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General Comment

See attached file(s)

Attachments

Joint Comment on NEI Topics Part 53 and Subpart H Final

February 28, 2025

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U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Comment on Draft 10 CFR Part 53, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," [NRC–2019–0062] RIN 3150–AK31

Dear Dr. Gavrilas:

We appreciate the opportunity to provide comments on the Nuclear Regulatory Commission's (NRC's) draft Part 53 rule, issued for formal comment on October 31, 2024. In December 2024, the NRC released additional proposed provisions in Part 53, Subpart H, § 53.1480, and included Question 13 with specific requests for comment in addition to those in the Part 53 *Federal Register* Notice (FRN 89 FR 86918).[1] We offer these comments based on 56 years of combined regulatory experience as former NRC staff.

1. General Comments

We fully support and incorporate by reference the comments submitted by the Nuclear Energy Institute (NEI) on February 14, 2025[2]. The proposed Part 53 rule "does not adequately address… relevant and major developments and fails to meet the moment for ensuring that the NRC is enabling the safety and secure use of nuclear energy technologies through an efficient and effective regulatory framework."[3] For example, it remains voluminous with duplicative requirements (e.g., requirement for an Integrated Assessment Program); overly prescriptive, including a prescriptive requirement for a probabilistic risk assessment (PRA); does not accommodate a rapid, high-volume reactor deployment model; retains concepts and definitions from existing requirements and regulatory practice for large light-water reactors (LLWRS) (e.g., overly broad definition of "utilization facility," prescriptive and deterministic LLWR-centric reporting requirements, and presumptive siting of stationary reactors away from population centers); and expands regulatory requirements for nonsafety-related structures, systems and components.

a. Acceptability of Codes and Standards

Of particular note, the draft rule excludes use of established industry codes and standards (e.g., ISO 9001) not previously endorsed or otherwise found to be acceptable by NRC despite directives for

[1] Subpart H – Licenses, Certifications and Approvals DRAFT Section 53.1480 – Combined license supporting testing of manufactured reactors, December 2024 (https://www.nrc.gov/docs/ML2434/ML24344A037.pdf)
[2] https://www.regulations.gov/comment/NRC-2019-0062-0418
[3] Ibid, NEI Transmittal Letter to Dr. Mirela Gavrilas, p. 1

"Federal agencies to adopt voluntary consensus standards wherever possible" and "to meet respective agency requirements in an efficient and cost-effective manner for the agency and its stakeholders."[4] It is imperative for NRC to recognize that key consensus standards provide the basis for currently operating plants, and some were not reviewed and endorsed by NRC. Safety improvements for advanced reactors over conventional large light-water reactors are often reflected in duly approved consensus standards before NRC gets involved. The NRC should not appoint itself as exclusive arbiter of what is acceptable for advanced reactors. Such actions create barriers to efficient licensing and oversight without an apparent safety benefit. Accredited standards developing organizations (SDOs) follow rules of practice that support technical requirements to enable deployment of new and advanced nuclear technologies. As such, resulting codes and standards should be recognized and considered to improve regulatory efficiency while maintaining reasonable assurance of adequate protection, consistent the NRC's updated mission. As a general comment, ***we recommend NRC conform with National directives and discontinue an inefficient and unnecessarily limiting practice of excluding from consideration codes and standards unless they have been reviewed and endorsed or otherwise found to be acceptable by NRC.***

b. Continued Conflation of Risk and Performance Concepts in Part 53

In Subpart B—Technology-Inclusive Safety Requirements, the staff introduces a discussion of § 53.220(b) that inappropriately comingles risk concepts and performance concepts:

> *The safety criterion in § 53.220(b) would include a requirement to use a comprehensive risk metric or set of metrics and associated* ***risk performance objectives*** [emphasis added] *against which calculated values of the risk metrics are compared. The comprehensive risk metrics or set of metrics and associated* ***risk performance objectives*** [emphasis added] *would support a* ***performance-based approach*** [emphasis added] *to developing an appropriate combination of design features and programmatic controls to prevent or mitigate LBEs other than DBAs. The applicant must propose the comprehensive risk metric or set of metrics and associated* ***risk performance objectives*** [emphasis added]*, and the comprehensive risk metric or set of metrics and* ***risk performance objectives*** [emphasis added] *must provide an appropriate level of safety.*[5]

It is incongruous to conflate estimated frequencies from a PRA with the observational criteria established through a performance-based approach. Comingling these orthogonal concepts has been a persistent challenge during the rulemaking process in terms of both communication and substance. In the SRM for SECY-23-0021, the Commission disapproved codification of the quantitative health objectives in the proposed Part 53 rule and directed the staff to "revise draft 10 C.F.R. 53.220 to specify that applicants must propose a **comprehensive plant risk metric (or set of metrics) and a description of the associated methodology** [emphasis added] used to demonstrate that the proposed design meets said metric(s). The methodology must explain the initial and boundary conditions and key assumptions used to develop and calculate the **risk metric(s)** [emphasis added]." The origins of "risk performance objectives" are unclear and unrelated to Commission direction in SRM-SECY-23-0021. An applicant should be required to perform a "risk evaluation" (vice PRA) as part of an "integrated safety assessment" under § 53.220. This terminology would more precisely account for an integrated, holistic combination of risk and performance attributes.

[4] https://www.nist.gov/standardsgov/what-we-do/federal-policy-standards/key-federal-directives
[5] FRN, p. 86925

To avoid further confusion and conflation of risk and performance concepts, ***we reiterate NEI's detailed comment B-3 on Subpart B – Technology Inclusive Safety Requirements. NRC should rename § 53.220 as "Safety Criteria for an Integrated Safety Assessment."*** ***See our response to NEI Topic 2 – Part 53, Subpart B – Comprehensive Risk Metrics.***

2. Specific Requests for Comment

Section VI, "Specific Requests for Comments," includes topics with specific questions and requests for comment. The comments herein are in response to specific requests involving Part 53, Subparts E and H—Manufacturing Licenses (NEI Topic 7), and Recent Legislation (NEI Topic 16).

While we support NEI's comments, we offer additional recommendations that would transform NRC's regulation of advanced reactors. For example, a fleet-scale approach to licensing and oversight of small and mobile reactors under a service provider license would efficiently integrate NRC's regulatory functions over the life cycle of manufactured reactors. Maximum use of performance monitoring would minimize the need for costly, inefficient inspection and significantly reduce associated costs during all phases of n^{th}-of-a-kind deployment and decommissioning.

a. NEI Topic 1 – Part 53—Overall Organization

NRC Question:

Part 53 is structured as one framework with subparts providing technical, licensing, and administrative requirements for the various stages of the life cycle of a commercial nuclear plant. The organization of part 53 in this manner puts a complete set of requirements for each stage of the life cycle in a separate subpart with additional subparts for licensing and administrative requirements.

The NRC is seeking comment on the proposed organization of the requirements in part 53 and possible improvements to how specific requirements (e.g., examples of which specific sections) could be consolidated or otherwise reorganized to make the rule clearer or more concise.
There are numerous references in proposed part 53 to other NRC regulations. Examples of such references include those in proposed § 53.610 to NRC regulations related to radiation protection (part 20), FFD (part 26), physical security (part 73), and MC&A (10 CFR part 74, "Material Control and Accounting of Special Nuclear Material") for facilities receiving byproduct or SNMs.

The NRC is seeking comment on whether such references to other regulations in various sections in the proposed part 53 provide benefits to applicants and licensees, or to other stakeholders seeking to understand the regulatory framework under part 53, or whether such references could be removed to reduce the length of part 53.

Response from Nuclear ROSE Consulting, LLC, and Kadambi Engineering Consultants:

We support an overall organization of Part 53 that is based on a performance-based decision-making structure that results in specification of requirements from within the framework with subparts providing technical, licensing, and administrative requirements specified for each of the stages in the lifecycle of a commercial nuclear plant. We are not proposing major changes to the draft framework; rather, we suggest that the organization reflect a systems-engineering approach. This can be accomplished with simple changes focused on the structure of the requirements specified in the

currently proposed rule language. Our proposal is based on the performance-based decision-making framework described in ANSI/ANS-30.3, "Light Water Reactor Risk-Informed, Performance-Based Design." Modifications along the lines proposed in this comment letter would significantly reduce the volume of the Part 53 rule. Relocating many portions of the existing rule text to guidance (as recommended by NEI[6] and other stakeholders[7]) would provide an optional (vice the currently prescribed) approach to meeting the rule.

i. Decision-Making Framework

ANSI/ANS-30.3 provides guidance for establishing a formal decision analysis process that is risk-informed and performance-based. This standard describes the framework needed for specifying requirements for a new commercial LWR but is equally applicable on a technology-inclusive basis to any of the currently proposed designs. A Part 53 framework along these lines would meet the NIEMA mandate for a technology-inclusive, risk-informed and performance-based framework.

The proposed Part 53 framework goes part way toward the type of decision-making structure that is consistent with the stated aspiration that the organization of the rule reflect a systems-engineering style approach. However, the draft rule needs to go further along these lines to realize the benefits of a decision-making framework that formally follows systems-engineering best practices. Such practices, in conjunction with existing guidance on risk-informed, performance-based approaches and methods, would provide for a structured set of requirements that are coherent throughout the life cycle of a commercial nuclear plant. A Part 53 structured in this way would allow applicants to propose requirements for their design, licensing, construction/assembly and operation seamlessly, employing any available methodologies that demonstrate their safety case.

ii. Examples of Small Changes with Major Impact

Example 1: Consider § 53.230, "Safety Functions." According to the structure described in ANSI/ANS-30.3, safety functions should be structured hierarchically with the highest-level safety functions being plant-level safety functions, with plant-level requirements, and the architecture of the plant-level design features. This is provided for in § 53.220, "Safety Criteria for Licensing-Basis Events Other than Design-Basis Accidents," as design features and programmatic controls. § 53.230(a) currently reads as follows:

> *(a) The primary safety function is limiting the release of radioactive materials from the facility and must be maintained during normal operation and for LBEs over the life of the plant.*

§ 53.230(a) identifies limiting release of radioactive materials as the primary safety function over the life of the plant. Hence, it is a requirement that applies all the way from design, to construction, to operation and finally to decommissioning. Interpreted according to the terms of ANSI/ANS-30.3, this constitutes the requirement that would apply at the plant level so that all design features and programmatic controls support this requirement. A plain language understanding of a "primary

[6] NEI Comment on Part 53 rule package, February 14, 2025 (https://www.regulations.gov/comment/NRC-2019-0062-0418)
[7] See "Stakeholder Consensus on Proposed Part 53 Major Topics," dated February 24, 2025 (https://www.nrc.gov/docs/ML2505/ML25056A010.pdf)

safety function" implies that the entire safety purpose of the Part 53 rulemaking will be served by having an applicant show that a particular design provides reasonable assurance of accomplishing that objective. From the perspective of structured performance objectives in a performance-based approach, the safety objective of limiting release of radioactive materials would occur at the highest level, then decomposed to show relationships and dependencies of other supporting functions.

The purpose of § 53.230 within Subpart B is to identify safety functions. The stated purpose of Subpart B in Section VII of the preamble is to "…establish a set of technology- inclusive performance standards that would be used throughout part 53 to determine appropriate regulatory controls for SSCs, human actions, and programs". Hence, the performance standard associated with the primary safety function should apply consistently for requirements specified for all phases. Again, interpreted according to the terms of ANSI/ANS-30.3, this implies structuring requirements in a hierarchy with appropriate definitions of requirements consistent with the system levels as described in the consensus standard. The basic point is that Subpart B of Part 53 should focus on clarifying the ability of an applicant to specify requirements optimally for a particular design. The primacy of limiting release of radioactive materials for the whole plant is communicated with greater clarity if § 53.230(a) were revised as follows:

> *(a) The primary safety function is limiting the release of radioactive materials from the facility ~~and must be maintained during normal operation and for LBEs~~ over the life of the plant.*

The elimination of verbiage does not detract from the effectiveness of § 53.230(a) because the specific requirements for the process associated with the deleted words is dealt with in Subpart C, "Design and Analysis Requirements." This example shows how the functional distinction between requirements in Subparts B and C are focusing each subpart on different but related requirements hierarchies. This separation of functions served by each of these subparts makes it easier for an applicant to craft design-specific requirements (using the guidance in ANSI/ANS-30.3, if they so choose) within a requirements hierarchical structure that offers much more flexibility.

Example 2: Similar reasoning applies to the draft wording of § 53.230(b):

> *(b) Additional safety functions needed to support the retention of radioactive materials during LBEs—such as controlling reactivity, heat generation, heat removal, and chemical interactions—must be identified for each commercial nuclear plant.*

This wording is potentially confusing because one could infer that the functionalities associated with controlling reactivity, heat generation, heat removal, and chemical interactions are significant only during those events identified as LBEs. Such an understanding would be technically erroneous because these functionalities are important considerations during all phases of the plant life cycle: design, construction, operation and decommissioning. Since LBEs are not considered during the construction and decommissioning phases, specifying "LBEs" in the regulation represents unnecessary and inapplicable requirements during these phases. Any potential for such confusion can be removed by a simple modification of § 530(b) as follows:

> *(b) ~~Additional s~~Safety functions needed to support the retention of radioactive materials ~~during LBEs~~ —such as controlling reactivity, heat generation, heat*

removal, and chemical interactions—must be identified for each commercial nuclear plant.

These and other relatively simple modifications would apply systems-engineering best-practices within the framework of Part 53. With these simple changes, the overall organization would bring about closer conformity with a performance-based approach to the design, licensing, operation, and ultimately decommissioning of future commercial nuclear plants.

iii. Additional Benefits of a Performance-based Approach

Employing a formal set of systems-engineering practices as described in ANSI/ANS-30.3 will enable a holistic approach to requirements management throughout the Part 53 framework. Together with a life-cycle approach that considers design, construction and operation as a continuum relative to requirements associated with design features and programmatic controls, this approach provides continuity with the frameworks in Parts 52/50. These and other simple changes like them would firmly establish continuity between Parts 50/52 and Part 53 relative to specifying key design and operational requirements that support very different regulatory frameworks. Within Part 53, consistency of the process for developing requirements can be established between, for example, plant level requirements and siting requirements in Subpart D. This type of coherence will minimize the need for an applicant to request exemptions during the licensing process.

iv. Repetition of Other Regulations

In response to NRC's request for comment regarding references to other regulations in various sections in the proposed Part 53, we support referencing other regulations as means to accomplish performance objectives within Part 53 without repeating the requirements associated with those other regulations. NRC's request for comment specifically mentions Parts 20, 26, 73, and 74. In each of these cases, any mention in Part 53 should state that the specific requirements should be coherent with the performance-based approach of the Part 53 framework as it relates to accomplishing the primary safety objective of limiting release of radioactive materials as provided in § 53.230(a). Hence, in response to the specific request relative to § 53.610, "Construction," and the reference made to Part 20, we find such a reference to be acceptable to the extent that Part 20 is a performance-based regulation. However, the incorporation of Appendix B to Part 50 (§ 53.610(a)(6)(i)) is incoherent with a performance-based approach and should be removed. The quality assurance program under Part 53, which is the subject being addressed in this request for comment, should enable using performance-based approaches employing, for example, consensus standards. Similarly, requirements in supporting regulations in Parts 26, 73, and 74 should be identified as means to accomplish the primary safety or security objective associated with design features and programmatic controls within a performance-based approach. In this way, the entirety of the particular regulation does not have to be repeated in Part 53.

We recommend the simple changes to provisions in the draft rule (described herein) to achieve an overall organization of Part 53 that is performance-based using systems engineering principles. If incorporated, these changes will result in a decision-making structure that satisfies the Nuclear Energy Innovation and Modernization Act (NEIMA) of 2019 and the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy (ADVANCE) Act of 2024. We further recommend that NRC avoid duplication of supporting regulations in Part 53.

b. NEI Topic 2 – Part 53, Subpart B – Comprehensive Risk Metrics

NRC Request:

The NRC is proposing to require the use of comprehensive risk metrics and associated risk performance objectives as one of several performance standards in part 53. Comprehensive risk metrics could include a risk metric or a set of risk metrics that approximate the total overall risk from the facility to the extent practicable. Associated risk performance objectives are pre-established values indicative of the comprehensive risk metrics that are used during risk-informed decision-making to gauge plant safety. Specifically, comprehensive risk metrics and associated risk performance objectives would provide one element of the safety criteria for LBEs other than DBAs in the proposed § 53.220. Comprehensive risk metrics, in the form of the IEFR and the ILCFR, and associated risk performance objectives, in the form of the QHOs of 5×10-7 per year and 2×10-6 per year, respectively, were similarly used in the LMP methodology to ensure that other evaluation criteria were conservatively defined and as a tool for focusing attention on matters important to managing the risks posed by nuclear power plants. The use of such comprehensive risk metrics and associated risk performance objectives in an integrated risk-informed decision-making process is similar to that used in RG 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," Revision 3.

The NRC is seeking comment on the use of comprehensive risk metrics and associated risk performance objectives in part 53 as one of several performance standards. The IEFR and ILCFR and the QHOs represent comprehensive risk metrics and associated risk performance objectives that the NRC has used for decades in a variety of capacities. What other performance standards could be used to address the comprehensive risks posed by proposed commercial nuclear plants? Please provide your considerations and rationale for your recommendation.

If an applicant proposes a novel approach to comprehensive plant risk and the NRC approves the approach, should the resulting NRC-approved comprehensive plant risk metrics and associated risk performance objectives be codified or otherwise memorialized over time and, if so, how?

Response from Nuclear ROSE Consulting, LLC, and Kadambi Engineering Consultants:

We support NEI's proposal to view a "comprehensive risk metric" as one piece of a holistic, integrated safety assessment. The focus of the regulation should be on safety criteria for an integrated safety assessment that accounts for both risk and the protection of safety margin. Such an approach is consistent with the decision-making framework in RG 1.174.

c. NEI Topic 7 – Part 53, Subparts E and H—Manufacturing Licenses

NRC Request 1:

The proposed requirements governing manufacturing are set forth in subpart E, and the proposed requirements governing the licensing processes are contained in subpart H. Some of the proposed requirements, including provisions related to the loading of unirradiated fuel into a manufactured reactor, are intended to cover a factory-fabrication model that has been suggested for some micro-reactor designs. However, as written, the proposed provisions are not limited to any size or type of reactor.

The NRC is seeking comment on whether the proposed regulations are sufficient to govern various scenarios for the possible manufacturing and deployment of manufactured reactors. If a comment indicates that the proposed regulations are not sufficient, please describe the reasons why, including, if applicable, any plausible scenario for which the commenter believes the proposed regulations are not sufficient.

Response from Nuclear ROSE Consulting, LLC, and Kadambi Engineering Consultants:

No, the proposed regulations are not sufficient to govern various scenarios for the possible manufacturing and deployment of manufactured reactors. For this reason, and in response to the ADVANCE Act, the NRC staff is seeking comment on how Part 53 could be revised to implement the mandates therein – specifically, Section 208, "Regulatory requirements for micro-reactors." Also, in December 2024 the staff released additional proposed provisions in 10 CFR Part 53, Subpart H, § 53.1480, and included Question 13 with specific requests for comment as part of the October 31, 2024, Part 53 *Federal Register* Notice (FRN). These post-FRN developments and solicitations for specific comment on new draft provisions under Subpart H provide clear evidence that the proposed regulations are insufficient to govern various scenarios for the possible manufacturing and deployment of manufactured reactors (e.g., mobile reactors). ***See our response to questions related to micro-reactors, and associated recommendations, under the heading of NEI Topic 16, "Recent Legislation."***

NRC Request 7:

Some stakeholders have suggested that a fueled manufactured reactor with appropriate protections against criticality should not be categorized as a utilization facility under NRC regulations or Section 11cc. of the Act.

The NRC is seeking comment on possible approaches where the NRC could find that a fueled manufactured reactor would not be a utilization facility, the basis for such a finding, and the potential benefits of and potential issues with such a finding.

Response from Nuclear ROSE Consulting, LLC, and Kadambi Engineering Consultants:

We believe that a fueled manufactured reactor with appropriate protections against criticality should ***not*** be categorized as a utilization facility under NRC regulations or Section 11cc. of the Act. Criticality is not inherently unsafe. In fact, reactors are designed to go critical. As such, the regulatory focus should be on ***uncontrolled or inadvertent criticality*** for this diverse class of reactors. Regulations (including those in Part 53) should not prescribe what constitutes "appropriate protections." Rather, in a performance-based framework, the developer or applicant should be afforded flexibility to demonstrate how risks from inadvertent criticality would be effectively managed through design features and/or programmatic controls, commensurate with those risks. Traditional, long-established double contingency principles and practices are sufficient for reactor and radiation safety.

More fundamentally, the Part 53 rulemaking presents an opportunity for NRC to redefine "utilization facility" altogether without any change to the AEA. The AEA ***does not*** define "utilization facility."

Rather, the Act defers to the Commission to define what constitutes a "utilization facility"within the broad parameters of the AEA:

> *Sec. 11. Definitions*
> *cc. The term "utilization facility" means (1) any equipment or device, except an atomic weapon,* ***determined by rule of the Commission*** [emphasis added] *to be capable of making use of special nuclear material in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public, or peculiarly adapted for making use of atomic energy in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public; or (2) any important component part especially designed for such equipment or device* ***as determined by the Commission*** [emphasis added].

The definition in § 53.2 adopts the same definition from § 50.2 (intended for LLWRs):

> *Utilization facility means* ***any commercial nuclear reactor*** [emphasis added] *other than one designed or used primarily for the formation of plutonium or uranium-233.*

The authority to redefine "utilization facility" within the four corners of the AEA, yet also in a more modern, risk-informed fashion (consistent with NEIMA), rests with the Commission. If the final Part 53 rule is sufficiently performance-based and defines "utilization facility" in a manner that departs from convention (e.g., excludes very low-hazard advanced and manufactured reactors), the rule might elegantly satisfy NEIMA and the ADVANCE Act. This Part 53 rulemaking presents a rare opportunity to adopt a more practical definition of "utilization facility" not only under Part 53, but also under Part 50 for regulatory consistency. The NRC should seize upon this opportunity as a lynchpin for streamlining attendant requirements (e.g., mandatory hearings) while still providing reasonable assurance of adequate protection through other regulatory provisions (e.g., fleetwide general license to provide a service, license to possess special nuclear material, license to temporarily store used fuel, manufacturing license, transportation license, etc).

A separate rulemaking to accommodate this class of small and mobile reactors will not meet NEIMA's urgent mandate for NRC to provide a technology-inclusive licensing framework; nor will it conform with the NRC's updated mission to enable nuclear energy with efficiency and for the benefit of society. The NRC staff need not wait until the comment period closes on Part 53 to contemplate and seize this opportunity to right-size its regulatory treatment of low-hazard advanced reactors.

The AEA empowers the NRC to define "utilization facility." Congress and two administrations have uncuffed NRC from conventional thinking on this matter. As such, ***we recommend that the NRC adopt a risk-informed definition of "utilization facility" that excludes low-hazard advanced reactors, including manufactured, small, and mobile reactors.***

<u>NRC Request 8:</u>

The proposed § 73.100 would identify the proposed performance-based physical security requirements with which future commercial power reactor applicants or licensees' physical protection programs would need to demonstrate compliance, without prescribing the specific methods that must be used to satisfy them. Applicants and licensees would have increased flexibility regarding the modern technologies and

methods that they could use. Implementing guidance in DG-5076 (proposed RG 5.97), "Guidance for Technology Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants," would be available to assist applicants and licensees. For example, DG-5076 provides detailed guidance, including performance standard recommendations, on the probability of detection and alternative sources of power for exterior intrusion detection systems (subsection 4.1.1.1.A), interior intrusion detection (subsection 4.1.1.1.B), intrusion assessment (subsection 4.1.1.2.A), security response/neutralization subsection (4.1.1.4.A), security communication (subsection 4.1.1.3.A), and security delay (subsection 4.1.1.4.C).

Does the NRC's proposed approach in § 73.100 provide a sufficient level of detail to be readily understood and easily applied to the licensing and oversight of new and advanced power reactors, or should the NRC consider moving some objective and measurable security performance standard recommendations from the draft implementing guidance in DG-5076 into proposed § 73.100? If so, which objective and measurable security performance standard recommendations should be moved from DG-5076 to § 73.100? Please provide the basis for your response.

Response from Nuclear ROSE Consulting, LLC, and Kadambi Engineering Consultants:

Yes, NRC's proposed approach in § 73.100 provides a sufficient level of detail to be readily understood and easily applied to the licensing and oversight of new and advanced power reactors. The NRC ***should not*** attempt to codify in § 73.100 objective and measurable security performance standards or recommendations from draft implementing guidance in DG-5076. In a performance-based licensing and oversight framework, high-level performance objectives should be established in regulatory requirements. The applicant or license holder should be afforded flexibility to demonstrate ***how*** performance objectives are met. Regulatory guidance (like DG-5076) describes one or more acceptable methods of meeting regulatory requirements. Guidance provides sufficient clarity for how high-level performance objectives ***can*** be met, but it is optional and leaves open other approaches and methods for demonstrating compliance with regulations. As such, the provisions in DG-5076 should not be codified as the only means for meeting high-level performance objectives in regulatory requirements. For these reasons, ***we recommend that the NRC refrain from codifying implementing guidance from DG-5076 (or any other sources) into § 73.100.***

Furthermore, we believe the NRC should amend the proposed § 73.100 requirements concerning armed responders. The high-level objective of physical security is to prevent a significant release of radionuclides. Some facilities will not require an armed response to maintain releases below those with consequences exceeding the offsite dose reference values defined in § 53.210(b). Requirements should prescribe only what is necessary for adequate protection. As such, a prescriptive requirement to provide armed responders will not always be necessary to meet this objective. Removing prescriptive requirements for armed responders to interdict and neutralize threats would incentivize more robust approaches to security-by-design, consistent with NRC policy, and ensure that no unnecessary regulatory burden is imposed on an applicant or license holder. Therefore, ***we recommend that the NRC remove prescriptive requirements for armed responders in § 73.100 to acknowledge that some facilities will not need an armed response capability to comply with offsite dose reference values defined in § 53.210(b).*** This comment is consistent with a related comment submitted on proposed changes to § 73.55(b)(3) under a separate rulemaking involving Parts 50 and 52. We incorporate that comment, dated October 22, 2024, by reference herein.[8]

[8] https://www.nrc.gov/docs/ML2429/ML24297A424.pdf

NRC Request 9:

The proposed § 73.110 would require licensees to demonstrate protection against cyberattacks in a manner that is commensurate with the potential consequences from those attacks, without prescribing the specific methods that must be used to demonstrate protection. Under proposed § 73.110(a), licensees would need to ensure that digital computer and communications systems are adequately protected against a potential cyberattack that would, for example, result in adverse impacts to the physical security digital assets used by the licensee to prevent unauthorized removal of material per § 53.860(a). Protecting against such a potential cyberattack would involve requiring cybersecurity for SNM at a commercial nuclear reactor licensed under part 53. Applicants and licensees would have increased flexibility regarding the modern technologies and methods that they could use for protecting against such a potential cyberattack. Detailed implementing guidance in DG-5075 (proposed RG 5.96), "Establishing Cybersecurity Programs for Commercial Nuclear Plants licensed under 10 CFR part 53," would be available to assist applicants and licensees. For example, DG-5075 provides guidance on the implementation of security by design features (e.g., facility design) for negating the potential consequences from such a potential cyberattack.

If a cyberattack were to compromise the availability, integrity, or confidentiality of data or systems associated with security systems/measures for the protection of SNM at a commercial nuclear reactor licensed under part 53, do the potential consequences warrant requiring cybersecurity for such material? Please provide the basis for your response including a detailed explanation of challenges, if any, posed by requiring cybersecurity for SNM at a commercial nuclear reactor licensed under part 53.

Response from Nuclear ROSE Consulting, LLC, and Kadambi Engineering Consultants:

The availability, integrity, or confidentiality of data or systems associated with security systems/measures for the protection of SNM ***may or may not*** warrant protection of such material, depending on the potential consequences of a cybersecurity attack. The performance-based approach provided in § 73.110 establishes a high-level performance objective of protecting against the design basis threat (DBT) of radiological sabotage. The likelihood and potential consequences of a cyberattack should inform cybersecurity measures proposed by a developer or license holder for such material. If the consequences of a cyber-attack are low, then a developer or license holder should be able to apply risk insights to demonstrate that their cyber-security provisions are sufficient for reasonable assurance of adequate protection against radiological sabotage.

Therefore, ***we believe the graded approach in 10 CFR 73.110 is appropriately focused on radiological consequences and supports a risk-informed, performance-based approach to safeguarding against consequences of radiological sabotage of light-water and non-light-water advanced reactors.***

NRC Question 13 – Part 53, Subparts E and H – Manufacturing Licenses:[9]

The NRC is seeking comment on whether provisions regulating the testing of fueled manufactured reactors in the manufacturing facility should be included in part 53 and, if so, what would be practical for

[9] In its December 2024 supplement, the NRC posed Question 13 for specific requests for comment on Subpart H – Licenses, Certifications and Approvals DRAFT § 53.1480 – Combined license supporting testing of manufactured reactors (https://www.nrc.gov/docs/ML2434/ML24344A037.pdf)

the holder of an ML while also providing adequate protection of public health and safety. One possibility could be COLs that would be issued to the holders of an ML to cover low power (e.g., <5% rated thermal power) nuclear physics testing of fueled manufactured reactors within the manufacturing facility prior to the manufactured reactors being transported to and incorporated into a commercial nuclear plant for the purpose of energy production. The NRC recognizes configuration changes are needed to perform nuclear physics testing and is seeking comment on what requirements should apply to the manufactured reactors and the manufacturing facility during such testing (e.g., limiting power levels). If a comment indicates that the regulations should address limited operations at manufacturing facilities, please describe the likely scenarios that would need to be addressed and suggest what would be appropriate requirements for such scenarios.

While an ML holder could accomplish nuclear physics testing by applying for a COL under the proposed subpart H of part 53, stakeholders have indicated that many of the requirements would likely be unnecessary, given the reduced risk profile posed by such activities. Therefore, the NRC is seeking comment on what requirements in subpart H of part 53 should apply to applicants for a COL who would perform testing of fueled manufactured reactors at the manufacturing plant. Examples of proposed requirements that might be relaxed or modified for applications for low power testing at manufacturing plants include those related to selection of LBEs to reflect limited inventory of radionuclides and decay heat, aircraft impact assessments, and earthquake engineering.

Additionally, the NRC is seeking comment on whether several other requirements in part 53 could be modified for applications for a low power testing COL at a manufacturing facility. For example, the NRC is seeking comment on how portions of the ML facility used to support testing should fall within the requirements for construction activities under § 53.610; whether §§ 53.710 and 53.715 (SSC configuration control) must be implemented to ensure portions of the ML facility relied on to limit potential radiological consequences from LBEs are available to perform their safety functions; and whether the requirements of § 53.730 could be modified to reflect the conditions of low power physics testing. If a comment indicates that some design and analysis requirements and related application requirements in subpart H of the proposed part 53 are not needed for the testing of fueled manufactured reactors, please provide a rationale supporting your comment and, if applicable, what alternate requirements would be appropriate.

Moreover, the licensing mechanism for the facility could present unique challenges. One option could be to issue a low power testing COL for each fueled manufactured reactor to be tested. This would comport with the agency's practice of issuing one license per reactor but could prove prohibitive from a cost standpoint and may provide very little safety benefit if all manufactured reactors are the same. Alternatively, one low power testing COL could be issued for the portions of the ML facility used to test the fueled manufactured reactors and allow multiple fueled manufactured reactors to be completed and tested over the course of the ML.

Under this approach, any ITAAC related to testing of the fueled manufactured reactors would need to be closed after they were manufactured but prior to testing, and the NRC would issue a notice of intended operation and provide the public an opportunity to request a hearing on whether each fueled manufactured reactor as constructed complies, or on completion will comply, with the acceptance criteria of the license. The NRC is seeking comment on the potential benefits and issues with having a COL for each fueled manufactured reactor to be tested versus having a COL cover the testing of multiple fueled manufactured reactors. If a comment indicates a preference for a particular approach, please

provide a rationale supporting the comment and describe the specific scenarios that the regulations need to address.

Response from Nuclear ROSE Consulting, LLC, and Kadambi Engineering Consultants:

The overly prescriptive Part 53 rule only recently (in December 2024[10]) included expanded provisions for micro-reactors, and those provisions do not accommodate the varied business strategies and deployment models (including rapid, high-volume deployment of small and mobile reactors) developers seek to employ.

A practical alternative approach would integrate licensing and oversight functions with high-level performance requirements that define outcome objectives related to reactor safety, radiation safety and safeguards. This performance-based approach would allow for maximum use of performance indicators and minimal need for inspection to ensure safety and security, delivering a substantially more efficient regulatory alternative to current practice. Continuous performance monitoring by the license holder and the NRC would provide evidence of sufficient margin for safe and secure manufacturing and operations, thereby establishing reasonable assurance of adequate protection of public health and safety. ***We recommend that the NRC consider an integrated approach to rapid, high-volume deployment of small and mobile reactors as described in the service provider licensing and oversight concept paper*** submitted to NRC in a separate Part 53 comment.[11] As noted in the concept paper, the NRC has options to respond to performance issues that may arise using reactive inspections, supplemental inspections, and even enforcement action and orders if circumstances warrant additional oversight and regulatory response.

The ADVANCE Act acknowledges "'the unique characteristics of micro-reactors,' including physical size, design simplicity, and source term; opportunities to incorporate specific improvements related to streamlining the review process; and other policy and licensing issues."[12] Part 53 should be revised to better address the ADVANCE Act's requirements related to strategies and guidance for micro-reactors, as described in our response to NRC's solicitation of comments on Recent Legislation (see Section d, NEI Topic 16 – Recent Legislation).

d. NEI Topic 16 – Recent Legislation:

NRC Question – Recent Legislation:

On July 9, 2024, the President signed into law the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024, also referred to as the ADVANCE Act. Section 203, "Licensing Considerations Relating to Use of Nuclear Energy for Nonelectric Applications," and Section 208, "Regulatory Requirements for Micro-Reactors," of the ADVANCE Act specifically mention the technology-

[10] In its December 2024 supplement, the NRC posed Question 13 for specific requests for comment on Subpart H – Licenses, Certifications and Approvals DRAFT Section 53.1480 – Combined license supporting testing of manufactured reactors (https://www.nrc.gov/docs/ML2434/ML24344A037.pdf)

[11] Comment (071) on 10 CFR Part 53 Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors and attached concept paper, entitled "Service Provider Licensing and Oversight: An Alternative Conceptual Strategy for Regulating Fleet-wide Small and Mobile Reactors." (See https://www.nrc.gov/docs/ML2503/ML25037A347.pdf.)

[12] FRN, p. 86988

inclusive regulatory framework to be established under section 103(a)(4) of NEIMA as a potential vehicle to be considered for the report to Congress required under section 203 and a potential vehicle to implement strategies and guidance for the licensing and regulation of micro-reactors required under section 208. This proposed rulemaking is, in part, how the NRC is implementing section 103(a)(4) of NEIMA.

The NRC is seeking comment on how part 53 could be revised to better enable its potential use to implement the ADVANCE Act. Specifically, Section 208 of the ADVANCE Act requires the NRC to develop and implement "risk-informed and performance-based strategies and guidance" in several areas for the licensing and regulation of micro-reactors, including with respect to "licensing mobile deployment." The ADVANCE Act requires the NRC to consider "the unique characteristics of micro-reactors," including physical size, design simplicity, and source term; opportunities to incorporate specific improvements related to streamlining the review process; and other policy and licensing issues. With regard to implementation, the ADVANCE Act provides the NRC with three options. The NRC may implement the developed strategies and guidance, as appropriate, via (1) the existing regulatory framework, (2) the Part 53 rulemaking, or (3) a pending or new rulemaking. Given the language included in Section 208, the NRC is seeking comment on how part 53 could be revised to better address the ADVANCE Act's requirements related to strategies and guidance for micro-reactors.

Response from Nuclear ROSE Consulting, LLC, and Kadambi Engineering Consultants:

Provisions for licensing and regulating micro-reactors should be included in Part 53 to ensure the rule delivers the technology-inclusive framework mandated by Congress in the most efficient, effective and expedient way possible. The rationale for this response is that NEIMA mandates a technology-inclusive framework for licensing advanced reactors. Since 2019[13], Part 53 has been intended and expected to deliver that technology-inclusive framework. Micro-reactors represent a class of advanced reactor technologies that must be accommodated by Part 53 to satisfy NEIMA.

Additionally, the NRC has been in pre-application engagement with micro-reactor developer Oklo since as early as 2016[14], several years before NEMA was enacted. Other micro-reactor developers[15,16] have engaged in pre-application activities since the early 2020s. However, there appears to be a lag in NRC's responsiveness to this class of advanced reactors. New proposed requirements issued in December 2024[17] included expanded provisions for micro-reactors; however, those provisions do not accommodate the varied business strategies and deployment models (including rapid, high-volume deployment of small and mobile reactors) developers seek to employ. Therefore, ***we recommend that the NRC be responsive to ADVANCE Act provisions (including Section 208, "Regulatory Requirements for Micro-reactors") in Part 53 to the maximum extent practicable.*** Attempting to

[13] SECY-19-0117, "Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors" (https://www.nrc.gov/docs/ML1831/ML18312A253.pdf)

[14] https://www.nrc.gov/reactors/new-reactors/large-lwr/col/aurora-oklo.html

[15] Westinghouse submitted its regulatory engagement plan for eVinci in November 2021 (see https://www.nrc.gov/docs/ML2132/ML21326A275.pdf).

[16] University of Illinois Urbana-Champaign and UltraSafe submitted their regulatory engagement plan for the Micro-Modular Reactor in June 2023 (see https://www.nrc.gov/docs/ML2317/ML23178A261.pdf).

[17] In its December 2024 supplement, the NRC posed Question 13 for specific requests for comment on Subpart H – Licenses, Certifications and Approvals DRAFT Section 53.1480 – Combined license supporting testing of manufactured reactors (https://www.nrc.gov/docs/ML2434/ML24344A037.pdf)

respond to the need for a framework that is useful and usable for micro-reactors under a separate rulemaking will exacerbate the lag in responsiveness.

If Part 53 is sufficiently performance-based in its overall organizational structure, and the definition of "utilization facility" is modernized to exclude very low-hazard advanced reactors, Part 53 can easily accommodate small and mobile reactors.

i. Utilization Facility

By definition, advanced reactors feature "significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of [NEIMA]."[18] As previously discussed, Part 53 presents an opportunity to define "utilization facility" in a more modern fashion that recognizes these safety improvements and excludes very low-hazard advanced reactors (including small and mobile reactors).

ii. Other Terms and Definitions for Small and Mobile Reactors

The Part 53 rulemaking opens a door for NRC to apply other terms and definitions in a risk-informed manner that reflects the reduced risk-profiles and dose consequences of advanced reactors. For example, the NRC proposes to adopt terms and definitions like "commercial nuclear plant" and "commercial nuclear reactor." However, these proposed definitions hinge from existing regulations for large light-water reactors:

> *The definition of "Commercial nuclear plant" refers to a "Commercial nuclear reactor," which is defined based on the definition of "Nuclear reactor" in § 50.2. However, the phrase ''in a self-supporting chain reaction'' was removed from the definition to enable applying part 53 to accelerator driven systems that use special nuclear material (SNM) but that do not involve self-sustaining chain reactions. Relatedly, "Utilization facility" is also defined in § 53.020 based on the definition of that term in § 50.2 but is also revised to refer to a "Commercial nuclear plant" as defined in § 53.020.*[19]

These definitions and other terms and concepts described in the FRN and Subpart H § 53.1480 may accommodate some deployment models involving stationary reactors deployed to a "final place of operation."[20] However, the definitions should, but currently do not, explicitly (and with thoughtful intentionality) open a space for other deployment models involving fuel loading and physics testing at a manufacturing facility, or rapid, high-volume deployment of small and mobile advanced reactors to multiple sites in series (i.e., series deployment).

The Part 53 rulemaking presents an opportunity for NRC to apply new concepts and definitions that are unconstrained by convention and more appropriate to technological advances and safety improvements in the design and manufacture of nuclear reactor components, systems and fuels. For

[18] NEIMA, Section 3, Definition of "Advanced Nuclear Reactor."
[19] FRN, p. 86923
[20] Subpart H – Licenses, Certifications and Approvals DRAFT § 53.1480 – Combined license supporting testing of manufactured reactors, December 2024 (https://www.nrc.gov/docs/ML2434/ML24344A037.pdf)

example, commencement of commercial operation should be practically defined in a risk-informed manner. Supporting basis to do so has been documented as follows:

> *… the NRC recognizes that operation of a manufactured reactor with the reactor only generating fission reactions sufficient to gather data on the performance of the fuel or other SSCs would present reduced risk compared to operations for energy production because of the smaller inventory of fission products and resulting limited levels of radioactivity and heat generated by radioactive decay.*[21]

In this light, the NRC should consider a fueled reactor undergoing testing at the manufacturing facility to be more like a test reactor, distinct from a commercial nuclear reactor that is ***used*** (i.e., operating commercially) to generate electricity, power and/or process heat. Similarly, commencement of commercial reactor operation should no longer be marked arbitrarily by initial loading of fuel; nor should it be tied to initiating the physical removal of an independent physical mechanism to prevent criticality. Rather, commencement of commercial reactor operation should be defined by the nature of its commercial purpose: intentional and controlled criticality to generate electricity, power and/or process heat.

In short, the NRC should consider more risk-informed definitions and interpretations of terms and concepts (e.g., "utilization facility" and "commencement of operation") and a performance-based approach to reactor and radiological safety (e.g., focus on performance outcomes vice prescriptive requirements for criticality management) in its regulations (including, but not limited to, Part 53). ***We recommend that the NRC work with stakeholders to (1) adopt more appropriate, risk-informed categorization of, and terms and definitions applied to, advanced reactors (including micro-reactors), as they are defined by NEIMA[22], and (2) apply more performance-based concepts within the rule structure (as described in Section a. NEI Topic 1 – Part 53—Overall Organization).***

iii. Population Density

Developers may limit deployment to only remote locations ***because of*** "NRC's longstanding preference for siting reactors in areas of low population density."[23] The FRN further states that this preference "would be maintained in Part 53 by using the current language from part 100 in proposed § 53.530(c)."[24] Absent this stated preference, deployment might otherwise be unlimited as long as adequate protection is demonstrated with reasonable assurance. In light of the reduced risk profiles and dose consequences of an advanced reactor, particularly small reactors, we see no risk-informed, performance-based, or legal justification for this "continued preference"; nor do we think it meets the letter or spirit of NEIMA, the ADVANCE Act, or the NRC's mission statement, which was recently updated to reflect the importance of nuclear energy as a national priority:

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[21] Subpart H – Licenses, Certifications and Approvals DRAFT § 53.1480 – Combined license supporting testing of manufactured reactors, December 2024 (https://www.nrc.gov/docs/ML2434/ML24344A037.pdf, p. 4)
[22] NEIMA defines the term "advanced reactor" as "a nuclear fission… reactor, including a prototype plant with significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of this Act."
[23] FRN, p. 86931
[24] Ibid.

The NRC protects public health and safety and advances the nation's common defense and security by enabling the safe and secure use and deployment of civilian nuclear energy technologies and radioactive materials through efficient and reliable licensing, oversight, and regulation for the benefit of society and the environment.[25]

It would be unfortunate if mere regulatory practice and preference were to unnecessarily limit the benefits of nuclear energy to society and the environment. In light of the significantly reduced risk posed by advanced reactors (including micro-reactors), the NRC should reconsider this preference and remove the associated limitation from § 53.530(c) and throughout the Part 53 rule. In a performance-based licensing framework, adequate protection of radiological safety would need to be demonstrated as part of an applicant's safety case. Prescriptive requirements governing ***how*** it is demonstrated should be carefully considered and appropriately focused on high-level performance outcomes. ***We recommend that the NRC reconsider its preference for siting reactors in areas of low population density and apply a more risk-informed and performance-based approach to radiation safety and adequate protection.***

3. Summary

In summary, we support NEI's comments. In light of the significantly reduced risk posed by advanced reactors (including micro-reactors), we recommend that the NRC be responsive to ADVANCE Act provisions (including Section 208) ***in Part 53*** to the maximum extent practicable. Stakeholders already have waited long enough for regulatory modernization. Initiating separate rulemakings at this late hour will not benefit society or the environment.

We further recommend that the NRC (1) consider an integrated approach to rapid, high-volume deployment of small and mobile reactors that is described in the service provider licensing and oversight concept paper; (2) adopt a more risk-informed definition of "utilization facility" that excludes low-hazard reactors; (3) adopt more appropriate, risk-informed categorization of, and terms and definitions applied to, advanced reactors (including micro-reactors); (4) apply more performance-based concepts within the rule structure; and (5) reconsider its preference for siting reactors in areas of low population density and apply a more risk-informed and performance-based approach to radiation safety and adequate protection.

Simple changes to provisions in the draft rule will achieve an overall organization of Part 53 that is performance-based using systems engineering principles. If incorporated, these changes will result in a decision-making structure that satisfies NEIMA and the ADVANCE Act. For example, renaming § 53.220 as "Safety Criteria for an Integrated Safety Assessment" would shift the currently PRA-centric rule toward a framework that considers risk and protection of safety margin in a holistic, integrated manner. We also urge NRC to conform with National directives and discontinue an inefficient and unnecessarily limiting practice of excluding from consideration codes and standards unless they have been reviewed and endorsed or otherwise found to be acceptable by NRC.

NRC should refrain from codifying implementing guidance from DG-5076 into § 73.100. We recommend that the NRC remove prescriptive requirements for armed responders in § 73.100 to acknowledge that some facilities will not need an armed response capability to comply with offsite dose reference values

[25] SRM-SECY-24-0083, "Mission Statement Update Options Pursuant to Subsection 501(a) of the Advance Act of 2024" (https://www.nrc.gov/docs/ML2502/ML25024A040.pdf)

defined in § 53.210(b). We believe the graded approach in 10 CFR 73.110 is appropriately focused on radiological consequences and supports a risk-informed, performance-based approach to protecting advanced reactors from radiological sabotage.

We recognize and appreciate that the recommendations herein represent a transformational departure from some regulatory practices, policies and licensing frameworks. As such, we are prepared to work with the NRC and other stakeholders to forge a path that enables deployment of advanced reactors (including the rapid, high-volume deployment of small and mobile reactors).

Thank you for the opportunity to provide these comments. If you have any questions, please contact Rani Franovich at rani@nuclearrosellc.com or Prasad Kadambi at prasad@kadambiecpl.com.

Sincerely,

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