October 12, 2018  

FOR:  
The Commissioners  

FROM:  
Margaret M. Doane  
Executive Director for Operations  

SUBJECT:  
PROPOSED RULE: EMERGENCY PREPAREDNESS FOR SMALL MODULAR REACTORS AND OTHER NEW TECHNOLOGIES  
(RIN 3150-AJ68; NRC-2015-0225)  

PURPOSE:  
The purpose of this paper is to obtain Commission approval to publish in the Federal Register the enclosed notice of a proposed rule (Enclosure 1) and draft guidance related to amended regulations for emergency preparedness (EP) for small modular reactors (SMRs) and other new technologies (ONTs). This paper addresses no new commitments.  

SUMMARY:  
The U.S. Nuclear Regulatory Commission (NRC) staff is proposing to amend regulations that would specify new alternative EP requirements for SMRs and ONTs. The new EP requirements and implementing guidance would acknowledge technological advancements and other differences from large light-water reactors (LWRs) inherent in SMRs and ONTs, such as non-LWRs and certain non-power production or utilization facilities (NPUFs). Concurrently, the NRC also proposes to issue for public comment draft regulatory guide (DG) DG-1350, “Emergency Preparedness for Small Modular Reactors and Other New Technologies.” The NRC staff plans to hold a public meeting to promote full understanding of the proposed rule and guidance and to facilitate public comments.  

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The proposed rule would be technology inclusive and would provide all existing and future SMR and non-LWR applicants and licensees, and future NPUF licensees that would be licensed after the effective date of the final rule the alternative to develop a performance-based EP program, rather than using the existing, deterministic, EP requirements in Title 10 of the Code of Federal Regulations (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 rule are those LWRs that are licensed to produce greater than 1,000 megawatts thermal power, fuel cycle facilities, or currently operating non-power reactors.

BACKGROUND:

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 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 range from small to large in power size and may apply modular construction concepts.

In SECY-15-0077, "Options for Emergency Preparedness for Small Modular Reactors and Other New Technologies," dated May 29, 2015 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15037A176), the staff sought Commission approval to initiate rulemaking for EP for SMRs and ONTs to provide for regulatory stability, predictability, and clarity in the licensing process. The paper stated the following:

The NRC technical staff will rigorously review design and licensing information to ensure that the information applicants provide on the offsite dose consequences is commensurate with the requested EPZ size and that the applicable requirements ensure adequate protection of public health and safety, and the environment.

Subsequently, the Commission issued SRM-SECY-16-0077, "Options for Emergency Preparedness for Small Modular Reactors and Other New Technologies," dated August 4, 2016 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15216A492), in which the Commission approved the NRC staff's recommendation to conduct rulemaking to address EP for SMRs and ONTs, and requested that the staff provide a plan and schedule for this rulemaking.

In response to SRM-SECY-15-0077, on May 31, 2016, the U.S. Nuclear Regulatory Commission staff issued SECY-16-0069, "Rulemaking Plan on Emergency Preparedness for Small Modular Reactors and Other New Technologies" (ADAMS Accession No. ML16020A388), proposing a rulemaking plan to address EP for SMRs and ONTs. In SECY-16-0069, the staff introduced the rulemaking plan and 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 proposed rulemaking plan and schedule in SRM-SECY-16-0069 (ADAMS Accession No. ML16174A166).

1 Emergency planning requirements for facilities licensed under 10 CFR Part 70 are set forth in 10 CFR 70.22(i).
On August 22, 2016, the NRC held a Category 3 public meeting to request feedback from interested stakeholders on a potential performance-based approach the NRC was considering for the EP for SMRs and ONTs rulemaking. Most meeting participants supported a performance-based approach to EP, indicating that it would be more effective because it would focus on achieving desired outcomes. Participants also favored the performance-based approach as one that would allow for innovation and flexibility in addressing the EP requirements. The potential need for an entire new suite of guidance documents, including the change process, was the only disadvantage identified by participants as it would require additional up-front work to reflect the new approach. The meeting summary details the results of this public meeting (ADAMS Accession No. ML16257A510). After considering the feedback received from the stakeholders, the NRC staff developed a draft regulatory basis to support a rulemaking that included a performance-based approach to EP.

On April 13, 2017, the NRC issued a draft regulatory basis, “Emergency Preparedness for Small Modular Reactors and Other New Technologies,” for a 75-day public comment period [Volume 82 of the Federal Register, page 17768 (82 FR 17768)]. Additionally, the NRC staff developed a preliminary regulatory analysis that was included in the draft regulatory basis. In the draft regulatory basis and the associated regulatory analysis, the NRC requested feedback from the public on topics related to the: scope of the draft regulatory basis, performance-based approach, regulatory impacts, and cumulative effects of regulation. In addition, the NRC held a public meeting on May 10, 2017, to facilitate the development of public comments on the draft regulatory basis and issued a summary of the meeting on May 24, 2017 (ADAMS Accession No. ML17139C860).

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 the Federal Emergency Management Agency (FEMA). The NRC staff reviewed all comments submitted on the draft regulatory basis, grouped the comments into categories by comment topic, and developed a resolution for each topic. These topics include: consequence-based approach, collocation, dose assessment, emergency planning zone (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 staff considered all public comments during the development of the regulatory basis and the associated regulatory analysis. The NRC staff published a Federal Register notice (FRN) announcing the public availability of the regulatory basis on November 15, 2017 (82 FR 52862). The NRC staff used the regulatory basis and the associated regulatory analysis (ADAMS Accession No. ML17206A265) to inform the development of the enclosed proposed rule.

Within this proposed rule, the NRC staff uses the term “ONTs” to refer to non-LWRs to be licensed under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” or 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” and medical radioisotope facilities that would be licensed under 10 CFR Part 50. This proposed rule would also define “non-power production or utilization facility” to clarify its usage in 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 the NRC’s proposed rule, “Non-Power Production or Utilization Facility License Renewal” (82 FR 15643; March 30, 2017). The definition would include non-power reactors and other production or utilization facilities licensed under 10 CFR 50.21, “Class 104 licenses; for medical therapy and research and development facilities,” or
10 CFR 50.22, "Class 103 licenses; for commercial and industrial facilities," that are not nuclear power reactors or fuel reprocessing plants. In the context of this proposed rule, medical radioisotope facilities that would be licensed under 10 CFR Part 50 would also be included within this definition. The term "non-power production or utilization facility" is used in this rulemaking 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 these 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 ONT facilities (i.e., non-LWRs and medical radioisotope facilities) for which the NRC expects to receive license applications under 10 CFR Parts 50 or 52. Therefore, those NPUFs that are not considered ONTs (i.e., currently operating non-power reactors) are not within the scope of this rule. Currently operating non-power reactors will continue to implement existing emergency planning requirements and guidance.

DISCUSSION:

Overview of Proposed Changes to Emergency Preparedness Regulations

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 future operation of SMRs and ONTs. Through this rulemaking, the NRC staff proposes to amend regulations and develop implementing guidance to create an alternative EP framework for SMRs and ONTs. The new EP requirements and implementing guidance adopt a consequence-oriented, risk-informed, performance-based, and technology-inclusive approach. The NRC staff's objective for this rulemaking is to create a set of 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 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 rule and guidance could affect existing and future SMR and ONT facilities to be licensed after the effective date of the final rule. These applicants and licensees would have the option to develop a performance-based EP program, rather than using the existing, deterministic, EP requirements in 10 CFR Part 50.

This proposed rule includes the following major provisions:

- 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 located contiguous to an SMR or ONT that considers any hazard that would adversely impact the implementation of emergency plans.
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- A scalable approach for determining the size of the plume exposure pathway EPZ.
- 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.

The plume exposure pathway EPZ for the current operating fleet of nuclear power reactors consists of an area about 10 miles in radius and the ingestion pathway EPZ (IPZ) for such facilities consists of an area about 50 miles in radius. (See 10 CFR 50.33(g) and 50.47(c)(2).) As discussed in the "Background" section of the enclosed proposed rule (Enclosure 1), 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; October 14, 2008) 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, 10 CFR 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 MW thermal may be determined on a case-by-case basis. Part 50, Appendix E, Section 1.3, states that the EPZs for facilities other than power reactors also may 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 from the requirements in 10 CFR 50.47(c)(2), in accordance with 10 CFR 50.12, "Specific exemptions," 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 rulemaking 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 rulemaking 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.

The NRC received a comment on its draft regulatory basis in 2017 that recommended that the NRC expand the scope of the 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 staff has included a question for public input, in the "Specific Request for Comments" section in the FRN, as to whether the NRC should consider a performance-based, consequence-oriented approach to EP for large LWRs, fuel cycle facilities, and currently operating NPUFVs.

The staff used lessons learned from the ongoing "Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning" and the "Non-power Production or Utilization Facility (NPUF) License Renewal" rulemakings, and coordination of the Tennessee Valley Authority early site permit review to inform the development of this proposed rule. As
such, the staff will continue to assess and coordinate this rulemaking effort with those activities moving forward. The staff will also continue interactions with the Federal Radiological Preparedness Coordinating Committee to discuss issues of mutual interest to the NRC, FEMA, and other government organizations.

Regulatory Analysis

The NRC staff prepared a draft regulatory analysis (Enclosure 2) to determine anticipated costs and benefits of this proposed rule. In particular, the draft regulatory analysis evaluates the costs and benefits associated with new requirements and the development of, or modifications to, NRC guidance and shows that the NRC staff’s recommendation for rulemaking and guidance development for EP for SMRs and ONTs is overall cost beneficial to the industry, Government, and society. The conclusion from the analysis is that this proposed rule alternative and associated guidance would result in net averted costs to the industry and the NRC ranging from $5.8 million using a 7-percent discount rate to $9.7 million using a 3-percent discount rate.

Cumulative Effects of Regulation

The NRC staff is following the process to consider the cumulative effects of regulations by engaging with external stakeholders throughout the development of this proposed rule and related regulatory activities. The NRC staff published the draft regulatory basis in the Federal Register (82 FR 17768; April 13, 2017), and sought public comment on specific questions and issues with respect to possible revisions to the NRC’s requirements. In addition, the NRC staff held a public meeting on May 10, 2017, to facilitate public comments on the development of the final regulatory basis and regulatory analysis.

The NRC staff will issue the draft implementing guidance with the proposed rule and draft regulatory analysis to support more informed external stakeholder feedback. Further, the NRC staff will continue to hold public meetings throughout the rulemaking process.

Implementing Guidance

The NRC staff will publish the following draft guidance document for public comment in conjunction with the proposed rule:

• 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).

The draft guidance document is intended for use by applicants, licensees, and the NRC staff. It describes an approach and method acceptable for implementing the requirements in 10 CFR 50.160, "Emergency preparedness for small modular reactors, non-light water reactors, and non-power production or utilization facilities." As a guidance document, DG-1350 does not establish additional requirements, and applicants and licensees are free to propose alternative ways for demonstrating compliance with the regulations.

Backfitting and Issue Finality Considerations

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

RESOURCES:

This rulemaking is designated as a medium-priority rulemaking with Commission direction, in accordance with the Common Prioritization of Rulemaking. The New Reactors Business Line includes resources for the proposed rule for fiscal years (FY) 2018 and 2019. The NRC staff will address resources beyond FY 2019, if needed, through the planning, budget, and performance management process and will prioritize these activities in a manner consistent with the current Common Prioritization of Rulemaking process and other priorities in the New Reactors Business Line.

RECOMMENDATIONS:

The NRC staff recommends that the Commission approve the enclosed proposed rule (Enclosure 1) for publication in the Federal Register.

The following six activities are related to the publication of the proposed rule:

(1) Upon Commission approval, the NRC will publish the proposed rule in the Federal Register for a 75-day public comment period.

(2) This proposed rule contains revised information-collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. § 3501 et seq.). The NRC staff will submit information collection requirements to the Office of Management and Budget for its review and approval on or immediately after the date of publication of the proposed rule in the Federal Register.

(3) The NRC staff has prepared a draft environmental assessment and determined a proposed finding of no significant impact (Enclosure 3).

(4) The Office of Congressional Affairs will keep the appropriate congressional committees informed.

(5) The Office of Public Affairs will issue a press release when the NRC publishes the proposed rule in the Federal Register.

(6) The NRC staff will hold a public meeting during the comment period for this proposed rule.
COORDINATION:

The Office of the General Counsel has no legal objection to the publication of the proposed rule related to EP for SMRs and ONTs. The NRC staff will provide an information copy of the FRN to the Advisory Committee on Reactor Safeguards after publication.

Margaret M. Doane
Executive Director
for Operations

Enclosures:
1. Federal Register Notice
2. Draft Regulatory Analysis
3. Draft Environmental Assessment
Commissioners' completed vote sheets/comments should be provided directly to the Office of the Secretary by COB Friday, November 30, 2018.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Friday, November 23, 2018, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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SUBJECT: PROPOSED RULE: EMERGENCY PREPAREDNESS FOR SMALL MODULAR REACTORS AND OTHER NEW TECHNOLOGIES (RIN 3150-AJ68; NRC-2015-0225) DATED:

ADAMS Accession Nos.: PKG: ML18134A086; SECY: ML18134A076 *concurred via e-mail

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