under part 52 of this chapter that is complying with the requirements of § 50.160 may not load fuel or operate except as provided in accordance with § 50.160(c)(2) and § 50.54(gg).

(f) Paragraphs (a)(2), (b), and (c)(2) of this section do not apply to offsite radiological emergency response plans if the onsite emergency plan is not required to meet § 50.47(b) or if the plume exposure pathway EPZ does not extend beyond the site boundary.

8. In § 50.54:

a. Revise paragraphs (q)(1)(iii) and (q)(2) through (4);

b. In paragraph (q)(5), remove the words “made after February 21, 2012”;

c. Add paragraph (q)(7);

d. In paragraph (s)(2)(ii), remove the words “after April 1, 1981,” remove the word “reactor” and add in its place the word “facility”, and add the words “or cease operation” after the words “shut down”;

e. In paragraph (s)(3), remove the words “The NRC” and add in their place the words “If the planning standards for radiological emergency preparedness apply to offsite emergency response plans, or if the planning activities in § 50.160(b)(1)(iv)(B) apply, then the NRC”; and

f. Revise paragraph (gg)(1) introductory text.

The addition and revisions read as follows:

§ 50.54 Conditions of licenses.

* * * * *

(q) * * *

(1) * * *

(iii) *Emergency planning function* means a capability or resource necessary to prepare for and respond to a radiological emergency.

* * * * *

(2)(i) Except as provided in paragraph (q)(2)(ii) of this section, a holder of a license under this part, or a combined license under part 52 of this chapter after the Commission makes the finding under § 52.103(g) of this chapter, shall follow and maintain the effectiveness of an emergency plan that meets the requirements in appendix E to this part and, for nuclear power reactor licensees, the planning standards of § 50.47(b).

(ii) A holder of a license under this part for a non-power production or utilization facility, a holder of a license under this part for a small modular reactor or a non-light water reactor, or a holder of a combined license under part 52 of this chapter after the Commission makes the finding under § 52.103(g) of this chapter for a small modular reactor or a non-light-water reactor, shall follow and maintain the effectiveness of either an emergency plan that meets the requirements in § 50.160 or an emergency plan that meets the requirements in appendix E to this part and, for nuclear power reactor licensees, the planning standards of § 50.47(b).

(3)(i) Except as provided in paragraph (q)(3)(ii) of this section, 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 appendix E to this part and, for nuclear power reactor licensees, the planning standards of § 50.47(b).

(ii) A non-power production or utilization facility, small modular reactor, or non-light-water reactor 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 either the requirements in § 50.160 or the requirements in appendix E to this part and, for nuclear power reactor licensees, the planning standards of § 50.47(b).

(4) The changes to a licensee's emergency plan that reduce the effectiveness of the plan as defined in paragraph (q)(1)(iv) of this section may not be implemented without prior approval by the NRC. A licensee desiring to make such a change shall submit an application for an amendment to its license. In addition to the filing requirements of §§ 50.90 and 50.91, 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 either the requirements in § 50.160 or the requirements in appendix E to this part and, for nuclear power reactor licensees, the planning standards of § 50.47(b).

* * * * *

(q)(7) Each holder of an operating license under this part or a combined license under part 52 of this chapter for a small modular reactor or non-light-water reactor or each holder of an operating license under this part issued after **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER]*** for a non-power production or utilization facility that wishes to transition to § 50.160 shall submit to the Commission, as specified in § 50.90, a license amendment request for implementing

an emergency preparedness program with the associated plan modification necessary to meet the requirements of § 50.160(b). This submittal must include an explanation of the schedule and analyses supporting the implementation of the emergency preparedness program.

* * * * *

(gg)(1) Notwithstanding § 52.103 of this chapter, if, following the conduct of the exercise required by either paragraph IV.f.2.a of appendix E to this part or § 50.160(c)(2), as applicable, FEMA identifies one or more deficiencies in the state of offsite emergency preparedness, the holder of a combined license under part 52 of this chapter may operate at up to 5 percent of rated thermal power only if the Commission finds that the state of onsite emergency preparedness provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. The NRC will base this finding on its assessment of the applicant's onsite emergency plans against the pertinent standards in either § 50.47 and appendix E to this part, or § 50.160, as applicable. Review of the applicant's emergency plans will include the following standards with offsite aspects:

* * * * *

9. After § 50.155, add undesignated center heading **Small Modular Reactors, Non-Light-Water Reactors, and Non-power Production or Utilization Facilities** and § 50.160 to read as follows:

SMALL MODULAR REACTORS, NON-LIGHT-WATER REACTORS, AND NON-POWER PRODUCTION OR UTILIZATION FACILITIES

§ 50.160 Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities.

(a) *Definitions.* For the purpose of this section:

(1) *Site boundary* means site boundary as defined in § 20.1003 of this chapter.

(2) [Reserved]

(b) *Requirements*. The emergency plan shall contain information needed to demonstrate compliance with the elements set forth in this paragraph. The applicable requirements of § 50.47(a)(1) apply to applications submitted under this section.

(1) *Performance-based framework*. Demonstrate effective response in drills and exercises for emergency and accident conditions.

(i) *Maintenance of performance*. Maintain in effect preparedness to respond to emergency and accident conditions and describe in an emergency plan the provisions to be employed to maintain preparedness.

(ii) *Performance objectives*.

(A) By the beginning of each calendar quarter, develop and maintain a complete list of performance objectives for that calendar quarter; and

(B) Maintain records showing the implemented performance objectives and associated metrics during each calendar quarter for the previous eight calendar quarters.

(iii) *Emergency response performance*. The emergency response team must have sufficient capability to demonstrate the following emergency response functions using drills or exercises:

(A) *Event classification and mitigation*. Assess, classify, monitor, and repair facility malfunctions in accordance with the emergency plan to return the facility to safe conditions.

(B) *Protective actions*. Implement and maintain protective actions for onsite personnel for emergency conditions, and recommend protective actions to offsite authorities as conditions warrant.

(C) *Communications*. Establish and maintain effective communications with the emergency response organization, and make notifications to response personnel and organizations who may have responsibilities for responding during emergencies.

(D) *Command and control*. Establish and maintain effective command and control for emergencies by using a supporting organizational structure with defined roles, responsibilities, and authorities for directing and performing emergency response functions as described in paragraph (b) of this section.

(E) *Staffing and operations*. Establish staffing for the facility necessary to implement the roles and responsibilities in paragraph (b)(1)(iii) of this section.

(F) *Radiological assessment*. Assess radiological conditions in and around the facility during emergencies, including:

(*1*) *Radiological conditions*. Assess, monitor, and report radiological conditions to the applicable response personnel using installed or portable equipment.

(*2*) *Protective equipment*. Issue and use protective equipment necessary to continue and expand mitigation and protective action strategies.

(*3*) *Core or vessel damage*. Assess, monitor, and report to the applicable response personnel the extent and magnitude of damage to the core or other vessel containing irradiated special nuclear material, such as fuel or targets, as applicable.

(*4*) *Releases*. Assess, monitor, and report to the applicable response personnel the extent and magnitude of all radiological releases, including releases of hazardous chemicals produced from licensed material.

(G) *Reentry*. Develop and implement reentry plans for accessing the facility after emergencies.

(H) *Critique and corrective actions*. Critique emergency response functions and implement corrective actions after drills and exercises, and after emergencies, if they occur.

(iv) *Planning activities*.

(A) Maintain the capability to:

(*1*) Prepare and issue public information during emergencies.

(*2*) Implement the NRC-approved emergency response plan in conjunction with the licensee's Safeguards Contingency Plan.

(*3*) Establish voice and data communications with the NRC for emergencies.

(*4*) Establish an emergency facility or facilities from which effective direction can be given and effective control can be exercised during an emergency, with capabilities to support the emergency response functions as described in paragraph (b)(1)(iii) of this section.

(*5*) Provide site familiarization training for any offsite organization that may respond to the site in the event of an emergency.

(*6*) Establish methods for maintaining the emergency plan, contacts and arrangements, procedures, and evacuation time estimate up to date, including periodic reviews by the onsite and offsite organizations.

(B) For a plume exposure pathway EPZ that extends beyond the site boundary, the emergency plan must describe:

(*1*) The contacts and arrangements made and documented with Federal, State, local, and Tribal governmental agencies, as applicable, with responsibilities for coping with emergencies, including the identification of the principal coordinating agencies, and the coordinated reviews of changes in offsite and onsite planning and preparation;

(*2*) Offsite organizations responsible for coping with emergencies and the means of notifying, in the event of an emergency, persons assigned to the emergency organizations, including the means of validating notifications, the time period by which notifications must be completed, and primary and secondary methods to complete notification;

(*3*) The protective measures to be taken within the EPZ to protect the health and safety of the public in the event of an emergency, including the procedures by which the protective measures are implemented, maintained, and discontinued;

(*4*) An evacuation time estimate of the areas within the EPZ;

(*5*) The offsite facility and any backup facilities to coordinate the onsite response with the offsite response;

(*6*) The means of making offsite dose projections and the means of communicating the offsite dose projections to the offsite response coordinating agencies;

(*7*) The means by which public information is provided to the members of the public concerning emergency planning information, public alert notification system, and any prompt actions that need to be taken by the public;

(*8*) The general plans and methods to allow reentry into the EPZ during and after an emergency; and

(*9*) The drill and exercise program that tests and implements major portions of planning, preparations, and the coordinated response by the onsite response organization with the offsite response organizations within the EPZ without mandatory public participation.

(2) *Hazard analysis*. Conduct a hazard analysis of any contiguous or nearby facility, such as industrial, military, and transportation facilities, and include any credible hazard into the licensee's emergency preparedness program that would adversely impact the implementation of emergency plans.

(3) *Emergency planning zone*. For an applicant whose analysis required by § 50.33(g)(2) meets the criteria in § 50.33(g)(2)(i), determine and describe the boundary and physical characteristics of the EPZ in the emergency plan.

(4) *Ingestion response planning*. Describe or reference in the emergency plan the capabilities that provide actions to prevent contaminated food and water from entering into the ingestion pathway.

(c) *Implementation*. (1) An applicant for an operating license issued under this part after **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** must establish, implement, and maintain an emergency preparedness program that meets the requirements of paragraph (b) of this section, as described in the emergency plan and license, and conduct an initial exercise to demonstrate this compliance within 2 years before the issuance of an operating license for the facility described in the license application.

(2) A holder of a combined license issued under part 52 of this chapter before the Commission has made the finding under § 52.103(g) of this chapter, must establish, implement, and maintain an emergency preparedness program that meets the requirements of paragraph (b) of this section, as described in the approved emergency plan and license, and conduct an initial exercise to demonstrate this compliance within 2 years before the scheduled date for initial loading of fuel.

10. In appendix E to part 50, revise paragraph I.3. and footnote 2 to I.3 to read as follows:

APPENDIX E TO PART 50—EMERGENCY PLANNING AND PREPAREDNESS FOR PRODUCTION AND UTILIZATION FACILITIES

I. * * *

3. The potential radiological hazards to the public associated with the operation of non-power production or utilization facilities licensed under 10 CFR part 50 and fuel facilities licensed under 10 CFR part 70 involve considerations different than those

associated with nuclear power reactors. Consequently, the size of Emergency Planning Zones[1] (EPZs) for facilities other than power reactors and the degree to which compliance with the requirements of this section and sections II, III, IV, and V of this appendix is necessary, will be determined on a case-by-case basis.[2]

[1] EPZs for power reactors 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. The size of the EPZs for a nuclear power plant shall be determined in relation to 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 nuclear reactors and for reactors with an authorized power level less than 250 MW thermal. Generally, the plume exposure pathway EPZ for nuclear power plants with an authorized power level greater than 250 MW thermal 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.

[2] Regulatory Guide 2.6, "Emergency Planning for Research and Test Reactors and Other Non-power Production and Utilization Facilities," may be used as guidance for the acceptability of non-power production or utilization facility emergency response plans.

* * * * *

PART 52 – LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS

11. The authority citation for part 52 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 101, 102, 103, 104, 105, 108, 122, 147, 149, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note; Sec. 109, Pub. L. 96-295, 94 Stat. 783.

12. In § 52.1, revise the definition of *Major feature of the emergency plans* to

read as follows:

§ 52.1 Definitions.

(a) * * *

Major feature of the emergency plans means an aspect of those plans necessary to:

(i) Address in whole or part either one or more of the 16 standards in 10 CFR 50.47(b) or the requirements of 10 CFR 50.160(b), as applicable; or

(ii) Describe the emergency planning zones as required in 10 CFR 50.33(g).

* * * * *

13. In § 52.17, revise paragraphs (b)(2)(i) and (ii) to read as follows:

§ 52.17 Contents of applications; technical information.

* * * * *

(b) * * *

(2) * * *

(i) Propose major features of the emergency plans, in accordance with either the requirements in § 50.160 of this chapter, or the requirements in appendix E to part 50 of this chapter and § 50.47(b) of this chapter, as applicable, 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 either the requirements in § 50.160 of this chapter, or the requirements in appendix E to part 50 of

this chapter and § 50.47(b) of this chapter. To the extent approval of emergency plans is sought, the application must contain the information required by § 50.33(g) and (j) of this chapter.

* * * * *

14. Revise § 52.18 to read as follows:

§ 52.18 Standards for review of applications.

Applications filed under this subpart will be reviewed according to the applicable standards set out in 10 CFR part 50 and its appendices and 10 CFR part 100. 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 Federal Emergency Management Agency, as applicable, whether the information required of the applicant by § 52.17(b)(1) shows that there is not a 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 § 52.17(b)(2)(i) are acceptable in accordance with either the requirements in § 50.160 of this chapter, or the requirements in appendix E to part 50 of this chapter and § 50.47(b) of this chapter, and whether any emergency plans submitted by the applicant under § 52.17(b)(2)(ii) provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

15. In § 52.79, revise paragraph (a)(21) to read as follows:

§ 52.79 Contents of applications; technical information in final safety analysis report.

(a) * * *

(21) Emergency plans complying with the requirements of § 50.47 of this chapter, and appendix E to part 50 of this chapter, or for a small modular reactor or a non-light-water reactor license applicant, emergency plans complying with either the requirements in § 50.160 of this chapter, or the requirements in appendix E to part 50 of this chapter and § 50.47(b) of this chapter;

* * * * *

PART 72 – LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTORRELATED GREATER THAN CLASS C WASTE

16. The authority citation for 10 CFR part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

17. In § 72.32, revise paragraph (c)(2) to read as follows:

§ 72.32 Emergency plan.

* * * * *

(c) * * *

(2) Located within the exclusion area as defined in 10 CFR part 100, of a nuclear power reactor licensed for operation by the Commission, the emergency plan that meets

either the requirements in § 50.160 of this chapter, or the requirements in appendix E to part 50 of this chapter and § 50.47(b) of this chapter shall be deemed to satisfy the requirements of this section.

* * * * *

Dated: Month XX, 2021

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.