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RULEMAKING ISSUE (Affirmation)

January 3, 2022

SECY-22-0001

FOR: The Commissioners

FROM: Daniel H. Dorman
Executive Director for Operations

SUBJECT: FINAL 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 the enclosed draft final rule (Enclosure 1) that would amend the U.S. Nuclear Regulatory Commission's (NRC) regulations to include new alternative emergency preparedness (EP) requirements for small modular reactors (SMRs) and other new technologies (ONTs). This paper does not address any new commitments or resource implications.

SUMMARY:

The draft final rule includes new alternative EP requirements for SMRs and ONTs. The final rule would be technology inclusive and would provide existing and future light-water SMR, non-light-water reactor (non-LWR) applicants and licensees, certain existing non-power production and utilization facilities (NPUFs), and NPUFs licensed after the effective date of the final rule, with 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, "Domestic Licensing of Production and Utilization Facilities."

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This draft final rule would also provide for reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency consistent with the existing EP requirements. The draft final rule does not include within its scope emergency planning, preparation, or response for large LWRs, fuel cycle facilities, or currently operating non-power reactors, commonly referred to as research and test reactors. For the purposes of this draft final rule, large LWRs are reactors that are licensed to produce greater than 1,000 megawatts thermal power.

BACKGROUND:

On May 12, 2020 (85 FR 28436), the NRC published in the *Federal Register* the proposed rule, "Emergency Preparedness for Small Modular Reactors and Other New Technologies," for a 75-day public comment period. On May 25, 2020 (85 FR 32308), the NRC published a notice to correct the definition of "Non-power production or utilization facility." The NRC received several requests to extend the comment period by 6 months or more due to the Coronavirus Disease 2019 public health emergency. On July 21, 2020 (85 FR 44025), the NRC extended the comment period by 60 days with a closing date of September 25, 2020. A public meeting was held on June 24, 2020, to discuss the proposed rule (meeting summary at Agencywide Documents Access and Management System (ADAMS) Accession No. ML20196L775). The NRC received comments from 2,212 individuals and organizations, including 2,087 form letters and form letters with non-substantive additional text. The staff's analysis identified 649 unique comments on the proposed rule and associated guidance, the regulatory analysis, and the environmental assessment. The commenters included State and local governments, Tribal governments and Tribal organizations, Federal agencies, members of the nuclear power industry, non-governmental organizations, and private citizens. The staff diligently assessed and considered all comments, both those in support of the rulemaking and those with concerns for specific aspects of the proposed rule and associated guidance. The resolution of comments is reflected in the final rule language and associated guidance. A summary of all comments and the NRC's responses to the comments can be found in the NRC Response to Public Comments (Enclosure 2).

In the draft final rule, the staff uses the term "ONTs" to refer to a wide range of new technologies. Non-LWRs to be licensed as power reactors under 10 CFR Part 50 or 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," are included within the definition of ONTs. However, the draft final rule is not limited to power reactors but also provides an alternative performance-based EP framework for certain "non-power production or utilization facilities." As used in the draft final rule, the term "non-power production or utilization facility" is defined to have the same meaning as the definition in the NRC's draft final rule, SECY-19-0062, "Final Rule: Non-Power Production or Utilization Facility License Renewal," dated June 17, 2019 (ADAMS Accession No. ML18031A000). The definition of NPUF includes 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 draft final rule, new non-power reactors and 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 part, in the draft final 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 Part 30, "Rules of General Applicability to

Domestic Licensing of Byproduct Material,” 10 CFR Part 40, “Domestic Licensing of Source Material,” and 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material.” Those facilities that would be licensed under 10 CFR Parts 30, 40, or 70 would be subject to existing emergency planning requirements in these parts. As such, the scope of this rule is limited to ONTs facilities (e.g., non-LWRs licensed as power reactors, new non-power reactors, and medical radioisotope facilities) for which the NRC expects to receive license applications under 10 CFR Parts 50 or 52. Those NPUFs that are not considered ONTs (i.e., currently operating non-power reactors) are not within the scope of the draft final rule. Currently operating non-power reactors will continue to implement existing emergency planning requirements and guidance.

DISCUSSION:

Existing emergency preparedness regulations and guidance are primarily focused on large LWRs and non-power reactors. In the draft final rule, the staff developed 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 new alternative EP requirements 1) continue to provide reasonable assurance that adequate protective measures can and will be implemented by an SMR or ONT licensee; 2) promote regulatory stability, predictability, and clarity; 3) reduce the need for requests for exemptions from EP requirements; 4) recognize technology advancements embedded in design features; 5) credit safety enhancements in evolutionary and passive systems; and 6) credit the potential benefits of smaller sized reactors and non-LWRs associated with postulated accidents, including slower transient response times and relatively small and slow release of fission products. This final rule and guidance could affect SMRs and ONTs and future 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 draft final rule includes the following four major provisions:

- (1) A new alternative performance-based EP framework in 10 CFR 50.160, “Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities,” including requirements for demonstrating effective response in drills and exercises for emergency and accident conditions.
- (2) A requirement for a hazard analysis of any facility located contiguous to or near an SMR or ONT that considers any hazard that would adversely impact the implementation of emergency plans developed under this framework.
- (3) A scalable approach for determining the size of the plume exposure pathway emergency planning zone (EPZ).
- (4) A requirement to describe ingestion response planning in the emergency plan, including the offsite capabilities and resources available to prevent contaminated food and water from entering the ingestion pathway.

The draft final rule package includes a new Regulatory Guide (RG) 1.242, “Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities” (ADAMS Accession No. ML20345A345), to

support the implementation of the final rule requirements. RG 1.242 provides guidance on implementing a performance-based EP program for SMRs, non-LWR power reactors, and NPUFs, including a general methodology for establishing the plume exposure pathway EPZ. Significant Changes from the Proposed Rule to the Final Rule

The staff made changes because of public comments and other considerations. These changes are described below:

- A commenter suggested that the definition of “small modular reactor” should indicate that an SMR can have a licensed thermal power up to 1,000 megawatts (MW(t)), and that this limit applies to each module in a facility rather than the total thermal power of all modules in a facility. The proposed rule’s definition of “small modular reactor” provided that an SMR was a power reactor licensed to produce heat energy up to 1,000 MW(t), which may be of modular design as defined in 10 CFR 52.1, “Definitions.” The staff agreed that this definition could be subject to more than one interpretation and revised the definition of “small modular reactor” to read: “a power reactor, which may be of modular design as defined in 10 CFR 52.1 of this chapter, licensed under 10 CFR 50.21 or 50.22 to produce heat energy up to 1,000 megawatts thermal per module.” The “per module” language is also consistent with the definition of “small modular reactor” in 10 CFR 171.5, “Definitions.”
- In the proposed rule, the plume exposure pathway EPZ would be determined as the area within which public dose, as defined in 10 CFR 20.1003, “Definitions,” is projected to exceed 10 millisieverts (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. The NRC received comments on the need for clarification of these terms, specifically the 10 mSv (1 rem) total effective dose equivalent over 96 hours and the definition of “spectrum of credible accidents.” The staff concluded that the determination of licensing basis events, including whether accidents are credible for the facility, is a part of the safety analysis for the facility and not specific to EP. As part of the NRC’s safety review of the application, the NRC reviews the applicant’s assessment of licensing basis events, event likelihood, and public dose consequences. The NRC’s determination of the acceptability of the applicant’s assessment will support the agency’s review of the applicant’s emergency plan.

As a result, the staff revised the requirements for an applicant complying with the new 10 CFR 50.160 by listing in new 10 CFR 50.33(g)(2)(i)(A) the major considerations for the radiological consequence analysis to be used in determining the appropriate plume exposure pathway EPZ size for the applicant’s facility: accident likelihood and source term, timing of the accident sequences, and meteorology. Consideration of accident likelihood in combination with event sequences makes it possible to arrive at the spectrum of accidents taken from the licensing basis events to develop the basis for the applicant’s site-specific plume exposure pathway EPZ. In addition, the staff added a second criterion to the plume exposure pathway EPZ size determination in new 10 CFR 50.33(g)(2)(i)(B): the plume exposure pathway EPZ is the area in which predetermined, prompt protective measures are necessary. This rule provision adds a functional criterion to the EPZ to be consistent with the planning basis approach in NUREG-0396, “Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power

Plants,” issued November 1978 (ADAMS Accession No. ML051390356), and Federal guidance contained in the U.S. Environmental Protection Agency’s early-phase Protective Action Guides Manual.

- The staff modified the language in 10 CFR 50.160(b)(3) because of the revisions made to 10 CFR 50.33(g)(2). The proposed 10 CFR 50.160(b)(3) required an applicant to “determine and describe the boundary and physical characteristics of the EPZ in the emergency plan.” During the development of the draft final rule, the staff recognized that the new EPZ size determination criteria in 10 CFR 50.33(g)(2) could result in an applicant having no plume exposure pathway EPZ. For this result to occur, the applicant’s analysis required by 10 CFR 50.33(g)(2) would need to show that one or both criteria in 10 CFR 50.33(g)(2)(i) are not met. So that an applicant without a plume exposure pathway EPZ would not need to request an exemption from 10 CFR 50.160(b)(3), the draft final rule includes an entry condition limiting that section to applicants and licensees with a plume exposure pathway EPZ. Those applicants are required to incorporate the boundaries and physical descriptions of the EPZ into their emergency plans. An applicant or licensee not having a plume exposure pathway EPZ would still be required to have an emergency plan that meets the requirements of 10 CFR 50.160(a), (b)(1)(i) through (iv)(A), (b)(2), (b)(4), and (c) in the draft final rule.
- The NRC received comments related to risks associated with the loading and storage of irradiated fuel. In reviewing the comments, the staff determined that a conforming change is needed to 10 CFR Part 72, “Licensing requirements for the independent storage of spent nuclear fuel, high-level radioactive waste, and reactor-related greater than Class C waste.” A 10 CFR Part 72 specific license for independent spent fuel storage installation (ISFSI) must comply with the EP requirements in 10 CFR 72.32, “Emergency plan.” Most power reactor licensees have 10 CFR Part 72 general licenses for their ISFSIs. For these ISFSIs, 10 CFR 72.32(c) provides that the emergency plan required by 10 CFR 50.47, “Emergency plans,” satisfies the EP requirements of 10 CFR 72.32. This provision means that an emergency plan that meets the requirements of 10 CFR 50.47 satisfies the EP requirements of 10 CFR 72.32. This same policy should apply to an ISFSI on the site of a power reactor whose licensee is complying with 10 CFR 50.160. To allow for this, the staff revised 10 CFR 72.32(c) to clarify that the emergency plan that meets the requirements of 10 CFR 50.47 or 10 CFR 50.160 satisfies the EP requirements of 10 CFR 72.32.
- The NRC received comments suggesting a change in the phrase, “The NRC will not issue an initial operating license to a licensee...” in proposed 10 CFR 50.160(b) to read, “The NRC will not issue an initial operating license to an applicant....” The staff agreed that it is more appropriate to refer to the applicant. However, the staff revised 10 CFR 50.160(b) from the proposed rule to state that the reasonable assurance finding made under 10 CFR 50.47(a)(1) necessary to issue an operating license, combined license, or early site permit to an applicant complying with 10 CFR 50.47 and Appendix E to Part 50 is also necessary to issue an operating license, combined license, or early site permit to an applicant complying with 10 CFR 50.160.
- The NRC received a public comment suggesting a revision to the proposed 10 CFR 50.160(b)(1)(iii)(F)(1), 10 CFR 50.160(b)(1)(iii)(F)(3), and 10 CFR 50.160(b)(1)(iii)(F)(4). The comment suggested that the phrase “and report

- radiological conditions to the response organization” be changed to read “and report radiological conditions to the onsite and offsite response organizations.” The staff acknowledged that the references to “response organization” in the proposed rule should be clarified and determined that that information would need to be reported to only certain personnel within the licensee’s emergency response organization. Therefore, the staff changed these rule provisions in the draft final rule, so the information is reported to the “applicable response personnel.”
- The NRC received comments on the evacuation time estimate (ETE) consideration of people located within a facility’s site boundary. The proposed 10 CFR 50.160(b)(1)(iv)(B)(5) would have required an ETE “of the areas beyond the site boundary and within the EPZ.” The staff acknowledges that the phrase “areas beyond the site boundary” could be interpreted to exclude, rather than include, the area within the site boundary. As such, the staff removed the phrase “beyond the site boundary and” in the draft final rule to clarify that an ETE is intended to estimate the time to evacuate various sectors and distances within a licensee’s plume exposure pathway EPZ, which includes the area within the plant’s site boundary.
- The NRC received comments on the proposed requirement for applicants to conduct an initial exercise to demonstrate effectiveness of the EP program by no later than 18 months before the issuance of a 10 CFR Part 50 operating license or the scheduled date for initial loading of fuel for a 10 CFR Part 52 combined license holder. The comments suggested that the 18-month timeframe for applicants or licensees to establish, implement, and maintain the emergency planning requirements before issuance of an operating license or initial fuel loading is not appropriate. In reviewing the comments, the staff determined that the timeframe in the proposed “no later than 18 months before” could be expanded. As a result, the draft final rule allows licensees greater flexibility in demonstrating regulatory compliance by revising the requirements in 10 CFR 50.160(c)(1) and (c)(2) from “no later than 18 months before” to “within 2 years before.” These changes also ensure consistency with the current requirement in Appendix E, “Emergency Planning and Preparedness for Production and Utilization Facilities,” to 10 CFR Part 50 for large LWRs, which requires an applicant to conduct a full-participation emergency planning exercise within 2 years before the issuance of an operating license for a 10 CFR Part 50 applicant or the scheduled date for initial loading of fuel for a 10 CFR Part 52 combined license holder.
- The NRC staff clarified that an applicant complying with 10 CFR 50.160 when the plume exposure pathway EPZ extends beyond the site boundary needs to submit an emergency plan of a “participating” Tribal government. A “participating” Tribal government means a Federally recognized Tribal government that has decided to participate in a Federal Emergency Management Agency (FEMA) offsite radiological emergency preparedness program and act as an independent entity with its own radiological emergency plan.

Tribal Participation

During the development of the final rule, the staff identified instances where the role of Tribes in EP was not explicitly addressed in 10 CFR 50.33, 50.47, and Appendix E to part 50. Because these provisions are applicable to large LWRs and the considered changes were outside the

scope of this rule, the staff will evaluate if any future regulatory changes are recommended and engage the Commission, as appropriate. Currently, the NRC encourages the involvement of Tribal governments in NRC activities under the Commission's January 9, 2017 "Tribal Policy Statement" (82 FR 2402) and NUREG-0654/FEMA-REP-1, Revision 2, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants." As such, the NRC staff will continue to implement the Commission's policy during the licensing of new and advanced technologies ensuring appropriate coordination and engagement with Tribes.

Cumulative Effects of Regulation Considerations

The staff followed its cumulative effects of regulation (CER) process by engaging with external stakeholders throughout this rulemaking and related regulatory activities. When the NRC issued the proposed rule in May 2020, the agency provided a public comment period of a total of 135 days, including a 60-day extension period. In accordance with the CER process, the NRC also issued a draft regulatory guide for public comment at the same time as the proposed rule. The staff engaged external stakeholders at public meetings and by soliciting public comments on the proposed rule and associated draft guidance document.

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

Implementation Guidance

As discussed in Section XVI, "Availability of Guidance," of the enclosed draft *Federal Register* notice, the staff will publish RG 1.242, Revision 0, concurrent with the publication of the final rule. The guidance provided in RG 1.242 provides one acceptable approach for use by applicants and licensees to demonstrate compliance with the requirements in 10 CFR 50.160 and conforming changes to Parts 50 and 52.

Backfitting and Issue Finality Considerations

The final 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. The final rule contains alternative requirements for EP for SMRs and ONTs applicants and licensees. As alternatives, these requirements would not be imposed on applicants and licensees and would not prohibit applicants and licensees from following existing requirements. For these reasons, the requirements in the final rule would not constitute backfitting or affect the issue finality of any approval issued under 10 CFR Part 52.

Regulatory Analysis

The staff prepared a final regulatory analysis (Enclosure 3) to determine anticipated costs and benefits of the final rule. In particular, the regulatory analysis evaluates the costs and benefits associated with new requirements and the development of, or modifications to, NRC guidance and shows that the 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 the final rule and associated guidance will result in net averted costs to the industry and the NRC ranging from \$7.98 million using a 7-percent discount rate to \$14.9 million using a 3-percent discount rate. The net benefits estimates are higher for the final rule relative to the proposed rule even though the staff refined the cost analysis to calculate and include the estimated additional costs to applicants and the NRC for probabilistic risk assessment (or other analyses) to support the scalable plume exposure pathway EPZ. This is because the cost analysis no longer includes the costs of the final rulemaking; all rulemaking costs are considered sunk costs at this stage.

Paperwork Reduction Act

The final rule contains amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The staff will submit information collection requirements to the Office of Management and Budget (OMB) for its review and approval prior to publication of the final rule in the *Federal Register*.

RECOMMENDATION:

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

OMB has determined that this is not a major rule under the Congressional Review Act of 1996.

If the Commission approves the staff's recommendation, the NRC will complete the following activities:

- The staff will publish a public comment resolution document (Enclosure 2), a regulatory analysis (Enclosure 3), and an environmental assessment (Enclosure 4) for this final rule.
- The staff will publish RG 1.242 with the publication of this final rule.
- The Office of Congressional Affairs will inform the appropriate congressional committees of this action.
- The staff will work with the Office of Public Affairs on an appropriate public communication when the NRC publishes the final rule in the *Federal Register*.

RESOURCE:

The EP for SMRs and ONTs rule activities are appropriately budgeted in the New Reactors Business Line. This rulemaking is designated as medium priority in accordance with the common prioritization of rulemaking. The New Reactors Business Line includes resources for this rulemaking through fiscal year (FY) 2022. The staff expects to complete this rulemaking in FY 2022 and has not requested resources beyond FY 2022. The staff will address resources beyond FY 2022, 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. Enclosure 5 describes the estimated resources required to complete this rulemaking.

COORDINATION:

The Office of the General Counsel has no legal objection to this rulemaking package.

The staff met with the Advisory Committee on Reactor Safeguards (ACRS) on November 2, 2021. The ACRS provided a letter, dated November 16, 2021 (ADAMS Accession No. ML21316A252), that recommends publication of the final rule and provides the following recommendations:

1. Revise proposed 10 CFR 50.47(f) to not exclude FEMA from being involved in reviewing emergency plans under this rule regardless of the boundaries of the EPZ to ensure applicable offsite agencies are capable to coordinate with onsite nuclear emergency organizations.
2. Revise RG 1.242 to:
 - a. Include additional clarifying guidance related to selection criteria for the spectrum of events to consider for determination of the source term that is to be applied for EPZ sizing.
 - b. Clearly indicate that for sites licensed for transportable and mobile reactors the license application review and associated proposed emergency plan must be set for the maximum number of modules, new arrivals, active, and shutdown or spent units. This ensures the emergency plan considers the cumulative on-site effect of all units during the full life cycle of the licensed site.
 - c. Include conforming changes regarding the changes made in response to Recommendation 1 above.

The staff reviewed the recommendations and provided its response to ACRS in a letter dated December 17, 2021 (ADAMS Accession No. ML21322A003). The staff determined that no changes were needed to the content of the rule or RG 1.242.

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Daniel H. Dorman
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Enclosures:

1. Final Rule: Federal Register Notice
2. Final Rule: NRC Response to Public Comments
3. Final Rule: Regulatory Analysis
4. Final Rule: Environmental Assessment
5. Final Rule: OUO - Resource Estimate

SUBJECT: FINAL RULE: EMERGENCY PREPAREDNESS FOR SMALL MODULAR REACTORS AND OTHER NEW TECHNOLOGIES (RIN 3150-AJ68; NRC-2015-0225) DATED: January 3, 2022

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 RA: ML21200A079
 EA: ML21200A080

***via email**

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