

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 52

[NRC-2015-0225]

RIN 3150-AJ68

Emergency Preparedness for Small Modular Reactors and Other New Technologies

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule and guidance; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to include new alternative emergency preparedness (EP) requirements for small modular reactors (SMRs) and other new technologies (ONTs), such as non-light-water reactors (non-LWRs) and certain non-power production or utilization facilities (NPUFs). The new EP requirements would acknowledge technological advancements and other differences from large LWRs that are inherent in SMRs and ONTs. Concurrently, the NRC is issuing for public comment draft Regulatory Guide (DG), DG-1350, "Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-power Production or Utilization Facilities." The NRC plans to hold a public meeting to promote full understanding of the proposed rule and guidance and to facilitate public comment.

DATES: Submit comments by July 27, 2020. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- **Federal Rulemaking Web Site:** Go to <https://www.regulations.gov> and search for Docket ID **NRC-2015-0225**. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic e-mail reply confirming receipt, then contact us at 301-415-1677.

- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

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

FOR FURTHER INFORMATION CONTACT: Robert Beall, Office of Nuclear Material Safety and Safeguards; telephone: (301) 415-3874, e-mail: Robert.Beall@nrc.gov; or Eric Schrader, Office of Nuclear Security and Incident Response; telephone: 301-287-3789; email: Eric.Schrader@nrc.gov; both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

EXECUTIVE SUMMARY:

A. Need for the Regulatory Action

The current EP requirements and guidance, initially developed for large light-water reactors (LWRs) and for non-power reactors, also referred to as research and test reactors (RTRs), as defined in part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), “Domestic Licensing of Production and Utilization Facilities,” do not consider the advances in designs and safety research and their application to future operation of SMRs and ONTs. Through this proposed rule, the NRC is proposing to amend its regulations to create an alternative EP framework for SMRs and ONTs. The new alternative EP requirements and implementing guidance in DG-1350 would adopt a performance-based, technology-inclusive, risk-informed, and consequence-oriented approach. The new alternative EP requirements and guidance would adopt a scalable plume exposure pathway emergency planning zone (EPZ) approach and address ingestion response planning. The new alternative EP requirements and guidance would: 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 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 smaller sized reactors’ and non-LWRs’ potential benefits associated with postulated accidents, including slower transient response times, and relatively small and slow release of fission products. This proposed rule and guidance could affect existing SMR and non-LWR applicants and licensees as well as SMRs, non-LWRs, and NPUFs that would be licensed after the effective date of the final rule. Those applicants and licensees would 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 proposed rule does not include within its scope emergency planning, preparation, or response for large LWRs, fuel cycle facilities,¹ or currently operating non-power

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).

reactors. For the purposes of this rule, large LWRs are reactors that are licensed to produce greater than 1,000 megawatts thermal (MWt) power.

B. Major Provisions

Major provisions of this proposed rule and guidance would 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 hazard analysis of any NRC-licensed or non-licensed facility contiguous or nearby to an SMR or ONT, that considers any hazard that would adversely impact the implementation of emergency plans;
 - A scalable approach for determining the size of the plume exposure pathway EPZ;
- and
- A requirement to describe ingestion response planning in the emergency plan, including the capabilities and resources available to prevent contaminated food and water from entering the ingestion pathway.

C. Costs and Benefits

The NRC prepared a draft regulatory analysis to determine the expected quantitative costs and benefits of this proposed rule and associated guidance as well as qualitative factors to be considered in the NRC's rulemaking decision. The conclusion from the analysis is that this proposed rule and associated guidance would result in net averted costs to the industry and the NRC ranging from \$5.89 million using a 7-percent discount rate to \$9.71 million using a 3-percent discount rate.

The draft regulatory analysis also considered qualitative aspects, such as greater regulatory stability, predictability, and clarity to the licensing process. These benefits would

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, please see the draft regulatory analysis (available in the NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML18134A077).

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

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 Web Site:** Go to <https://www.regulations.gov> and search for Docket ID **NRC-2015-0225**.
- **NRC's ADAMS:** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in section XVII, "Availability of Documents."
- **Attention:** The Public Document Room (PDR), where you may examine and order copies of public documents is currently closed. You may submit your request to the PDR via e-mail at pdr.resource@nrc.gov or call 1-800-397-4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID **NRC-2015-0225** in your comment submission. To facilitate NRC review, please distinguish your comments between comments on the proposed rule and comments on the proposed guidance. The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information. If you are requesting or aggregating comments from

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

II. Background

Current EP requirements and guidance, initially developed for large LWRs and non-power reactors, do not consider advances in designs and safety research and their applications to existing or future operation of SMRs and ONTs. Within the “Supplementary Information” section of this document, the NRC uses the term “ONTs” to refer to new technologies, such as non-LWRs and proposed medical radioisotope facilities that would be licensed under 10 CFR part 50. Further, within this document, the NRC uses the term “existing” or “current” when referring to existing applicants or licensees for an SMR or ONT facility. This proposed rule would also define “non-power production or utilization facility” to clarify the applicability of the proposed performance-based EP framework. As used in this proposed rule, the term “non-power production or utilization facility” would be defined to have the same meaning as the definition used in SECY-19-0062, “Final Rule: Non-power Production or Utilization Facility License Renewal” (ADAMS Accession No. ML18031A000), dated June 17, 2019.² The definition would include 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 proposed rule, medical radioisotope facilities that would be licensed under 10

² Any changes made to the definition of “non-power production or utilization facility” based on Commission direction will be reflected in the final rule on EP for SMRs and ONTs.

CFR part 50 would also be included within this definition of NPUF. The term “non-power production or utilization facility” is used in this proposed rule to distinguish between those medical radioisotope facilities that would be licensed as production or utilization facilities under 10 CFR part 50 and other facilities to be used for the production of medical radioisotopes that would be 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 that would be licensed under 10 CFR parts 30, 40, or 70 would be covered by 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 proposed rule and associated draft guidance. As such, the scope of this proposed rule is limited to those ONT facilities (i.e., non-LWRs and medical radioisotope facilities) for which the NRC expects to receive license applications under 10 CFR part 50 or 10 CFR part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.” Therefore, those NPUFs that are not considered ONTs (i.e., currently operating non-power reactors) are not within the scope of this proposed rule. Currently operating non-power reactors will continue to implement existing emergency planning requirements and guidance.

In the staff requirements memorandum (SRM) to SECY-15-0077, “Options for Emergency Preparedness for Small Modular Reactors and Other New Technologies,” dated August 4, 2015 (ADAMS Accession No. ML15216A492), the Commission approved the staff’s recommendation to conduct rulemaking to address EP for SMRs and ONTs. In December 2016, the NRC developed and published “NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness” (ADAMS Accession No. ML16356A670), with a goal to further develop the NRC’s non-LWR regulatory, technical, and policy infrastructure in order to be ready to efficiently and effectively review potential licensing

applications for non-LWR technologies. This proposed rule contributes to the NRC's overall plan to optimize non-LWR regulatory readiness. In particular, the NRC's objective for this proposed rule is to create alternative EP requirements that would: 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 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 smaller sized reactors' and non-LWRs' potential benefits associated with postulated accidents, including slower transient response times, and relatively small and slow release of fission products.

A. Existing Emergency Preparedness Framework for Nuclear Power Reactors

Appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities," to 10 CFR part 50 identifies the specific items required to be included in emergency plans. Additionally, the regulation in § 50.47, "Emergency plans," 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."

Large LWRs use a variety of guidance documents in support of EP programs. The two most notable guidance documents for the development and maintenance of emergency plans are: NUREG-0654/FEMA-REP-1, Rev.1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants" (ADAMS Accession No. ML040420012), 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; and Regulatory Guide (RG) 1.219, Rev. 1, "Guidance on Making Changes to Emergency Plans for Nuclear Power Reactors" (ADAMS Accession No. ML16061A104), 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.

This regulatory framework has defined the EP programs for large LWRs for several decades. These standards have been effectively used in practice and provided a basis to draw from in developing the proposed EP regulatory framework for SMRs and ONTs.

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, EP 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 RTRs that reflected the lower potential radiological hazards associated with these facilities. While RTRs and other NPUFs must meet the emergency planning requirements of §§ 50.34(a)(10) and (b)(6)(v) and 50.54(q) and appendix E to 10 CFR part 50, the requirements of § 50.47 do not apply to these facilities. 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 other facilities, stating that the size of EPZs and the degree to which compliance with sections I through V of appendix E to 10 CFR part 50 is necessary will be 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,” will be used as guidance for the acceptability of RTR emergency response plans. Regulatory Guide 2.6 was initially issued in January 1979 (ADAMS Accession No. ML12184A008) 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 (ADAMS Accession No. ML17263A472). Consistent with the radiological risks associated with operating power levels between 5 watts thermal and 20 MWt for currently

operating RTRs, RG 2.6, Revision 2 endorses the use of the source term and power-level based emergency planning guidance 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” (ADAMS Accession No. ML062190191). 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 to 800 meters from the operations boundary³ 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. In addition to NUREG-0849 and ANSI/ANS-15.16, 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” (ADAMS Accession Nos. ML042430055 and ML042430048) and the Interim Staff Guidance augmenting NUREG-1537, Parts 1 and 2, for the licensing of radioisotope production facilities and aqueous homogeneous reactors (ADAMS Accession Nos. ML12156A069 and ML12156A075) provide additional emergency planning considerations for

³ 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.

NPUFs. For example, relevant radioisotope production facility emergency planning considerations (e.g., hazardous chemicals) contained in the Interim Staff Guidance augmenting NUREG-1537 are based on NUREG-1520, Revision 1, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility” (ADAMS Accession No. ML101390110).

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 a basis for developing the consequence-oriented approach to establishing EPZs and the planning commensurate with the radiological risk.

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 proposed rule.

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' rated thermal power could range 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" (ADAMS Accession No. ML13253A431) in June 1988 to provide guidance on developing new regulatory requirements to support advanced reactor designs. With the issuance of this initial guidance came questions concerning EP requirements for such designs.

In response, the NRC staff stated 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"⁴ (ADAMS Accession No. ML040210725), dated April 8, 1993, that no change to existing EP regulations for advanced reactors was currently 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 SRM (ADAMS Accession No. ML003760774) for SECY-93-092, dated July 30, 1993, that it was premature to reach a conclusion on EP for

⁴ "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.

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" (ADAMS Accession No. ML992920024), dated January 27, 1997, the NRC 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 (ADAMS Accession No. ML042590576), the NRC 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 (ADAMS Accession No. ML050550131) for SECY-04-0236, dated February 23, 2005. The Commission directed that:

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 (ADAMS Accession No. ML061910707), 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 (ADAMS Accession No. ML070080411) for SECY-06-0200, dated January 8, 2007, the Commission approved the NRC staff's recommendation for the development of a rulemaking plan and guidance changes to enhance EP regulations and guidance. The Commission also approved 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" (ADAMS Accession No. ML13238A018), dated April 4, 2014, the NRC 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 NRC staff asserted that the performance-based framework would simplify EP regulations and focus inspections more on response-related performance, the NRC 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 for implementing a performance-based framework and could introduce regulatory uncertainty. Additionally, the NRC 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 (ADAMS Accession No. ML14259A589) 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.

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 (ADAMS Accession No. ML093290268), the NRC 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. Additional information on these meetings can be found in the summaries for the October 8-9, 2009 and July 28, 2010 meetings (ADAMS Accession Nos. ML092940138 and ML102380209 respectively). 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 module, potentially forming the basis for smaller EPZs relative to large LWRs.

The NRC 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 (ADAMS Accession No. ML112570439). The paper informed the Commission of the NRC staff’s proposed actions to develop an emergency planning and preparedness framework for SMR facilities. In the document, the NRC staff stated its intent to develop a technology-neutral, dose-based, consequence-oriented EP framework for SMR sites that would take into account the various designs, modularity, and collocation of these facilities, 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 SMR-appropriate EPZs. 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 (ADAMS Accession No. ML13364A345), 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 has reviewed the White Paper and has discussed the development of the regulatory framework with NEI and stakeholders; however, the NRC has not endorsed the paper.

In the enclosure to SECY-10-0034, the NRC 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 NRC 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" (ADAMS Accession No. ML15037A176), dated May 29, 2015, the NRC 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 NRC 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 existing 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” (ADAMS Accession No. ML15194A276), 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 staff has considered NEI’s recommendations in the development of this proposed rule.

In addition to the NEI white papers, the NRC staff has had several interactions with the public concerning licensing issues related to SMRs and ONTs, including DOE-NRC Workshops on Advanced Non-Light-Water Reactors held on September 1-2, 2015 and June 7-8, 2016. The NRC staff 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 the summaries available at ADAMS Accession Nos. ML15265A165 and ML16188A226.

Rulemaking Activity

In response to SRM for SECY-15-0077, on May 31, 2016, the NRC staff submitted a rulemaking plan to the Commission (SECY-16-0069, “Rulemaking Plan on Emergency Preparedness for Small Modular Reactors and Other New Technologies” (ADAMS Accession No. ML16020A388)) 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

approved the staff's rulemaking plan in SRM-SECY-16-0069 (ADAMS Accession No. ML16174A166).

On August 22, 2016, the NRC staff held a Category 3 public meeting to request feedback from interested 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. Additional information about this public meeting is detailed in the meeting summary (ADAMS Accession No. ML16257A510). After considering the feedback received from the stakeholders in support of the performance-based approach to EP, the NRC staff 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. Additional information about this public meeting is detailed in the meeting summary (ADAMS Accession No. ML16257A510).

The NRC received 57 comment submissions on the draft regulatory basis and the associated regulatory analysis, which contained 223 individual comments related to EP. The commenters included individuals, environmental groups, industry groups, a Native American Tribal organization, 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 comment submissions and discussions from the public meeting as it finalized the regulatory basis. The NRC published a notice in the *Federal Register* announcing the public availability of the regulatory basis on November 15, 2017 (82 FR 52862).

III. Discussion

Objective and Applicability

The NRC's objective for this rulemaking is to create alternative EP requirements that would: 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 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 smaller sized reactors' and non-LWRs' potential benefits associated with postulated accidents, including slower transient response times, and relatively small and slow release of fission products. This proposed rule would apply to existing and future SMR and ONT facilities. These applicants and licensees would 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 proposed rule does not include within its scope emergency planning, preparation, and response for large LWRs, which for the purposes of this

proposed rule are those LWRs that are licensed to produce greater than 1,000 MWt power; fuel cycle facilities; or currently operating non-power reactors.

In SRM-SECY-15-0077, the Commission approved the staff's recommendation to conduct rulemaking for SMRs and ONTs, including non-LWRs and medical radioisotope facilities. 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 §§ 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. The Commission Policy Statement on the Regulation of Advanced Reactors (73 FR 60612) stated that the Commission "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 § 50.47(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 proposed 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 proposed rule would provide 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 proposed 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 proposed rule would define the different types of affected facilities. The NRC would amend § 50.2 to include the terms “small modular reactor,” “non-light-water reactor,” and “non-power production or utilization facility.” In developing the proposed definition for “small modular reactor,” the NRC referred to a variety of existing definitions and policy documents. The following discussion describes these sources of information in more detail.

In this proposed rule, the NRC has included a definition of “non-light-water reactor” to cover other new technologies, including liquid-metal-cooled reactors, gas-cooled reactors, and molten-salt-cooled reactors. Having a separate definition for these non-LWR technologies would clarify the applicability of the existing EP standards and requirements in 10 CFR part 50, which are specific to LWRs, and would maintain consistency between this proposed rule and the “Variable Annual Fee Structure for Small Modular Reactors” final rule (81 FR 32617; May 24, 2016) (referred to herein as the “SMR Fee Rule”).

The NRC has evaluated the suitability of using the existing definition of “small modular reactor” in § 171.5, “Definitions” for the purposes of this EP proposed 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 electrical or less per module. Although similar, this proposed 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, the NRC determined that using the thermal power equivalent of electric power generating capacity would be fair because SMRs should pay annual fees that are commensurate with the economic benefit received from their license (81 FR 32617, 32623). Because electrical generating power capacity is not a criterion the NRC uses to determine EP requirements, this proposed rule’s definition would focus on thermal power rating.

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 appropriate 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 for applicants, licensees, and the NRC stemming from the applicant- or licensee-specific nature of exemption requests.

This proposed rule would create a transparent alternative EP regulatory framework for SMR and ONT applicants and licensees that would continue to provide reasonable assurance that adequate protective measures can and will be implemented in a radiological emergency. The proposed alternative EP requirements would consider a wide-range of views and 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 proposed rule would also support the principles of good regulation, including openness, clarity, and reliability.

Proposed Changes

Technical Basis

The NRC is proposing 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 proposed rule, and the following discussion addresses the technical basis for each.

Performance-Based Approach

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 and supporting regulatory guidance 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 actions can and will be taken in a radiological emergency.

The NRC anticipates that existing and future SMR and ONT applications will reflect a wide range of potential designs and source terms. Because the technology for certain SMR and ONT designs is 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 proposed performance-based framework, inspection and enforcement program, and design-specific review process would provide reasonable assurance that protective actions 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. A graded approach to EP was also considered, which 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, are one 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 MW(t), 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.

Technology-Inclusive Approach

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 proposed 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 with, or nearby to, NRC-licensed or non-licensed facilities could lead to a variety of accident frequencies, progression times, and potential consequences for SMRs or ONTs. To incorporate recent and potential existing or future technology advancements and reduce the need for future EP rulemaking, the NRC is therefore proposing 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.

As described further in the “Performance-Based Framework” section of this document, the NRC’s proposed 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 proposed § 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 would 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.

Risk-Informed and Consequence-Oriented Approaches to Emergency Planning

The NRC is proposing a consequence-oriented approach to establish EP requirements for SMRs and ONTs. In this context, consequence-oriented means the principle of basing decisions of the extent of EP required upon the level and severity of the consequences of a

credible radiological accident. 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 actions. Emergency preparedness is risk-informed rather than risk-based, and therefore emergency planning is independent of accident probability.

The NRC has 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” (ADAMS Accession No. ML18012A019), dated May 22, 2018). This review identified that all of the existing types of NRC-licensed nuclear facilities use a consequence-oriented approach and take into account other considerations 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, EPA-400/R-17/001, was issued in January 2017. A similar consequence-oriented rationale also would be one option for establishing the EPZ for SMR or ONT designs.

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” (ADAMS Accession No. ML051390356), introduced the concept of generic EPZs as the basis for preplanned response actions. These 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 actions in the event of a reactor accident that would result in offsite dose consequences. Other considerations in the planning basis include the stipulation that no single specific accident sequence should be isolated as the

one for which to plan because each accident could have different consequences, both in nature and degree. Planning should 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 (dose, 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 for large LWR accident scenarios in planning 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 their operation involve considerations different than those associated with nuclear power reactors.

In this proposed rule, the NRC would establish a plume exposure pathway EPZ boundary that provides public protection from dose levels above a 10 millisieverts (mSv) [1 roentgen-equivalent man (rem)] total effective dose equivalent (TEDE) threshold. The

primary purpose of the plume exposure pathway EPZ is to provide an area where predetermined protective actions are implemented, which result in dose savings and a reduction in early health effects. In determining this boundary, the applicant would consider plume exposure doses from a spectrum of credible accidents for the facility. The NRC expects that areas outside of the site's proposed plume exposure pathway EPZ would not exceed the dose threshold of 10 mSv (1 rem) TEDE based on site-specific meteorology for a spectrum of credible accidents for the facility. The proposed rule would apply the same dose standard for predetermined protective actions to SMRs or ONTs as is required of the current operating large LWRs. By maintaining this consistency, the regulations described in proposed § 50.33(g)(2) would afford the same level of protection of the public health and safety as the current regulatory framework.

The principle of using dose savings 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).

With the expected safety enhancements in SMR designs and the potential for reduced accident source terms and fission product releases, the NRC is proposing that SMR applicants would develop reduced EPZ sizes commensurate with their accident source terms, fission product releases, and accident dose characteristics. Pre-application conversations between the NRC and SMR designers have indicated that SMRs also could have reduced offsite dose consequences in the unlikely event of an accident.

To support this proposed rule, the NRC conducted research about EPZ size determinations for SMRs and ONTs. Because of the uncertainty and potential variation in SMR or ONT designs, the NRC cannot conduct a comprehensive evaluation of source terms and spectra of accidents as part of this proposed rule. Instead, the research study, "Generalized

Dose Assessment Methodology for Informing Emergency Planning Zone Size Determinations” (ADAMS Accession No. ML18064A317), 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. That review, and a subsequent set of recommended analyses documented in “Required Analyses for Informing Emergency Planning Zone Size Determinations” (ADAMS Accession No. ML18114A176), dated June 2018, can be used in conjunction with the criterion that the EPZ should encompass an area such that public dose does not exceed 10 mSv (1 rem) TEDE over 96 hours from the release of radioactive materials resulting from a spectrum of credible accidents (design-basis accidents, less severe accidents, and less probable but more severe accidents) at the SMR or ONT facility. The information from these reports was used to develop the methodology described in Appendix A of DG-1350, “Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light Water Reactors, and Non-power Production or Utilization Facilities” (ADAMS Accession No. ML18082A044).

This proposed rule would require applicants to submit an analysis under proposed § 50.33(g)(2) to justify the technical basis for the proposed plume exposure pathway EPZ size. The NRC would then evaluate 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.

This proposed rule does not provide for a specific ingestion pathway planning zone. The NRC is proposing 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 onsite and offsite exposure pathways for ingestion of contaminated food and water. This proposed rule would require applicants and licensees who comply with § 50.160 to describe in their emergency plan the licensee, Federal, Tribal, State, and local resources for 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 would remain unchanged.

These emergency response capabilities are implemented either by the licensee within the site boundary or by Federal, Tribal, State, and local authorities in the intermediate or later-stage response to an accident involving the release of radioactive material. Although the sampling, assessing, and imposing of a quarantine or embargo are longer-term issues, some immediate, precautionary actions could be taken prior to a significant release occurring. For example, Tribal, State, and local authorities could instruct individual farmers to wash vegetables and fruits and to place livestock in fields, such as cows, goats, sheep, and so forth, on stored feed. Federal, Tribal, and State authorities frequently issue similar precautionary actions, or implement quarantines or embargos for non-radiological contamination of foods. Further, Federal resources are available upon request to Tribal, State, and local 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.

Performance-Based Framework

This proposed rule would create a new section, § 50.160, that would provide a performance-based EP framework for SMRs and ONTs, which would be an alternative to the current regulations. Under proposed § 50.54(q)(2)(ii), licensees would be required to follow and maintain an emergency plan that meets the requirements in either § 50.160 or appendix E to 10 CFR part 50 and, except for NPUF licensees, the planning standards of § 50.47(b). Proposed §§ 50.34 and 52.79, “Contents of applications; technical information in final safety analysis report,” would stipulate that SMR and ONT applicants would have the option to choose either approach. Proposed § 50.160 would include: 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 proposed provision applies, 3) requirements for considering credible hazards associated with contiguous or nearby NRC-licensed and non-licensed industrial facilities, 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 would be required under proposed § 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 would need to include a description of how the emergency response functions in proposed § 50.160(b)(1)(iii) and the planning activities in proposed § 50.160(b)(1)(iv), if applicable, would 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 (ROP)).⁵ Under the proposed performance-based approach to EP, performance and results are the primary basis for regulatory decision-making, 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 would focus on actual performance competencies, rather than control of emergency plans and procedures. Regulatory oversight would focus on performance, instead of processes and procedures. The performance-based regimen would provide 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 proposed § 50.160 address the most risk-significant aspects of EP (e.g., classification, notification, protective action recommendation,

⁵ For further information on the ROP, see: <https://www.nrc.gov/reactors/operating/oversight.html>.

mitigation), as well as several planning activities currently required under appendix E to 10 CFR part 50. Compliance under the proposed framework would be 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 the EPZ extends beyond the site boundary, would still make reasonable assurance determinations on emergency plans, but the determination would be based on demonstrations of required emergency response functions through drills and exercises and NRC inspections. Between drills and exercises, licensees would maintain a set of performance objectives to measure emergency response performance. See the "Reasonable Assurance" section of this document for a discussion of how the proposed approach would maintain reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

Application Process

Current applicants for a construction permit (CP), early site permit (ESP), operating license (OL), or combined license (COL) are required to provide emergency planning information as described under § 50.33, § 50.34, § 52.17, "Contents of applications; technical information," or § 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), applicants for ESPs 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, applicants also have the option of proposing major features of emergency plans (under § 52.17(b)(2)(i)) or complete and integrated emergency plans (under § 52.17(b)(2)(ii)) for 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

government agencies 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 would be given a choice between complying with either proposed § 50.160 or the requirements in appendix E to 10 CFR part 50 and, except for NPUF licensees, the planning standards in § 50.47, this proposed rule includes a number of conforming changes to clarify application requirements for applicants choosing the performance-based requirements.

- Construction permit and OL applicants would still need to include emergency planning information in their PSARs and FSARs, respectively, and proposed § 50.34(a)(10) and (b)(6)(v) would clarify that the information should describe how the applicant would comply with either appendix E to 10 CFR part 50 or proposed § 50.160.
- Combined license and ESP applicants would need to continue to include emergency planning information in their site safety analysis report and FSAR; proposed §§ 52.17(b)(2), 52.18, and 52.79(a)(21) would clarify that the information should describe how the applicant would comply with either the applicable requirements in § 50.47 and appendix E to 10 CFR part 50, or the proposed requirements in § 50.160.
- Applicants choosing to comply with proposed § 50.160 would need to describe how their emergency plans will meet the performance-based requirements in proposed § 50.160(b). A proposed revision to § 52.1, “Definitions,” would clarify 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 proposed § 50.160(b).

- Proposed § 50.33(g)(2)(i)(A) would clarify requirements to submit Tribal, State, and local 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, “Definitions”), the applicant must submit Tribal, State, and local emergency response plans.

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

Performance Objectives

Applicants and licensees adopting the performance-based regulations would need to 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 proposed § 50.160(b)(1)(iii). The NRC anticipates that performance objectives needed to demonstrate compliance with performance-based requirements would vary by design. Therefore, future additional guidance may be developed by the NRC or by the industry related to performance objectives for specific designs or classes of designs.

Proposed § 50.160(b)(1)(ii) would require applicants and licensees 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 would maintain records showing the implemented performance objectives and associated metrics during each calendar quarter for the previous eight calendar quarters. The NRC would monitor the performance objectives and metrics under the ROP to ensure that licensees are maintaining adequate emergency planning and preparedness. During evaluated exercises, the NRC would

assess the performance of the licensee and review the ability of the licensee to take corrective actions in a timely manner before performance decreases below performance objective thresholds. In addition, licensees would need to identify downward trends in the implementation of performance objectives or indications that a performance objective has crossed a threshold as part of their corrective action program required under § 50.160(b)(1)(iii)(H).

Drills and Exercises

A key feature of this proposed rule would be the use of drills and exercises to demonstrate that the applicant's and licensee's EP program is capable of carrying out an effective response in the event of emergency and accident conditions. Current regulations in appendix E to 10 CFR part 50, section IV.F and § 50.47(b)(14) include requirements for periodic drills and exercises for nuclear power reactor licensees. Proposed § 50.160(b)(1)(iii) would establish the emergency response functions to be demonstrated through drills and exercises. Unlike the existing drill and exercise requirements in appendix E to 10 CFR part 50, the proposed performance-based requirements would not define the required frequency of drills and exercises or their scenarios. However, the NRC anticipates that applicants and licensees would adopt an exercise cycle of eight years during which licensees would vary the content of exercise scenarios to provide ERO members the opportunity to demonstrate proficiency in the key skills necessary to respond to several specific scenario elements. Applicants and licensees would be required to describe exercise scenario elements necessary to demonstrate the emergency response functions in their emergency plans. Under proposed § 50.160(c), prior to operating the facility, the NRC also would require the applicant for an OL or a holder of a COL prior to the Commission's § 52.103(g) finding to conduct an initial exercise to demonstrate the effectiveness of the EP program no later than 18 months before the issuance of the OL for the applicant or 18 months before fuel loading for the COL holder.

For facilities with EPZs that do not extend beyond the site boundary, OROs would not be required to participate in radiological drills and exercises. Participation would not be required because Tribal, State, and local government organizations would not need to 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 Tribal, State, or local 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 proposed § 50.160(b)(1)(iii), the applicant’s or licensee’s emergency response team would need to have sufficient capability to demonstrate the following emergency response functions:

- Event classification and mitigation. The applicant or licensee would need to establish an emergency classification and action level scheme with established criteria for determining the need for notification of Tribal, State, and local agencies, and participation of those agencies 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 would 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. The requirements of this section are not meant to apply to severe accident management guidelines, extensive damage mitigation guidelines, or other non-emergency plan implementing procedures or programs.
- Protective actions. The drill and exercise program would need to demonstrate that consequences to onsite personnel could be reduced through the effective use of protective

actions. Applicants and licensees would need to demonstrate the ability to recommend protective actions to offsite authorities as conditions warrant.

- Communications. The drill and exercise program would need to demonstrate that control room staff are capable of making effective communications to the ERO, including emergency response personnel. 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 would need to notify and maintain communications with the fire brigade, rescue squad or medical dispatch, and law enforcement according to established agreements. As EP programs are developed, applicants and licensees would need to determine if notification to OROs is appropriate. If notification to OROs is necessary, then drills and exercises would need to demonstrate notifying the Tribal, State, and local officials of an emergency.

- Command and control. The drill or exercise would need to demonstrate continuity of operations through one or more shift changes of emergency response personnel, including the augmentation of the ERO. The applicant's or licensee's supporting organizational structure would need to have defined roles, responsibilities, and authorities, and the drill or exercise would need to show how key emergency response organization 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) would be maintained around the clock throughout the emergency.

- Staffing and operations. The drills or exercises would need to demonstrate effective emergency response with the level of staffing at the SMR or ONT as described in the emergency plan. There would need 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 proposed rule, drills and exercises would 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 would 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 proposed drills or exercises, control room staff, on-shift personnel, and the emergency response team would 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; use protective equipment; and demonstrate implementation of onsite protective actions.

- Reentry. Reentry is the temporary movement of people into an area of actual or potential hazard. The applicant or licensee also would need to demonstrate general plans for reentry after an emergency through drills or exercises. The applicant or licensee would need 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, including the outcomes of drills and exercises (or responses to actual emergencies), would be evaluated to identify areas for improvement in the EP program. The applicant or licensee would need to use a corrective action program to evaluate, track, and correct EP deficiencies. Deficiencies may include items such as errors in the emergency plan or implementing procedures, ERO weaknesses identified in drills or exercises, downward trends in the achievement of performance objectives or indications that a performance objective has crossed a threshold, or degraded conditions in emergency response facilities, systems, and equipment. Corrective actions may require a variety of actions, including remedial exercises to demonstrate that the deficiencies have been fully addressed.

Planning Activities

In addition to an applicant's or licensee's performance demonstrations through drills and exercises, the NRC is proposing 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 proposed rule includes two sets of planning activities: § 50.160(b)(1)(iv)(A) would establish planning activities for all applicants and licensees complying with § 50.160; and § 50.160(b)(1)(iv)(B) would establish planning activities that would 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 proposed § 50.160(b)(1)(iv)(A)(1), SMR and ONT applicants and licensees would be required to be capable of preparing and issuing information to the public during emergencies to protect public health and safety. The NRC is proposing 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. In proposed § 50.160(b)(1)(iv)(A)(3), the NRC would require applicants and licensees to have 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 would provide timely updates to the NRC on the implementation of the emergency plan during and after an emergency. Finally, proposed § 50.160(b)(1)(iv)(A)(4) would require applicants and licensees to have the capability to establish emergency response facilities to support the emergency response functions required in § 50.160(b). Applicants and licensees would 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 would need to include descriptions of the facilities' functional capabilities, activation times, staffing, and communication systems.

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 and, 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 proposed § 50.160 that establish a plume exposure pathway EPZ at the site boundary, the NRC would not mandate offsite radiological emergency planning activities. Proposed § 50.160(b)(1)(iv)(B) would establish 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 would include:

- Contacts/arrangements with governmental agencies. Applicants and licensees would need to describe in emergency plans their contacts and arrangements with OROs for offsite radiological emergency response, including the roles of each organization in the ERO. Applicants and licensees would need to ensure regular coordination with these organizations, including review of emergency plan changes.
- Notification of OROs. Applicants and licensees would need to establish primary and backup means of notifying OROs and a message authentication scheme. The emergency plan would need to include the proposed time period within which notifications to OROs would be made.
- Protective measures. Applicants and licensees would need to maintain the capability to issue offsite protective action recommendations to OROs (e.g., evacuation, sheltering). The emergency plan would need to describe the procedures by which protective measures are implemented, maintained, and discontinued in their emergency plans.
- Offsite agency training. Applicants and licensees would need to provide site familiarization training to individuals whose assistance may be needed in the event of a radiological emergency, including personnel from offsite organizations.
- Evacuation time estimate study. Applicants and licensees would need to conduct an evacuation time estimate (ETE) study and maintain the ETE up-to-date. The methodologies described in existing NRC published or endorsed guidance should be used to prepare the ETE.
- Emergency response facilities. Applicants and licensees would 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 would need to be capable of making offsite dose assessments and communicating their results to OROs. The emergency

plan would need to describe the methods and instruments available for conducting these assessments.

- Dissemination of public information. Applicants and licensees would 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 would need to describe the public alert and notification system.

- Reentry. Applicants and licensees would need to describe in their emergency plans coordination with OROs on offsite reentry plans including the conditions necessary to allow reentry. 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 would 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 would need to describe in their emergency plans how offsite radiological emergency response is incorporated into their drill and exercises. Drill and exercise scenarios would need to incorporate offsite response, and applicants and licensees would need to coordinate with offsite organizations, including FEMA, for their participation in drills and exercises and implementation of corrective actions.

- Emergency plan maintenance. Applicants and licensees would need to maintain up-to-date the emergency plan, contacts and arrangements with OROs, procedures, and ETEs. Emergency plans would need to include a description of the periodic coordination with OROs.

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 proposed rule, FEMA findings and determinations regarding reasonable assurance under proposed § 50.54(s)(3) would only be needed for a facility where the plume exposure pathway EPZ extends beyond the site boundary requiring dedicated offsite radiological EP plans for the facility.

The NRC's proposal not to require offsite planning activities for facilities with plume exposure pathway EPZs at the site boundary would 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 would 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 and local governments with technical advice related to the safety and security of any proposed SMR or ONT facility.

In cases where the 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. As provided for in the Tenth Amendment to the U.S. Constitution and State

constitutions and statutes, State and local governments are responsible for the overall protection of public health and safety in their localities when the Federal government does not have such authority. Each of the states has established an emergency management organization to facilitate the safeguarding of the life and property of its citizens.⁶ Based on the NRC's evaluation of a limited set of ORO capabilities in NUREG/CR-7248, "Capabilities and Practices of Offsite Response Organizations for Protective Actions in the Intermediate Phase of a Radiological Emergency Response" (ADAMS Accession No. ML18170A043), dated June 2018, the NRC has high confidence in the ability of OROs to implement appropriate response actions when necessary. The OROs' general emergency response capabilities are not unique to radiological emergency response. The NRC's confidence is further strengthened by the NRC's regulations in § 50.47(c)(1)(iii) and the NRC's recognition of national-level efforts (e.g., National Incident Management System,⁷ National Preparedness Goal,⁸ Core Capabilities,⁹ National Preparedness System,¹⁰ National Planning Frameworks¹¹), in which the NRC participates, to improve the state of emergency planning at all levels of government and within the whole community.¹² Consequently, for SMR and ONT facilities 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.

⁶ See FEMA's Emergency Management Agencies website <https://www.fema.gov/emergency-management-agencies>.

⁷ For further information on the National Incident Management System, see: <https://www.fema.gov/pdf/emergency/nims/nimsfaqs.pdf>.

⁸ For further information on the National Preparedness Goal, see: <https://www.fema.gov/national-preparedness-goal>.

⁹ For further information on Core Capabilities, see: <https://www.fema.gov/core-capabilities>.

¹⁰ For further information on the National Preparedness System, see: <https://www.fema.gov/national-preparedness-system>.

¹¹ For further information on the National Planning Frameworks, see: <https://www.fema.gov/national-planning-frameworks>.

¹² For more information on the definition of "whole community," see: <https://www.fema.gov/whole-community#>.

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 proposing 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 proposed § 50.160 or the approach to EP under appendix E to 10 CFR part 50. The NRC's proposal includes a number of conforming changes to § 50.54(q).

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

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

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 would not be applicable to applicants and licensees choosing to comply with § 50.160. Applicants and licensees choosing § 50.160 would be required to describe in their emergency plans the data links with the NRC for use in emergencies. Specific parameters to be reported would be determined for the specific technology during the license application process under 10 CFR part 50 or 10 CFR part 52. The NRC would review each applicant’s data transmission capabilities on a case-specific basis. The NRC is not proposing any changes to its ERDS regulations.

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 would require additional

EP considerations relative to an independently sited facility. For example, SMRs or ONTs may need to be prepared for events associated with other contiguous or nearby facilities' proximate 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 non-licensed facility. For example, a nuclear power facility could be sited contiguous or nearby to 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 or nearby to a non-licensed facility but, under each scenario, the hazards of the non-licensed facility must be factored into the EP program of the nuclear facility to ensure the protection of public health and safety, and the environment.

For SMR or ONT applicants and licensees located contiguous or nearby to another facility, proposed § 50.160(b)(2) would require 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 would need 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 would 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 would assess the combined radiological and industrial hazards at the site.

The NRC is issuing DG-1350 for public comment with this proposed rule that includes guidance on hazard analyses for contiguous or nearby facilities.

Emergency Planning Zones

The NRC is proposing a consequence-oriented, technology-inclusive approach to EPZ size determinations for SMRs and ONTs. This proposed 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. Pre-application 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) and 50-mile (80-km) EPZs 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 proposing an alternative scalable methodology for determining EPZ size on a case-specific basis. This methodology would be established in guidance (DG-1350) generically without design- or site-specific information regarding source term, fission products, or projected offsite dose. Applicants would 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. The NRC is proposing an EPZ size determination process that is consistent with this philosophy. Proposed § 50.33(g)(2) would establish an EPZ size determination process 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 would be required to submit the analysis used to establish their proposed plume exposure pathway EPZ size. Applicants would 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 resulting from a spectrum of credible accidents for the facility. 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 proposed § 50.33(g)(2) would require 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. Proposed § 50.160(b)(3) would require applicants and licensees to incorporate the boundaries and physical descriptions of the EPZ into their emergency plans.

To support the technical basis for this proposed rule, the NRC conducted research studies (ADAMS Accession Nos. ML18064A317 and ML18114A176), dated June 2018 to support EPZ size determinations for SMRs and ONTs. Supported by the results of these studies, the NRC is including guidance in Appendix A to DG-1350 for determining the EPZ size based on the NRC staff’s evaluation of a spectrum of accidents and the criterion in proposed

§ 50.33(g)(2) that the plume exposure pathway EPZ should be established as the area in which public dose is projected to exceed 10 mSV (1 rem) TEDE over 96 hours from the release of a spectrum of credible accidents for the facility. In the DG, the NRC is providing general guidance and anticipates that industry will develop and implement detailed design-specific calculations for NRC review and approval. The NRC's guidance is not a regulatory requirement and applicants and licensees may use alternative approaches to meeting regulatory requirements as long as appropriately supported and justified.

Upon receiving an OL, COL, ESP, or CP applicant's technical basis for proposed site-specific plume exposure pathway EPZ size, the NRC would review the design and licensing information to ensure that the information that the applicants provide 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 and the environment. 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 would consider an appropriate spectrum of accidents to provide a basis for judging the adequacy of features such as functional containment design and the need for offsite emergency planning. The NRC also would assess the need to provide site-specific guidance concerning the accident scenarios being considered.

In addition to the proposed plume exposure pathway EPZ size determination process, the NRC is proposing to include ingestion response planning requirements under proposed § 50.160(b)(4). Applicants and licensees complying with proposed § 50.160 would be required to describe in their emergency plans the capabilities to protect contaminated food and water from entering the ingestion pathway. The capabilities described in the emergency plan would 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 hours 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 would reference capabilities of Federal, Tribal, State, and local Federal authorities.

Three notable incidents documented by the Center for Disease Control and Prevention that demonstrate the capability to conduct large-scale quarantines are 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 planning zone.

Implementation

The NRC is proposing implementation schedules for existing and future applicants and licensees of facilities choosing to comply with proposed § 50.160. Per the requirements of proposed § 50.160(c)(1), an applicant for an operating license issued under 10 CFR part 50 after the effective date of this proposed rule desiring to comply with the performance-based approach to EP and within the scope of that approach as stated in this proposed rule would be required to establish, implement, and maintain an EP program that meets the requirements of proposed § 50.160(b) and conduct an initial exercise to demonstrate this compliance no later than 18 months before the issuance of an operating license for the first unit described in the license application. Per the requirements of § 50.160(c)(2), a holder of a combined license 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) would be required to establish, implement, and maintain an emergency preparedness program that meets the requirements of proposed § 50.160(b), as described in the emergency plan and license, and conduct an initial

exercise to demonstrate this compliance no later than 18 months before the scheduled date for initial loading of fuel.

As discussed in the “Changes to Emergency Plans” section of this document, for existing or future SMRs or ONTs that hold operating or combined licenses, proposed § 50.54(q)(7) would stipulate 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 proposed changes.

Reasonable Assurance

The NRC’s authority to regulate the use of radioactive materials is set forth in the AEA and Title II of the Energy Reorganization Act of 1974, as amended (ERA). Both the AEA and ERA confer broad regulatory powers to the Commission and specifically authorize it to issue regulations it deems necessary to fulfill its responsibilities under those statutes. 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 will make licensing decisions or take 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 will base 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 Tribal, State, and local emergency plans are adequate and whether there is reasonable assurance that they can be implemented.

The proposed performance-based approach to EP under § 50.160 would provide for an adequate basis for an acceptable state of EP and ensure that coordination and applicable arrangements with offsite agencies are maintained (e.g., notification and assistance resources). Reasonable assurance will be maintained under the proposed 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 proposed 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 or non-licensed facilities; and 6) the NRC's inspection and enforcement program. Proposed § 50.160(b) would state that the NRC would not issue an initial operating license to a licensee complying with proposed § 50.160 unless a reasonable assurance finding is made.

For applicants and licensees with plume exposure pathway EPZs beyond the site boundary, the NRC, in consultation with FEMA, would continue to make a determination of reasonable assurance 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, the NRC is proposing that FEMA findings and determinations regarding reasonable assurance under § 50.54(s)(3) would not be needed for SMRs or ONTs with plume exposure pathway EPZs that do not extend beyond the site boundary. The NRC would continue to make 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.

Administrative and Clarifying Changes to the Regulations

The NRC is proposing clarifying changes to the following paragraphs.

1. Section 50.54(q)(4), which required after February 21, 2012, any changes to 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 proposing to delete "after February 21, 2012" and retain 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 proposing to delete "after February 21, 2012" from this provision, as the date has expired, and retain 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 proposing to delete "after April 1, 1981" and retain the remainder of the provision.

The NRC is proposing to revise these paragraphs in the interest of regulatory clarity. Eliminating these requirements would not relax currently effective regulatory requirements or cause any regulatory burden for existing or future licensees.

IV. Specific Requests for Comments

The NRC is seeking public comment on this proposed rule. The NRC staff is particularly interested in comments and supporting rationale from the public on the following:

- Terminology used to describe the requirements: This proposed rule continues the practice from SECY-11-0152, “Development of an Emergency Planning and Preparedness Framework for Small Modular Reactors,” of describing the alternative framework for EP as “technology-neutral, dose-based, and consequence-oriented.” The NRC recognizes, however, that the overarching term “risk-informed” as defined by the Commission in “STAFF REQUIREMENTS - SECY-98-144 - White Paper on Risk-Informed and Performance-Based Regulation” (ADAMS Accession No. ML003753601), includes consideration of both the likelihood of a spectrum of events and their consequences. In the context of EP, the consequences of concern would be dose. The NRC is therefore considering aligning the discussion of the EP framework in this rule with its other risk-informed, performance-based regulations and considering eliminating the use of the descriptors “dose-based” and “consequence-oriented,” but intends no change to the meaning of the proposed regulations. Would such a change impact the clarity and predictability of the regulations?

- Scope of this proposed rule: This proposed rule would allow SMRs and ONTs to establish an alternative performance-based, consequence-oriented approach to EP. The NRC received a comment on its draft regulatory basis in 2017 that recommended that the NRC expand the scope of this proposed rule to include large LWRs. Large LWRs were not included by the NRC in the scope of this proposed rule because an EP licensing framework already exists for those reactors, and licensees for those plants have not presented a clear interest in changing that framework. Nonetheless, in light of the public comment on the draft regulatory basis, and although this proposed rule is written for SMRs and ONTs, the NRC is open to

considering a performance-based, consequence-oriented approach to EP for large LWRs, fuel cycle facilities, and currently operating NPUFs.

Are the proposed “non-light-water reactor,” “non-power production or utilization facility,” and “small modular reactor” definitions in § 50.2 sufficient to address EP for existing and anticipated technologies? Are there any unintended consequences of including each of these classes of facilities within the scope of this proposed rule? Please provide the basis for your response.

Should the NRC consider a performance-based, consequence-oriented approach to EP for entities besides SMRs and ONTs (e.g., large LWRs, fuel cycle facilities, and currently operating NPUFs) in a future rulemaking? Please provide a basis for your response.

If the NRC considers a performance-based, consequence-oriented approach to EP for entities other than SMRs and ONTs, what criteria should such entities be required to meet to use a performance-based, consequence-oriented approach to EP in a future rulemaking? Please provide a basis for your response.

If the NRC does not consider a performance-based, consequence-oriented approach to EP for entities other than SMRs and ONTs, should the NRC offer mechanisms (other than the existing exemption process) that would allow other entities to request NRC approval to use the EP framework proposed in this rulemaking? If so, what mechanisms? Please provide a basis for your response.

- Performance-based requirements: Under this proposed rule, applicants and licensees choosing to comply with the performance-based approach would need to demonstrate emergency response functions required under § 50.160(b)(1)(iii) through the use of drills or exercises and performance objectives. Are there additional emergency response functions that the NRC should consider for incorporation in this proposed rulemaking? Please provide the basis for your answer.

- Drills or exercises: Under proposed § 50.160(b)(1), applicants and licensees would need to develop a drill and exercise program to demonstrate compliance with performance-based requirements. Would an 8-year exercise cycle (as is currently required for large LWRs) be appropriate for SMRs or ONTs choosing to comply with the performance-based approach? If not, would an alternative cycle length be appropriate? Please provide the basis for your answer.

- Planning activities: The NRC is proposing four planning activities under § 50.160(b)(1)(iv)(A) that all applicants and licensees choosing the performance-based approach to EP would need to comply with and 11 offsite planning activities under § 50.160(b)(1)(iv)(B) that are designed for applicants and licensees with an EPZ that extends beyond the site boundary. These planning activities identify certain EP-related activities that are not readily observable and cannot be effectively measured through drills and exercises. Are there any planning activities that should be added to or removed from the NRC's proposed list? Please provide the basis for your answer.

- Hazard analysis for contiguous or nearby facilities: The NRC is proposing to require applicants and licensees choosing a performance-based approach to EP to submit a hazard analysis under § 50.160(b)(2). To what extent should this analysis be harmonized with or rely upon the analysis conducted under 10 CFR 100.20, "Factors to be considered when evaluating sites," for man-related hazards? What kinds of facilities might be located contiguous or nearby to SMRs or ONTs? Should the NRC change the scope of the hazard analysis? If so, how should the scope of the hazard analysis change? Please provide the basis for your answer.

- Emergency planning zones: The NRC is proposing to require applicants and licensees choosing to comply with proposed § 50.160 to submit the analysis used to establish a site-specific plume exposure pathway EPZ size. The analysis for the proposed EPZ size would be reviewed on a case-specific basis by the NRC to ensure that design- and site-specific

accident scenarios are appropriately incorporated and that reasonable assurance is maintained with the proposed EPZ size. Applicants and licensees would need to establish their plume exposure pathway EPZ as the area within which public dose is projected to exceed 10 mSv (1 rem) TEDE over 96 hours from the release of radioactive materials resulting from a spectrum of credible accidents for the facility. Is the proposed 10 mSv (1 rem) criterion appropriate? Are there particular factors and technical considerations that need to be included in an EPZ size analysis? If the analysis demonstrates that the EPZ is within the facility's site boundary, would the need for a dedicated, Federal-mandated offsite radiological emergency preparedness program exist? If the applicant or licensee provides an adequate description of the existing Federal, Tribal, State, and local Federal capabilities to interdict contaminated food and water, would the need for an IPZ exist? Please provide the basis for your answer.

- Costs: The NRC recognizes that all power reactor applicants will develop a PRA to meet existing requirements and support development of their application. The NRC would allow applicants the option to further the use of PRA to support a risk-informed approach for the development of source terms. The NRC is seeking information on the incremental cost estimates for any additional PRA modeling necessary to generate the credible accident sequences and the development of the source terms used in determining a site-specific EPZ size.

V. Section-by-Section Analysis

The following paragraphs describe the specific changes proposed by this proposed rule.

Section 50.2 Definitions.

In § 50.2, this proposed rule would add 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 proposed rule would add 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 proposed rule would revise 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 construction permit or limited work authorization is necessary to commence construction.

Section 50.33 Contents of applications; general information.

In § 50.33, this proposed rule would revise paragraph (g) to create new subparagraphs (g)(1) and (2). Paragraph (g)(1) would contain the original text of paragraph (g) and would add the qualifier “except as provided in paragraph (g)(2) of this section.”

Paragraph (g)(2) would establish an EPZ size determination process for SMR, non-LWR, and NPUF applicants complying with § 50.160.

Section 50.34 Contents of applications; technical information.

In § 50.34, this proposed rule would revise paragraph (a)(10) to require SMR, non-LWR, or NPUF construction permit 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 proposed rule also would revise paragraph (b)(6)(v) to require SMR, non-LWR, and NPUF applicants for an operating license 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 proposed rule would make conforming changes to paragraph (b) and add new paragraph (f) denoting when the offsite emergency response plan requirements in paragraph (b) of this section do not apply.

Section 50.54 Conditions of licenses.

In § 50.54, this proposed rule would revise paragraph (q)(1)(iii) to remove the reference to appendix E to 10 CFR part 50 and § 50.47(b).

It would revise paragraph (q)(2) to include new subparagraphs (i) and (ii). Paragraph (i) would contain the original text of paragraph (q)(2) and would add the qualifier “except as provided in paragraph (q)(2)(ii) of this section, and paragraph (ii) would allow 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, except for NPUF licensees, § 50.47(b).

It also would revise paragraph (q)(3) to include new subparagraphs (i) and (ii). Paragraph (i) would contain the original text of paragraph (q)(3) and would add the qualifier “except as provided in paragraph (q)(3)(ii) of this section” and paragraph (ii) would specify 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.

Paragraph (q)(4) and (5) would be revised to remove the date February 21, 2012, and paragraph (q)(4) would be 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, would need to specify the basis for concluding how their revised emergency plans continue to meet the requirements of that section.

This proposed rule would add new paragraph (q)(7) that would contain the details for submitting license amendment requests for SMR, non-LWR, or NPUF licensees implementing

emergency preparedness programs with the associated plan modifications necessary to meet the requirements of new § 50.160.

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

This proposed rule would revise 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 would base its findings on a review of FEMA’s findings and determinations.

This proposed rule would also revise paragraph (gg)(1) 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 proposed rule would add new subpart, “Small Modular Reactors, Non-Light-Water Reactors, and Non-power Production or Utilization Facilities,” and new § 50.160, which would contain alternative EP requirements for SMRs, non-LWRs, and NPUFs.

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

In appendix E to part 50, this proposed rule would 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.

Section 52.1 Definitions.

In § 52.1, this proposed rule would revise the definition of *Major feature of the emergency plans* to include new § 50.160, as applicable.

Section 52.17 Contents of applications; technical information.

In § 52.17, this proposed rule would revise paragraph (b)(2) to include new § 50.160, as applicable.

Section 52.18 Standards for review of applications.

This proposed rule would revise § 52.18 to include new § 50.160, as applicable.

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

In § 52.79, this proposed rule would revise paragraph (a)(21) to require applicants for SMRs or non-LWRs to comply with either § 50.160 or § 50.47 and appendix E to 10 CFR part 50.

VI. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule, if adopted, will not have a significant economic impact on a substantial number of small entities. This proposed 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 (10 CFR 2.810).

VII. Regulatory Analysis

The NRC has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The

conclusion from the analysis is that this proposed rule and associated guidance would result in net savings to the industry and the NRC of \$5.89 million using a 7-percent discount rate and \$9.71 million using a 3-percent discount rate. The NRC requests public comment on the draft regulatory analysis. The draft regulatory analysis is available as indicated in the “Availability of Documents” section of this document. Comments on the draft regulatory analysis may be submitted to the NRC as indicated under the ADDRESSES caption of this document.

VIII. Backfitting and Issue Finality

This proposed rule and implementing guidance would not be subject to the NRC’s backfitting regulation at § 50.109, “Backfitting,” or issue finality regulations in 10 CFR part 52. This proposed rule would contain new alternative requirements for SMR and ONT applicants and licensees. Because these alternative requirements would not be imposed upon applicants and licensees and would not prohibit applicants and licensees from following existing requirements, the proposed requirements would not constitute backfitting or a violation of issue finality.

As described in section XV, “Availability of Guidance,” in this document, the NRC is issuing a draft regulatory guide (DG) that, if finalized, would provide guidance on the methods acceptable to the NRC for complying with aspects of this proposed rule. Issuance of the DG in final form would not constitute backfitting under § 50.109 and would not otherwise violate issue finality under 10 CFR part 52. As discussed in the “Implementation” section of the DG, the NRC has no current intention to impose the DG on holders of an operating license or COL.

Furthermore, in general, the backfitting provisions under 10 CFR part 50 and the issue finality provisions under 10 CFR part 52 do not apply to current or future applicants because neither the backfitting nor issue finality provisions were intended to apply to every NRC action that substantially changes the expectations of current and future applicants. Applicants have no

reasonable expectation that future requirements will not change (“Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants; Final Rule,” 54 FR 15372, at 15385-15386; April 18, 1989).

The exceptions to this general principle include a 10 CFR part 50 power reactor operating license applicant that references an NRC-issued construction permit, limited work authorization, or design certification rule with issue finality, or a 10 CFR part 52 applicant that references a 10 CFR part 52 license (e.g., an ESP), an NRC regulatory approval (e.g., a design certification rule), or both, with specified issue finality provisions. The NRC does not currently intend to impose the positions represented in the DG in a manner that would constitute backfitting or would be inconsistent with any issue finality provision of 10 CFR part 52. If, in the future, the NRC seeks to impose positions stated in the DG in a manner that would constitute backfitting or be inconsistent with an issue finality provision, 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

The NRC is following its CER process by engaging with external stakeholders throughout this proposed rule and related regulatory activities. Public involvement has included: (1) a public meeting held on August 22, 2016, to request feedback from interested stakeholders on a potential performance-based approach for EP for SMRs and ONTs; (2) the publication of the draft regulatory basis for public comment (82 FR 17768) on March 15, 2017; (3) a public meeting held on May 10, 2017, to facilitate public comments on the development of the final regulatory basis; (4) a public meeting held on June 14, 2018 to discuss initiatives within the industry and NRC related to the development and licensing of non-LWRs, including the status of

the proposed rule; and (5) an Advisory Committee on Reactor Safeguards Subcommittee meeting held on August 22, 2018 to discuss the proposed rule.

Another opportunity for public comment is provided to the public at this proposed rule stage. The NRC will be issuing the draft implementing guidance also for comment, along with this proposed rule to support more informed external stakeholder feedback. Further, the NRC will continue to hold public meetings throughout the rulemaking process. Section XV, "Availability of Guidance," of this document describes how the public can access the draft implementing guidance for which the NRC seeks external stakeholder feedback.

In addition to the questions on the implementation of this proposed rule presented in the "Specific Requests for Comments" section of this document, the NRC is requesting CER feedback on the following questions:

1. In light of any current or projected CER challenges, does this proposed rule's effective date provide sufficient time to implement the new alternative proposed requirements, including changes to programs, procedures, and facilities?
2. If CER challenges currently exist or are expected, what should be done to address them? For example, if more time is required for implementation of the new alternative requirements, what period of time is sufficient?
3. Do other (NRC or other agency) regulatory actions (e.g., orders, generic communications, license amendment requests, inspection findings of a generic nature) influence the implementation of this proposed rule's requirements?
4. Are there unintended consequences? Does this proposed rule create conditions that would be contrary to this proposed rule's purpose and objectives? If so, what are the unintended consequences, and how should they be addressed?
5. Please comment on the NRC's cost and benefit estimates in the draft regulatory analysis that supports this proposed rule. The draft regulatory analysis is available as indicated under the "Availability of Documents" section of this document.

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 31883). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

XI. Environmental Assessment and Proposed Finding of No Significant Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in subpart A of 10 CFR part 51, that this proposed rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and an environmental impact statement is not required. The following sets forth the basis of this determination. This majority of the provisions in the proposed rule are administrative or procedural in nature and either would not affect the physical environment at all or would have no noticeable effects. Further, the NRC has evaluated proposed 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 proposed § 50.33(g) and the ingestion response planning requirements under § 50.160(b)(4), and determined that this proposed rule would not have a significant environmental impact for the following reasons. Under the existing EP requirements and these proposed alternative EP requirements, the dose criteria under which predetermined protective actions would be taken (e.g., evacuation, sheltering) would be similar under both

rules, and therefore, the dose consequence to the public would be similar. The proposed ingestion response planning requirements under proposed § 50.160(b)(4), while not requiring SMR and ONT applicants and licensees to establish an IPZ, would 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 proposed ingestion response planning requirements are similar to that of the existing EP requirements. For these reasons, the NRC concludes that the proposed EPZ requirement under § 50.33(g) and ingestion response planning requirement under § 50.160(b)(4) would 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.

Public stakeholders should note, however, that comments on any aspect of this environmental assessment may be submitted to the NRC as indicated under the ADDRESSES caption. The environmental assessment is available as indicated under the “Availability of Documents” section of this document.

The NRC has sent a copy of the environmental assessment and this proposed rule to each of the FEMA, EPA, Tribal Representatives, and State Liaison Officers, and has requested comment.

XII. Paperwork Reduction Act

This proposed rule contains new and amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This proposed rule has been submitted to the Office of Management and Budget (OMB) for review and approval of the information collections.

Type of submission, new or revision: Revision

The title of the information collection: 10 CFR parts 50 and 52, Emergency Preparedness for Small Modular Reactors and Other New Technologies: Proposed Rule

The form number if applicable: Not Applicable

How often the collection is required or requested: Emergency plans are submitted once at time of application. Once an EP program is implemented, EP records are updated quarterly and reports are submitted every eight years for drills and exercises. Records of the approved EP program, and any changes, are kept for the life of the license. Quarterly records of the EP performance objectives and metrics are kept for eight quarters.

Who will be required or asked to respond: SMR, non-LWR, and NPUF applicants and licensees.

An estimate of the number of annual responses: Part 50: decrease of 1 reporting response (the current number of recordkeepers remains the same does not change under the proposed rule). Part 52: the number of reporting responses remains the same (recordkeepers are captured under part 50).

The estimated number of annual respondents: Reporting: Part 50 = one respondent; Part 52 = one respondent. Three recordkeepers will maintain records under the current and proposed rule.

An estimate of the total number of hours needed annually to comply with the information collection requirement or request: Part 50: reduction of 2,407 hours (1,333 reporting + 1,074 recordkeeping). Part 52: reduction of 740 reporting hours

Abstract: The proposed rule would provide SMR, non-LWR, and NPUF applicants or licensees that are regulated by 10 CFR part 50 or 10 CFR part 52, the alternative to submit for NRC approval a performance-based EP program to include a scalable EPZ and licensee-defined performance objectives and metrics data. If the EP program is approved by the NRC, the proposed rule would require the applicants or licensees to develop and maintain at the beginning of each calendar quarter a list of performance objectives for that calendar quarter. Each licensee would also maintain records showing the implemented performance objectives and associated metrics during each calendar quarter for the previous eight calendar quarters. The reports and recordkeeping requirements allow the NRC to evaluate the adequacy of the proposed EP program for approval and to assess the ongoing adequacy once implemented. The recordkeeping requirements allow the NRC to determine whether to take actions, such as to conduct inspections or to alert other licensees to prevent similar events that may have generic implications. The information is also used to update information in the NRC Emergency Operations Center used in support of an NRC response to an actual emergency, drill, or exercise.

The proposed rule would allow applicants and licensees to reduce their emergency plan information collection requirements compared to the current framework based on the potential for smaller EPZs and the reduction in license amendments and exemptions. The submission of emergency plans to the NRC is required in order to allow the NRC to determine that the emergency plans and EP continue to provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

The NRC is seeking public comment on the potential impact of the information collection(s) contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of the burden of the proposed information collection accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the proposed information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the OMB clearance package is available in ADAMS under Accession No. ML18134A086. You may obtain information and comment submissions related to the OMB clearance package by searching on <https://www.regulations.gov> under Docket ID NRC-2015-0225.

You may submit comments on any aspect of these proposed information collection(s), including suggestions for reducing the burden and on the above issues, by the following methods:

- **Federal Rulemaking Web Site:** Go to <https://www.regulations.gov> and search for Docket ID NRC-2015-0225.

- **Mail comments to:** Information Services Branch: T6-A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to Infocollects.Resource@nrc.gov.

- **Submit to OMB Directly:** Written comments and recommendations for the proposed information collection should be sent within 60 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. You may find this particular information collection by selecting "Currently Under Review - Open for Public Comments" or by using the search function. Comments on the information collections will be publicly available in ADAMS and on Reginfo.gov.

Submit comments by July 27, 2020. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

Public Protection Notification

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

XIII. Criminal Penalties

For the purposes of Section 223 of the AEA, the NRC is issuing this proposed rule that would amend or create §§ 50.2, 50.8, 50.10, 50.33, 50.34, 50.47, 50.54, 50.160, 52.1, 52.17, 52.18, 52.79, 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 parts 50 and 52 are discussed in §§ 50.111 and 52.303.

XIV. 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. The NRC did not endorse any consensus standards for use in this proposed rule. In this proposed rule, the NRC will revise regulations associated with

emergency preparedness in 10 CFR parts 50 and 52. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XV. Availability of Guidance

The NRC is issuing for comment new draft guidance, DG-1350, "Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-power Production or Utilization Facilities," that will support implementation of the requirements in this proposed rule. The guidance is available in ADAMS under Accession No. ML18082A044. You may obtain information and comment submissions related to the draft 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 the regulations. As a guidance document, DG-1350 does not establish additional requirements, and applicants and licensees are able to propose alternative ways for demonstrating compliance with the requirements in proposed § 50.160.

You may submit comments on this draft regulatory guidance by the methods provided in the ADDRESSES section of this document.

XVI. Public Meeting

The NRC will conduct a public meeting to explain the changes in this proposed rule and to answer questions from the attendees to facilitate the development of public comments.

The NRC will publish a notice of the location, time, and agenda of the meeting on <http://www.regulations.gov> and on the NRC's public meeting Web site within at least 10 calendar days before the meeting. Stakeholders should monitor the NRC's public meeting Web

site for information about the public meeting at: <https://www.nrc.gov/public-involve/public-meetings/index.cfm>.

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
Draft Regulatory Analysis, "Emergency Preparedness for Small Modular Reactors and Other New Technologies Proposed Rule — Draft Regulatory Analysis."	ML18134A077
Draft Environmental Assessment, "Emergency Preparedness for Small Modular Reactors and Other New Technologies."	ML18134A079
Draft Information Collection Clearance Package	ML18184A308 ML18184A309
Draft Regulatory Guide DG-1350, "Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-power Production or Utilization Facilities."	ML18082A044
NUREG-0396, "Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light-water Nuclear Power Plans," December 1978.	ML051390356
NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors," October 1983.	ML062190191
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

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
NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Revision 1, May 1, 2010.	ML101390110
NUREG-1226, "Development and Utilization of the NRC Policy Statement on the Regulation of Advanced Nuclear Power Plants," June 1988.	ML13253A431
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
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
SECY-97-020, "Results of Evaluation of Emergency Planning for Evolutionary and Advanced Reactors," January 27, 1997.	ML992920024
SECY-04-0236, "Southern Nuclear Operation Company's Proposal to Establish a Common Emergency Operating Facility at its Corporate Headquarters," December 23, 2004.	ML042590576
SECY-06-0200, "Results of the Review of Emergency Preparedness Regulations and Guidance," September 20, 2006.	ML061910707
SECY-10-0034, "Potential Policy, Licensing, and Key Technical Issues for Small Modular Reactor Designs," March 28, 2010.	ML093290268
SECY-11-0152, "Development of an Emergency Planning and Preparedness Framework for Small Module Reactors," October 28, 2011.	ML112570439

SECY-14-0066, "Request by Dominion Energy Kewaunee Inc., for Exemptions from Certain Emergency Planning Requirements," June 27, 2014.	ML14072A257
SECY-14-0118, "Request by Duke Energy Florida, Inc., for Exemptions from Certain Emergency Planning Requirements," October 29, 2014.	ML14219A444
SECY-14-0038, "Performance-Based Framework for Nuclear Power Plant Emergency Preparedness Oversight," April 4, 2014.	ML13238A018
SECY-15-0077, "Options for Emergency Preparedness for Small Module Reactors and Other New Technologies," May 29, 2015.	ML15037A176
SECY-16-0069, "Rulemaking Plan on Emergency Preparedness for Small Module Reactors and Other New Technologies," May 31, 2016.	ML16020A388
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
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
SRM-SECY-06-0200, "Staff Requirements—Results of the Review of Emergency Preparedness Regulations and Guidance," January 8, 2007.	ML070080411
SRM-SECY-14-0038, "Staff Requirements—SECY-14-0038—Performance-Based Framework for Nuclear Power Plant Emergency Preparedness Oversight," September 16, 2014.	ML14259A589
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
SRM-SECY-16-0069, "Staff Requirements—Rulemaking Plan on Emergency Preparedness for Small Module Reactors and Other New Technologies," June 22, 2016.	ML16174A166
"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.	ML15333A371

“Emergency Planning and Preparedness,” Final Rule, July 13, 1982.	47 FR 30232
“NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light-Water Reactor Mission Readiness,” December 2016.	ML16356A670
“Enhancements to Emergency Preparedness Regulations,” Final Rule, November 23, 2011.	76 FR 72559
Regulatory Basis for Regulatory Improvements for Power Reactors Transitioning to Decommissioning Rulemaking, 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
Regulatory Guide (RG) 2.6, “Emergency Planning for Research Reactors,” January 1979.	ML12184A008
RG 2.6, “Emergency Planning for Research and Test Reactors and Other Non-power Production and Utilization Facilities,” September 2017.	ML17263A472
“Specific Exemptions; Clarification of Standards,” December 12, 1985.	50 FR 50764
“Regulation of Advanced Nuclear Power Plants, Statement of Policy,” July 8, 1986.	51 FR 24643
“Policy Statement on Regulation of Advanced Reactors,” October 14, 2008.	73 FR 60612
EP for Small Modular Reactors and Other New Technologies, Draft Regulatory Basis, April 13, 2017.	82 FR 17768
EP for Small Modular Reactors and Other New Technologies, Regulatory Basis, November 15, 2017.	82 FR 52862
Variable Annual Fee Structure for Small Modular Reactors, Proposed Rule, November 4, 2015.	80 FR 68268
Variable Annual Fee Structure for Small Modular Reactors, Final Rule, May 24, 2016.	81 FR 32617
NEI White Paper, “White Paper: Proposed Methodology and Criteria Establishing the Technical Basis for Small Modular Reactor Emergency Planning Zone,” 2013.	ML13364A345
NEI White Paper “Proposed Emergency Preparedness Regulations and Guidance for Small Modular Reactors Facilities,” July 2015.	ML15194A276
“Summary of September 1-2, 2015, Nuclear Regulatory Commission and Department of Energy Co-Hosted Workshop on Advanced Non-Light-Water Reactors,” October 15, 2015.	ML15265A165

“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
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
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
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
NEI 99-02, “Regulatory Assessment Performance Indicator Guideline,” Revision 7, August 13, 2013.	ML13261A116
FEMA-NC MOU re: Radiological Emergency Response, Planning, and Preparedness, dated December 7, 2015.	ML15344A371
“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
Homeland Security Presidential Directive 5, “Management of Domestic Incidents,” February 28, 2003.	https://www.dhs.gov/publication/homeland-security-presidential-directive-5
Presidential Policy Directive (PPD)-8, “National Preparedness,” March 30, 2011.	https://www.dhs.gov/presidential-policy-directive-8-national-preparedness
Nuclear Innovation Alliance “Enabling Nuclear Innovation: Strategies for Advanced Reactor Licensing,” June 7, 2016.	https://docs.wixstatic.com/ugd/5b05b3_71d4011545234838aa27005ab7d757f1.pdf
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.	http://www.ans.org/store/item-240305/
“Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants, Final Rule,” April 18, 1989.	54 FR 15372
“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

“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
NUREG/CR-7248, “Capabilities and Practices of Offsite Response Organizations for Protective Actions in the Intermediate Phase of a Radiological Emergency,” June 2018.	ML18170A043
“10 CFR Parts 50 and 70, Emergency Planning; Final Rule,” August 19, 1980.	45 FR 55402
SECY-19-0062, “Final Rule: Non-power Production or Utilization Facility License Renewal,” June 17, 2019	ML18031A000

Throughout the development of this proposed rule, the NRC may post documents related to this rule, including public comments, on the Federal rulemaking Web site at <https://www.regulations.gov> under Docket ID NRC-2015-0225. The Federal rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: 1) Navigate to the docket folder (NRC-2015-0225); 2) click the “Sign up for E-mail Alerts” link; and 3) enter your e-mail address and select how frequently you would like to receive e-mails (daily, weekly, or monthly).

List of Subjects

10 CFR Part 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.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is proposing to adopt the following amendments to 10 CFR parts 50 and 52:

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, licensed under § 50.21 or § 50.22 to produce heat energy up to 1,000 megawatts-thermal, which may be of modular design as defined in § 52.1 of this chapter.

* * * * *

§ 50.8 [Amended]

3. In § 50.8(b), add “50.160” after “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 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 establish the size of the plume exposure pathway EPZ. The plume exposure pathway EPZ is determined as the area within which 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, resulting from a spectrum of credible accidents for the facility.

(i) 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 Tribal, State, and local 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.

(ii) 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 paragraph (b) introductory text and add paragraph (f).

The revision and addition read as follows:

§ 50.47 Emergency plans.

* * * * *

(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:

* * * * *

(f) Paragraphs (a)(2) and (b) of this section do not apply to offsite radiological emergency response plans if the licensee's emergency plan is not required to meet these planning standards 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) of this part apply, the NRC"; and

f. Revise paragraph (gg)(1).

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 an emergency plan that meets the requirements in either § 50.160 or appendix E to this part and, except for a holder of a license under this part for a non-power production or utilization facility, 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 the

requirements in either § 50.160 or appendix E to this part and, except for a non-power production or utilization facility licensee, 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 the requirements in either § 50.160 or, appendix E to this part and, for nuclear power reactor licensees, the planning standards of § 50.47(b).

(5) The licensee shall retain a record of each change to the emergency plan made without prior NRC approval for a period of three years from the date of the change and shall submit, as specified in § 50.4, a report of each such change made, including a summary of its analysis, within 30 days after the change is put in effect.

* * * * *

(q)(7) Each holder of an operating license under this part or a combined license under 10 CFR part 52 for a small modular reactor or non-light-water reactor or each holder of an operating license under this part issued after **[DATE 30 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE 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 10 CFR 52.103, 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. 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:

Sec.

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

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 NRC will not issue an initial operating license to a licensee unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. No finding under this section is necessary for issuance of a renewed power reactor operating license.

(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 this paragraph.

(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 response organization 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 response organization 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 response organization 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) of this section.

(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 local, State, Tribal and Federal 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) The site familiarization training for any offsite organization that may respond to the site in the event of an emergency;

(5) An evacuation time estimate of the areas beyond the site boundary and within the EPZ;

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

(7) The means of making offsite dose projections and the means of

communicating the offsite dose projections to the offsite response coordinating agencies;

(8) 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;

(9) The general plans and methods to allow entry into the EPZ during and after an emergency;

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

(11) The 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.

(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.* 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 protect contaminated food and water from entering into the ingestion pathway.

(c) *Implementation.* (1) An applicant for an operating license issued under this part after **[DATE 30 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE 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 no

later than 18 months 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 no later than 18 months 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 Zones¹ (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 as necessary will be determined on a case-by-case basis.²

* * * * *

²Regulatory 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.

* * * * *

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 paragraph (b)(2) 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 pertinent standards of § 50.47 of this chapter and the requirements of appendix E to part 50 of this chapter, or § 50.160 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 applicable standards of § 50.47 of this chapter and the requirements of appendix E to part 50 of this chapter, or § 50.160 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 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 applicable standards of § 50.47 of this chapter and the requirements of appendix E to part 50 of this chapter, or § 50.160 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, the requirements in either § 50.160 of this chapter or appendix E to part 50 of this chapter and § 50.47 of this chapter;

* * * * *

Dated at Rockville, Maryland, this 1st day of May, 2020.

For the Nuclear Regulatory Commission.

/RA/

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

Note: The following Appendix will not appear in the Code of Federal Regulations.

Separate Views of Commissioner Baran

For the last 40 years, NRC has required emergency planning zones, or EPZs, around nuclear power plants “to assure that prompt and effective actions can be taken to protect the public in the event of an accident.”¹ Every one of the 96 operating large light-water reactors in the country has a plume exposure pathway EPZ that extends about 10 miles around the site with dedicated offsite radiological emergency plans and protective actions in place to avoid or reduce radiation dose to the public during an accident. An ingestion exposure pathway EPZ with a radius of 50 miles around each of these sites is designed to avoid or reduce dose from consuming food and water contaminated by a radiological release. The EPZs and dedicated radiological emergency plans are meant to provide multiple layers of protection – or defense-in-depth – against potential radiological exposure. Other NRC requirements are focused on preventing or mitigating a radioactive release. The emergency planning regulations are there to provide another layer of defense in case a release occurs despite those safety requirements. In other words, EPZs and radiological emergency planning are designed to address low-probability, high-consequence events. The Federal Emergency Management Agency (FEMA) assesses the adequacy of the offsite emergency plans, and NRC regulations require licensees to hold offsite emergency preparedness drills at each plant at least once every 2 years to practice implementing the plans.²

Under this proposed rule, emergency planning for small modular reactors (SMRs) and non-light-water reactors would be flimsy by comparison. Instead of a 10-mile plume exposure

¹ NUREG-0396, *Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants* (1978) at 11.

² The regulations require a full set of emergency preparedness exercises to be conducted at each plant over an 8-year cycle.

pathway EPZ, these reactors would have EPZs that encompass only areas where the projected dose from “credible” accidents could exceed 1 rem. An EPZ extending only to the site boundary is explicitly permitted under this methodology. In the case of a site-boundary EPZ, NRC would not require dedicated offsite radiological emergency planning and FEMA would have no role in evaluating the adequacy of a site’s emergency plans. In addition, the proposed rule would eliminate the requirement for an ingestion exposure pathway EPZ and no longer require a specific drill frequency for emergency planning exercises. Overall, this proposed rule represents a radical departure from more than 40 years of radiological emergency planning.

No new SMR or non-light-water reactor designs have yet been approved by NRC, and only one SMR design has been submitted for the staff’s review. These new designs could potentially be safer than current large light-water-reactor designs. But that does not eliminate the need for EPZs and dedicated offsite emergency planning to provide defense-in-depth in case something goes wrong.

Since 1978, when the concept of an EPZ was first developed, the size of an EPZ has never been exclusively based on the likelihood of an accident occurring. The joint NRC-EPA task force that introduced the EPZ concept specifically stated: “Emergency planning is not based upon quantified probabilities of incidents or accidents.”³ Its foundational task force report, referred to as NUREG-0396, explained that “[r]adiological emergency planning is not based upon probabilities, but on public perceptions of the problem and what could be done to protect health and safety.”⁴ This was not an isolated statement. The task force found that EPZ size should be “derived from the characteristics of design basis and Class 9 accident

³ *Id.* at 1-2.

⁴ *Id.*

consequences.”⁵ Class 9 accidents were defined as those “considered to be so low in probability as not to require specific additional provisions in the design of a reactor facility,” including total core melt scenarios “in which the containment catastrophically fails and releases large quantities of radioactive materials directly to the atmosphere.”⁶ Today, we refer to these as beyond-design-basis accidents. NRC and EPA understood that these kinds of extreme accidents were unlikely, but they also knew that EPZs should be in place to provide defense-in-depth because “the probability of an accident involving a significant release of radioactive material, although small, is not zero.”⁷ The task force further concluded that nuclear accidents were unique in important ways. The report explained: “the potential consequences of improbable but nevertheless severe power reactor accidents, while comparable in some sense to severe natural or man-made disasters which would trigger an ultimate protective measure such as evacuation, do require some specialized planning considerations.”⁸

NRC’s recognition of the important role emergency planning plays in providing defense-in-depth endured over the years. In the 1986 Safety Goals Policy Statement, even as the Commission focused on the quantitative risk of nuclear reactor accidents, the Commission recognized “emergency planning as [an] integral part[] of the defense-in-depth concept associated with its accident prevention and mitigation philosophy.”⁹ The Commission stated that “emergency response capabilities are mandated to provide additional defense-in-depth protection to the surrounding populations.”¹⁰ Similarly, when the agency was working through non-light-water reactor issues in 1993, the NRC staff proposed “no changes to the existing

⁵ *Id.* at 16.

⁶ *Id.* at 26, I-6.

⁷ *Id.* at II-1.

⁸ *Id.* at III-1, III-2.

⁹ 51 FR 28044 (1986).

¹⁰ *Id.*

regulations governing EP for non-light-water reactor licensees,” explaining that it “views the inclusion of emergency preparedness by advanced reactor licensees as an essential element in NRC’s ‘defense-in-depth’ philosophy.”¹¹ Four years later, the staff emphasized the importance of getting the buy-in of federal, state, and local emergency response agencies for any emergency response changes relating to new, potentially safer reactor designs.¹²

But these considerations are sidelined with the proposed rule. Under the rule’s EPZ sizing methodology, the quantitative dose formula exclusively determines the size of the EPZ. It is a purely quantitative, risk-based determination rather than a risk-informed decision that accounts for expert judgment, defense-in-depth, and public confidence. With this proposed rule, no one is exercising any human judgment about how large an EPZ should be. It is simply a mathematical calculation.

The NRC staff acknowledges in the draft proposed rule that emergency planning is supposed to be “risk-informed rather than risk-based” and “independent of accident probability.”¹³ After all, an existing plant’s EPZ does not change every time a plant modification reduces the risk of an accident. A large light-water-reactor licensee does not (and should not) get a smaller EPZ because it installs an additional emergency diesel generator or stores FLEX equipment on site. But the proposed rule embodies just that sort of exclusively quantitative approach. Instead of risk being one important factor considered in setting emergency planning requirements, it would become the only factor that matters. For any SMR or non-light-water reactor that met the dose criteria for a site boundary EPZ, there would be no dedicated off-site

¹¹ SECY-93-0092, *Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and Their Relationship to Current Regulatory Requirements* at 13.

¹² SECY-97-0020, *Results of Evaluation of Emergency Planning for Evolutionary and Advanced Reactors*.

¹³ SECY-18-0103, *Proposed Rule: Emergency Preparedness for Small Modular Reactors and Other New Technologies*, Enclosure 1, Draft Proposed Rule at 30.

radiological emergency planning. That element of defense-in-depth would be dropped completely.

FEMA has expressed major concerns about the NRC staff's approach. It disagrees that quantitative dose criteria should completely determine the size of an EPZ. Consistent with NUREG-0396, FEMA has expressed its support for "a methodology for EPZ sizing that takes into account such 'non-technical' criteria" as public confidence.¹⁴

Moreover, "FEMA has consistently raised concerns about a methodology that allows for a site boundary EPZ for a commercial nuclear power plant."¹⁵ In the absence of an EPZ and dedicated offsite radiological emergency planning, emergency responders would be left with all-hazards planning. FEMA does not believe that all-hazards planning would be adequate in the event of an actual nuclear power plant accident. According to FEMA, "Radiological [emergency planning] is not sufficiently addressed within the All Hazards framework – radiological [emergency planning] is unique. In a Worst-Case Scenario, our [offsite response organizations] could be challenged to effectively protect the health and safety of the public using an ad hoc [emergency planning] construct."¹⁶ FEMA explains that "[a]dvanced planning – such as provided by an EPZ – reduces the complexity of the decision-making process during an incident."¹⁷ And FEMA "stress[es] that the proven best way to ensure offsite readiness is to develop, exercise, and assess [offsite response organization] radiological capabilities, as is now done throughout the offsite EPZ."¹⁸ While a radiological emergency plan could be "scaled up" to

¹⁴ Letter from Michael S. Casey, Director, Technological Hazards Division, FEMA to NRC (Aug. 24, 2019) (ML19240A938).

¹⁵ *Id.*

¹⁶ Letter from Michael S. Casey, Director, Technological Hazards Division, FEMA to NRC (July 8, 2019) (ML19189A318).

¹⁷ *Id.*

¹⁸ *Id.*

address a more severe accident than what was planned for, FEMA notes that it is “unrealistic” to scale up “non-existent plans” and that the resulting “lack of necessary equipment, and shortage of trained emergency personnel could have unfortunate consequences.”¹⁹

In short, all-hazards planning would not be as effective as dedicated radiological emergency planning in an actual radiological emergency. As a result, a site boundary EPZ with all-hazards planning would not provide the same level of protection for a community located near a reactor site as an offsite EPZ with dedicated radiological emergency planning. FEMA, therefore, “believes that the NRC staff conclusion that the proposed methodology of offsite emergency preparedness maintains the same level of protection as a ten-mile EPZ is unsupported.”²⁰

We need to take FEMA’s warnings seriously. FEMA has a key role in determining whether the emergency planning for a nuclear power plant site is adequate. Under NRC’s regulations, a nuclear power plant license cannot be issued unless NRC makes a finding that the major features of the emergency plan meet the regulatory requirements. And NRC is supposed to base its finding on FEMA’s determinations as to whether the offsite emergency plans are adequate and whether there is reasonable assurance that they can be implemented. In fact, under NRC’s regulations, “in any NRC licensing proceeding, a FEMA finding will constitute a rebuttable presumption on questions of adequacy and implementation capability.”²¹ FEMA has this prominent role in our licensing process because of its well-known expertise in

¹⁹ Letter from Michael S. Casey, Director, Technological Hazards Division, FEMA to NRC (Aug. 24, 2019) (ML19240A938).

²⁰ *Id.*

²¹ 10 CFR § 50.47.

this area. Yet, under the proposed rule, FEMA would have no role in assessing the adequacy of offsite emergency plans and capabilities for reactors with a site boundary EPZ.²²

In addition to the issues identified by FEMA, there are several other significant problems with the proposed rule.

First, the logic of the proposed EPZ sizing methodology could be applied to the existing fleet of large light-water reactors to weaken the current level of protection. As the Advisory Committee on Reactor Safeguards noted:

No technical basis is stated in the rule or the guidance for restricting the use of the new rule to SMRs and [other new technologies] with a limit on thermal power. The rule could apply to any reactor technology regardless of size. During our meetings, the staff acknowledged this point.²³

In fact, the proposed rule explicitly seeks comment on whether to apply this kind of approach to large light-water reactors.²⁴ This opens the door to smaller EPZs and reduced emergency planning for the existing fleet of power reactors. If the proposed rule's formulaic approach is adopted, a precedent will be established for applying a purely risk-based methodology to EPZ sizing.

²² See Draft Proposed Rule at 47 ("for SMRs and [other new technologies] within the scope of this proposed rule, FEMA findings and determinations regarding reasonable assurance ... would only be needed for a facility where the plume exposure pathway EPZ extends beyond the site boundary requiring dedicated offsite radiological EP plans for the facility.")

²³ Letter from Michael Corradini, Chairman, ACRS to NRC (Oct. 19, 2018) (ML18291B248).

²⁴ Draft Proposed Rule at 60.

Second, the proposed rule does not account for the possibility of accidents affecting more than one SMR module. Even though some SMR designs contemplate several reactors at one site, the EPZ sizing methodology addresses each reactor in isolation. This ignores a key lesson of the Fukushima accident – that severe natural disasters can simultaneously threaten multiple reactors at a site. Under the draft proposed rule, a SMR is defined as a power reactor that produces less than 1,000 megawatts-thermal. The combined heat energy produced by just two SMRs of this size could be larger than that of some existing large light-water reactors in the U.S. But, under the proposed rule, each module could individually qualify for a site boundary EPZ without consideration of the other.

Third, unlike the existing regulations for large light-water reactors, the proposed rule “would not define the required frequency of drills and exercises” for emergency preparedness.²⁵ As a result, SMR and non-light-water reactor licensees would not be required to conduct a full offsite emergency preparedness drill every 2 years. The NRC staff provides no basis for this weaker standard.

Finally, the proposed rule would eliminate the ingestion pathway EPZ for SMRs and non-light-water reactors. The NRC staff argues that prior quarantines of spinach and eggs in response to E. Coli and salmonella infections “demonstrate[] that a response to prevent ingestion of contaminated foods and water could be performed in an expeditious manner without a predetermined planning zone.”²⁶ No FEMA evaluation of this change is provided. Nor is there any discussion of the effectiveness of ad hoc responses to previous radiological releases. Moreover, if the staff’s unbounded rationale were adopted, it could ultimately lead to ingestion pathway EPZs being dropped for the existing fleet of large light-water reactors.

²⁵ Draft Proposed Rule at 39.

²⁶ Draft Proposed Rule at 55.

For these reasons, I do not support finalizing the proposed rule in its current form. NRC needs a rule that provides regulatory certainty for potential applicants and recognizes that SMRs and non-light-water reactors will be different than traditional, large light-water reactors. It makes sense to have a graded approach that accounts for potential safety improvements in new designs. But the rule should not be purely risk-based, relying entirely on the results of a dose formula. Instead, NRC should issue a rule to establish the following emergency planning requirements for three categories of nuclear power plants.

SMRs and non-light-water reactors with a thermal output of more than 20 megawatts would be eligible for a 2-mile EPZ, as long as they meet the dose standard at that distance. A 2-mile EPZ recognizes that these new technologies could be safer than large light-water reactors while ensuring that there will be dedicated offsite radiological emergency planning to provide defense-in-depth in the unlikely event of a severe accident. To account for future potential technological advances, an alternate EPZ smaller than 2 miles should be available if NRC, FEMA, and the host state all agree that the alternate EPZ would provide for an effective and adequate response in the event of a severe radiological emergency. The rule should include an EPZ sizing methodology that accounts for the possibility of accidents affecting more than one SMR module, provide for an appropriately-sized ingestion pathway EPZ, and maintain the existing requirements to conduct an offsite emergency preparedness drill every 2 years and the full suite of emergency preparedness exercises over an 8-year cycle.

SMRs and non-light-water reactors with a thermal output of 20 megawatts or less would be eligible for a site boundary EPZ, as long as they meet the dose standard at that distance. Reactors of this size, essentially micro-reactors, would present accident consequences

comparable to existing research and test reactors, which are not subject to offsite emergency planning requirements.²⁷

Large light-water reactors, as well as any SMRs or non-light-water reactors that do not meet the dose standard for a 2-mile EPZ, would continue to have a 10-mile EPZ.

In my view, this approach strikes the right balance. It recognizes the potential for improved designs with lower risks, while maintaining defense-in-depth to protect the public. It builds on 40 years of experience with emergency planning rather than discarding it. During the comment period, a broad range of stakeholders will have an opportunity to offer their views on how this approach can be further refined in the rule.

²⁷ The largest currently operating test reactor has a power level of 20 megawatts thermal.