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NUCLEAR ENERGY INSTITUTE

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Mr. John Tappert
Director, Division of Rulemaking, Environmental, and Financial Support
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: NEI Input on the NRC Rulemaking Plan on, *Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)*

Project Number: 689

Dear Mr. Tappert:

The Nuclear Energy Institute (NEI)[1] and its members appreciate the Nuclear Regulatory Commission's (NRC) efforts to establish a technology-inclusive, risk-informed, and performance-based regulatory framework for advanced reactors, commonly referred to as the Part 53 rulemaking. We are pleased to see that the Commission approved, in SRM-SECY-20-0032, the staff's proposal to create 10 CFR Part 53, "Licensing and Regulation of Advanced Nuclear Reactors," in keeping with Section 103(a)(4) of the Nuclear Energy Innovation and Modernization Act (NEIMA). While we believe the staff's proposed schedule for a final rule in October 2027 is more conducive to the transformational rulemaking that is needed for future new reactors, we are prepared to support the accelerated schedule directed by the Commission that will result in a final rule in October 2024.

The purpose of this letter is to inform the staff's activities as it undertakes the Part 53 rulemaking, including creating the milestone schedule requested by the Commission within 30 days after the issuance of SRM-20-0032. Specifically, this letter focuses on three key elements to a successful rulemaking: 1) a well-defined vision and goals for the final rule, 2) a systematic approach to the rulemaking effort, and 3) predictable and meaningful stakeholder interactions. These three factors are important to ensuring that Part 53 protects the public health and safety while still allowing for the efficient licensing of advanced nuclear technologies to maximize their contributions to an affordable, reliable and clean energy supply.

[1] The Nuclear Energy Institute (NEI) is responsible for establishing unified policy on behalf of its members relating to matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect and engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations involved in the nuclear energy industry.

Well Defined Vision and Objectives for the Final Rule

Having a well-defined vision and goals is the paramount factor determining whether a large and complex project, like the Part 53 rulemaking, is successful. While there are several documents that describe the objectives of the Part 53 rulemaking, including NEIMA, SECY 20-0032, and the July 2020 NRC White Paper, these documents are not comprehensive or sufficiently detailed to adequately define success before initiating the rulemaking. Thus, we provide the following input for your consideration.

The industry vision for Part 53 is that licensing new reactors under the new rule will be the most efficient option for all new reactor applicants and will meet industry needs for schedule, cost and predictability, consistent with congressional directives, the NRC's own advanced reactor policies and initiatives, and the agency's Principles of Good Regulation.

To achieve this vision, we suggest that the following goals be established for the final Part 53 rule:

1. **Safety Focused** – Part 53 must provide reasonable assurance of adequate protection of the public health and safety and common defense and security. In so doing, Part 53 should use a risk-informed and performance-based approach. The risk-informed aspects should allow for different approaches to balance the use of probabilistic risk assessments (PRAs) with deterministic and defense-in-depth approaches. For example, for designs with minimal potential for public health consequences, an applicant may prefer to rely more on deterministic approaches to demonstrate safety (e.g., based on a maximum credible accident) and make less use of PRA. In cases where postulated accident consequences could be greater, an applicant may prefer make more extensive use of PRA to understand the risk contributions from various events, and thus rely less on deterministic methods. Furthermore, performance-based requirements and guidance should be defined in terms of the direct impacts to public health and safety to the maximum extent possible.

2. **Technology Inclusive** – Part 53 should be available to license any new nuclear reactor, regardless of technology. While the rulemaking effort may necessarily focus on non-Light-Water Reactors (LWRs), micro-reactors, LWR Small Modular Reactors (SMRs), and fusion reactors, a technology-inclusive rule would not exclude the licensing of other technologies, such as large LWRs.[2] A technology-inclusive approach will necessarily consider both current and future technological innovations that result in reduced radiological risks and more efficient means to provide reasonable assurance of adequate protection of public health and safety.

3. **Efficient** – The technical requirements in Part 53 should be developed around the fundamentals of nuclear safety, namely the protection of the public from radiological hazards. Such an approach should be based on a modern and efficient safety paradigm that integrates safety, security and emergency preparedness, and recognizes the adequacy of commercial quality assurance standards. Furthermore, Part 53 should focus on an affirmative safety-basis approach that would avoid the need for exemptions and regulation of portions of the plant that do not pose an unacceptable

[2] In SECY 20-0032, the staff appears to exclude large LWRs from being able to use Part 53 based on the definition of advanced reactors in NEIMA. However, in SECY 20-0032, the staff also notes that NEIMA provides broad discretion to the NRC in establishing the Part 53 rule. We believe that this discretion extends to the scope of applicability for Part 53, and that the exclusion of any particular technology, such as large LWRs, would not be consistent with the NEIMA requirement for a technology-inclusive rule.

radiological risk to the public. For some designs, this may mean that they do not need to describe some portions of the plant design or the site.

Achieving an efficient Part 53 also requires addressing administrative and process requirements, including reporting and the role of the Advisory Committee on Reactor Safeguards. Licensing under Part 50 and Part 52 has proven to be inefficient, resulting in excessively long licensing schedules and costs, even for light-water technologies that are well established. While such delays have been caused by a number of factors, an overly complex regulatory framework that leads to the review of information not necessary to provide reasonable assurance of adequate protection and a lack of focus on the safety significance of issues have been major contributors. The same is true for licensee change control processes that often require NRC approval for changes that have no impact on public health and safety or the common defense and security. Implementing these efficiencies in Part 53 should enable the NRC to achieve more reasonable licensing schedule and cost goals (e.g., less than 2 years and $10M), and regulatory oversight goals (e.g., less than 0.5% of the operations and maintenance costs of the plant) that are compatible with the needs of industry to make pragmatic, informed business decisions about licensing new technologies.

4. **Flexible** – A flexible Part 53 should allow a variety of licensing approaches to demonstrate that the design provides reasonable assurance of adequate protection of the public health and safety and common defense and security. This means that the Part 53 rule language necessarily will be at a higher level, as compared to Part 50 and Part 52. While guidance may be used to provide details for one or more approaches, applicants should have flexibility to demonstrate reasonable assurance of adequate protection without the need to follow pre-established guidance. Flexibility will also be needed for the interface with Parts 50 and 52. For example, a location with a Part 50 construction permit or a Part 52 early site permit may want to bring forward the associated conclusions and finality for a Part 53 operating license application after the Part 53 rule is finalized. Furthermore, the Part 53 rule should be available to license reactors for a diverse set of uses and applications beyond grid-scale electricity, such as remote locations, disaster response, flexible operations and integrated energy systems.
5. **Informed** – Part 53 should be informed in three key areas. First, it should incorporate relevant insights from previous related efforts, such as NEI 02-02, *A Risk Informed Performance Based Regulatory Framework for Power Reactors*. Second, it should incorporate lessons learned from near-term licensing of advanced reactors, including the development of the Licensing Modernization Project (LMP), Technology Inclusive Content of Application Project (TICAP) and NRC Advanced Reactor Content of Application Project (ARCAP), while also recognizing that the near-term experience is constrained by the limitations of having to comply with 10 CFR Part 50 and Part 52. Finally, Part 53 should incorporate lessons learned from regulatory frameworks in other countries, recognizing that designs licensed by the NRC are likely to be deployed around the world, and that the minimization of differences between the U.S. and other countries' regulatory frameworks, where appropriate, would make it easier to export U.S. designs.

6. **Clarity** – The Part 53 regulations and any necessary guidance should be written to avoid confusion or ambiguity that would lead to differing interpretations, thereby promoting regulatory stability and predictability. While it is expected that the Part 53 regulations will be higher-level (i.e., less prescriptive) in nature to meet the technology-inclusive and flexibility goals of NEIMA, this does not

mean that they will lack clarity or technical rigor. High-level, performance-based rules can and should provide clarity about why they are required to provide reasonable assurance of adequate protection and how they interrelate with other regulations. Similarly, guidance for Part 53 should clearly state why the specified approach and requested information are necessary for the NRC to make a determination of reasonable assurance of adequate protection.

Systematic Approach to the Rulemaking

The approach that is used for a large and complex rulemaking, especially with an accelerated schedule, has a great influence on achieving a successful final rule. We encourage the NRC to pursue a systematic approach for developing Part 53 that is not constrained by past practices. Rather than start from what exists, such an approach would begin with the underlying requirements for Part 53 that come from the Atomic Energy Act, as well as the vision and goals highlighted earlier. This is in contrast to an approach that would modify and "force fit" the requirements of 10 CFR Part 50 and Part 52 to meet the goals of technology-inclusive, risk-informed and performance-based. While such an incremental approach is tempting, especially given the time constraints, ultimately it would not yield a Part 53 final rule that provides many benefits relative to the current regulations.

This approach allows for a more flexible, efficient and effective Part 53 final rule, since it allows for a more holistic and integrated approach to safety and security. The Part 50 safety and security requirements have been added over the years, in what the NRC has called a "patchwork", and while they provide reasonable assurance of adequate protection, they do not do so with optimal efficiency. A systematic, holistic approach should not ignore the current regulatory framework; rather, it considers how Part 50 and 52 requirements can be leveraged after the more modern and efficient Part 53 safety paradigm is established.

While the natural tendency may be to jump directly to crafting the Part 53 rule, we believe that a measured, systematic approach is more efficient and will yield better results in the long run. While we appreciate the NRC's pursuit of topics in the July 2020 white paper, we are concerned that proceeding without a well-structured plan for the systematic development of Part 53 will result in schedule and resource inefficiencies. Therefore, we recommend that the NRC take the following steps for the Part 53 rulemaking. Each step has a target milestone based on the assumption that the draft rule text will need to be developed within 12 months to meet the Commission's schedule for a final rule in October of 2024. Taking the time over the next few months to lay the proper foundation for Part 53 will pay dividends in achieving the desired endpoint on schedule.

A five step process is proposed:

Step 1 – Frame the Part 53 Rulemaking Effort (Complete by November 30, 2020)

a) Establish the vision and goals for the final rule, and the process steps for the rulemaking
b) Identify requirements and constraints (e.g., Atomic Energy Act) for final rule

c) Establish the success criteria for the final rule (a.k.a., project requirements) and key decisions that must be addressed in the rulemaking

Step 2 – Establish the scope of the final rule (Complete by January 31, 2021)

a) Regulated activities, such as licensing, construction and operation
b) Technical requirements, such as safety, security, emergency preparedness to protect against the radiological hazard
c) Administrative requirements, such as license change control and reporting
d) Licensing process, such as CP/OL, ESP/DC/COL, or new/modified processes

Step 3 – Create the Safety Paradigm (Complete by June 30, 2021)

a) Identify what can be learned/incorporated from previous/on-going efforts (e.g., NEI 02-02, LMP/TICAP)
b) Identify what can be learned/incorporated from other countries/international frameworks
c) Establish the safety criteria to meet the standard of adequate protection (e.g., dose limits, NRC Safety Goals)
d) Create a more modern and efficient safety construct (e.g., integrated approach, commercial QA)
e) Identify and address key policy or technical issues

Step 4 – Identify how to document the regulatory framework (Complete by September 30, 2021)

a) Determine scope, level of detail and structure of regulations versus guidance
b) Determine relationship with other Parts of the regulations, such as Part 20 and Part 100 (e.g., incorporate by reference, new language in Part 53)
c) Write the draft rule language

Step 5 – Develop the proposed rule (Complete by October 2022)

a) Complete the proposed rule
b) Develop any necessary guidance to accompany the proposed rule (note that some guidance may continue through the development of the final rule)

Predictable and Meaningful Stakeholder Interactions

We support the NRC's plan to rely on extensive stakeholder interactions in lieu of an Advanced Notice for Proposed Rulemaking or a Regulatory Basis. However, we also recognize that such an approach can be challenging given the relatively short amount of time allotted for this complex rulemaking. Therefore, it is important that the NRC clearly communicate to the public the opportunities for stakeholder interactions, including the purposes of those interactions – i.e., to convey information to stakeholders, to receive input or feedback from stakeholders, or to facilitate NRC-stakeholder dialogues on key issues. It is also important that the NRC identify far in advance the topics that are to be covered, so that stakeholders can adequately prepare for the meetings. The utilization of a systematic step-wise approach to the rulemaking would be useful in this regard, especially if the NRC overlays the stakeholder interactions on these steps.

To this end, we have established a special "Part 53 Task Force" to formulate industry positions and provide input to the NRC during this rulemaking. The NEI Part 53 Task Force will coordinate with, and includes a subset of members from, the NEI Advanced Reactor Regulatory Task Force. The NEI Part 53 Task Force recognizes the importance of the Part 53 rulemaking in ensuring that the final rule achieves the vision of being the most efficient and adaptable option for all new reactor applicants; meets industry needs for schedule, cost and predictability; and comports with congressional directives.

We look forward to working with the NRC on the Part 53 rulemaking. In accordance with the steps proposed above, this letter addresses Step 1.a (establish the vision and goals for the final rule, and the process steps for the rulemaking). Our plan is to provide input on Steps 1.b and 1.c in a letter after the NRC public meeting in November. If you have questions concerning our input, please contact me at 202-739-8131 or mrn@nei.org.

Sincerely,

Marcus Nichol

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