NUCLEAR INNOVATION ALLIANCE

August 31st, 2022
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Subject: Nuclear Innovation Alliance Comments on Preliminary Proposed Rule Language, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors" [Regulation Identifier Number RIN-3150-AK31; Docket ID NRC-2019-0062]

Dear U.S. Nuclear Regulatory Commission Staff:

The Nuclear Regulatory Commission (NRC) is continuing work to develop a risk-informed, performance-based, and technology-inclusive regulatory framework in 10 CFR Part 53 ("Part 53") to support the regulation and deployment of advanced reactors. We thank the NRC staff for their engagement and on-going solicitation of stakeholder feedback on the draft rule text.

Our comment provides the Nuclear Innovation Alliance's perspective on the status of the Part 53 rulemaking process as staff concludes public engagement on the draft rule text and prepares to finalize the draft rule for Commission review. Development of an effective risk-informed, performance-based, and technology-inclusive regulatory framework is critical to enabling the meaningful deployment of advanced nuclear reactors at scale and pace commensurate with meeting the climate challenge.

This comment focuses on how the use of existing regulatory precedent and overreliance on future revisions to advanced reactor regulatory frameworks will not satisfy needs of technology developers, utilities, other energy users, or the public. We need to pursue a revolutionary, holistic regulatory framework for advanced reactors that can enable the safe, effective, efficient, and widescale deployment of advanced nuclear reactors in the next two decades to help satisfy societal demands for clean energy. We believe that a process-based approach to Part 53 with multiple approaches, licensing methods, and operational programs (leveraging existing draft text) can support a Part 53 rule that meets all stakeholder needs and provides for a predictable performance-based, technology-inclusive, and risk-informed regulation of advanced reactors.

We again thank NRC staff and management for their on-going work to make Part 53 an effective regulatory framework that can enable the safe development and deployment of advanced reactors. If you have any questions, please contact me at pwhite@nuclearinnovationalliance.org.

Sincerely,

Patrick White
Project Manager
Nuclear Innovation Alliance

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NIA Public Comment on Part 53 Rulemaking Process

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Introduction

The 2019 Nuclear Energy Innovation and Modernization Act (NEIMA) directed what is now known as the Part 53 rulemaking process. One major provision in NEIMA was direction to the Nuclear Regulatory Commission (NRC) to "develop the expertise and regulatory processes necessary to allow innovation and the commercialization of advanced nuclear reactors."[1] This legislative direction was largely based on a desire by Congress to enable the development of advanced nuclear energy to help meet national clean energy and energy security needs. The existing regulatory processes for new nuclear reactor licensing in the United States were perceived as impeding the development and commercialization of innovative advanced nuclear energy technologies. NEIMA was intended to create new regulatory processes that would enable commercialization and deployment of advanced nuclear energy.

The creation of a new regulatory framework for advanced reactors has been described as a "once-in-a-generation" *opportunity*. Regulatory frameworks have direct and indirect effects on the design, construction, operation, and decommissioning of nuclear power plants. Regulatory frameworks affect investment decisions, business cases, and public perception of nuclear facilities. Most importantly, regulatory frameworks help ensure the safe design and operation of nuclear power plants. The opportunity to develop a new regulatory framework carries significant implications for the future of advanced nuclear energy.

The creation of a new regulatory framework for advanced reactors should also be described as a "once-in-a-generation" *challenge*. While the following factors result in a complex and sometimes contradictory set of objectives and constraints that NRC staff must address when developing the new regulatory framework, an ideal regulatory framework should:

- Enable the licensing of a diverse set of reactor technologies, use cases, and reactor sizes that may use innovative methods to either meet, or demonstrate compliance with, regulatory requirements.
- Be risk-informed and performance-based while enabling the efficient licensing of reactor technologies that range from reactor designs with tens of thousands of reactor-years of operating experience to reactor designs with minimal operating experience.
- Meet the needs of diverse stakeholders including advanced reactor developers licensing first-of-a-kind demonstration (FOAK) reactors, utilities or industrial companies licensing subsequent

[1] Public Law No: 115-439 (01/14/2019)

standardized designs, and civil society, each with a range of different priorities with respect to the safety, siting, and deployment of new nuclear reactors.

One of the current regulatory frameworks, 10 CFR Part 50 ("Part 50"), is an evolutionary product of decades of regulatory experience and incorporation of lessons learned from the design, construction, and operation of large light water reactors (LWRs). Rules for nuclear reactor design were codified to provide regulatory certainty for a rapidly expanding industry that sought predictability in the licensing and regulation of a single reactor technology (large LWRs). Rules for nuclear reactor operational programs were developed and modified over time based on an evolving understanding of LWRs and emergence of industry best practices for ensuring safe reactor operation. Other programmatic rules (such as emergency planning zones) and required methods for evaluating reactor safety (such as probabilistic risk assessment) reflected an evolving understanding of nuclear reactor safety and development of new methods to assess and characterize nuclear power plant safety. The cumulative result of thousands of reactor-years of light water reactor operating experience is a regulatory framework that enables the predictable (but not necessarily efficient) licensing of large LWRs through prescriptive and largely deterministic regulatory requirements.

The creation of the 10 CFR Part 52 ("Part 52") regulatory framework provided new regulatory pathways for licensing new nuclear reactors. The Part 52 framework was based largely on regulator and industry experience with the Part 50 regulatory framework. Part 52 focused on reducing repetitious regulatory reviews for subsequent deployment of standardized designs, increasing predictability of start-up and plant operations following reactor construction, and leveraging new risk information. Overall, Part 52 was intended to facilitate the more effective regulation of new standardized reactors. This approach was a significant departure from the Part 50 framework but retained many of the regulatory assumptions, technical requirements, and paradigms from the existing Part 50. Thus, Part 52 was a major evolutionary progression in nuclear reactor regulation but still retained many of the prescriptive and deterministic regulatory requirements for large LWRs.

The development of the Part 53 regulatory framework continues in the context of these previous evolutionary regulatory frameworks. In addition to the challenges associated with incorporating the views of a diverse group of rule stakeholders and a diverse set of use-cases and technologies into the Part 53 regulatory framework by the NRC staff, there is limited regulatory precedent for the creation and implementation of a performance-based, technology-inclusive, and risk-informed regulatory framework for a novel technology.

Discussion on Part 53 Rulemaking Process

The current Part 53 rule development process initiated by NEIMA directed NRC to create a new regulatory framework that enabled "innovation and the commercialization of advanced nuclear reactors". While the legislative direction is relatively simple and aligns with national priorities on clean energy, it is difficult to assess the adequacy of any proposed regulatory framework for Part 53 without first having a clear understanding of the desired outcome of the regulation.

The NRC staff were essentially tasked with developing a regulatory framework that could effectively and efficiently license any advanced nuclear reactor and fuel cycle, at any power level or size, and for any use case or deployment model. This regulatory framework needed to be developed with little precedent on how to license advanced reactor technologies and with limited operating experience for many of these technologies. There was also little modern regulatory precedent for this scope of rulemaking. NRC staff

would need to either develop novel regulatory processes or heavily leverage previous regulatory frameworks developed and optimized for large LWRs.

Pressure to complete the rulemaking process rapidly further complicated NRC staff's efforts to develop a new regulatory framework for advanced reactors. NEIMA directed NRC to complete the Part 53 rulemaking by 2027 but Congress and external stakeholders urged the Commission to commit to completing the rulemaking by 2025. Shortening the schedule give NRC staff less than 5 years to plan, develop, discuss, revise, and promulgate a novel regulatory framework applicable to all advanced reactors. This compressed schedule limited NRC staff's ability to incorporate advanced reactor operating experience, licensing lessons learned, and extensive regulatory engagement with potential applicants that would use the new rule. The shortened schedule helped decide the final rulemaking direction: NRC staff would leverage existing regulatory frameworks and initial industry-led efforts on advanced reactor licensing as the basis for the new Part 53 regulatory framework.

The proposed draft Part 53 regulatory framework is largely based on existing regulatory frameworks in Part 50 and Part 52 for large LWRs. While these existing frameworks have enabled the licensing and safe operation of the existing nuclear reactor fleet, they are evolutionary regulatory frameworks. The frameworks are the product of gradual incorporation of lessons learned, best practices, and new regulatory methods from decades of operating experience with large LWRs. These rules represent the evolutionary optimization of the regulation to a specific reactor technology and safety paradigm, but this selective optimization has limited the rule's applicability to different reactor technologies and alternative methods or paradigms for ensuring reactor safety. Initial industry-led efforts to develop advanced reactor regulations, specifically the Licensing Modernization Project (LMP), focused on the continued evolution of existing regulations to be applied to advanced reactor technologies. LMP and other recent efforts on advanced reactor rulemaking were designed to create a near-term pathway for licensing advanced reactors using the existing regulatory frameworks and paradigms but are inherently limited in impact because they are evolutionary and not revolutionary. These incremental regulatory framework changes will only result in incremental improvements for advanced reactor licensing.

The NRC staff's decision to utilize existing regulatory frameworks and initial industry-led efforts on advanced reactor licensing (e.g., LMP) as the basis for Part 53 is understandable given both the inherent challenges of development of such a broad regulatory framework, and the time and staff constraints associated with development of Part 53. The initial rulemaking efforts in 2020 appeared to align with industry interest and met the needs of other stakeholders interested in rapid development of new regulations for advanced reactors. The past two years of preliminary rule development, however, illustrate that an evolutionary approach to a new regulatory framework does not meet the needs of the wide variety of advanced reactor stakeholders and applicants interested in licensing advanced reactors using new regulations. The preliminary rule text and direction are simply a small step towards licensing novel advanced reactor technologies and use cases, while a giant leap forward in regulatory frameworks is needed to meet the underlying intent of NEIMA to enable innovation and the commercialization of advanced nuclear reactors to meet clean energy needs.

Historically, evolutionary development of regulatory frameworks aligned with the business cycles for nuclear energy. New nuclear energy projects were undertaken by state-owned or regulated utilities that could support long-term projects and revise regulatory strategies over multiple decades as power plants were designed, sited, constructed, commissioned, and operated. The regulatory environment was largely aligned with these long-duration deployment models, with regulators and industry incorporating lessons learned into their processes and operations. Today, the business model for energy production in the

United States has changed. Energy projects are brought online with shorter timelines and less tolerance for delays and cost overruns, as both public and private investors are less willing to take on financial risk. The public need to rapidly deploy clean energy to reduce greenhouse gas emissions puts additional pressure on clean energy projects to meet large-scale, cost-effective, and rapid deployment targets. These challenges put a new pressure on the regulation of advanced nuclear energy. There is not time to undergo the regulatory iteration cycle previously used to incorporate lessons learned and best practices gradually into nuclear regulations.

Advanced nuclear energy cannot take two decades and multiple generations of license applications to complete the evolutionary incorporation of lessons learned that could ultimately produce an effective Part 53 rule for advanced reactors. Use of the existing rule precedent and overreliance on evolutionary changes to advanced reactor licensing will not meet the needs of technology developers, utilities, other energy users, or the public. We need a revolutionary, holistic regulatory framework for advanced reactors that can catalyze the safe, effective, efficient, and widescale deployment of advanced nuclear reactors in the next two decades to help satisfy societal demands for clean energy.

Clarifying the goals of the Part 53 rulemaking

Development of a revolutionary Part 53 framework for licensing advanced reactors requires a clear statement and understanding of what an ideal Part 53 rule would accomplish. The simplest statement of the Part 53 regulatory framework objectives is based on the legislative direction from NEIMA to enable the innovation and the commercialization of advanced nuclear reactors while still ensuring the NRC's mandated provision of reasonable assurance of adequate protection. The main challenge is that the new Part 53 rule needs to enable innovation across a wide variety of reactor designs, reactor owner/operators, and business models. The rule should enable the flexible licensing of initial advanced nuclear energy projects, but also continue natural regulatory evolution going forward to more readily adapt to lessons learned without the need for additional rulemaking. The rule should also enable NRC staff and applicants to more rapidly iterate on licensing to incorporate regulatory lessons learned and operating experience with advanced reactors. These needs provide the broader context for characterizing the goals of the Part 53 rulemaking process.

Highlighting the variety of advanced nuclear reactor technologies and fuel cycle, power levels and size, and use cases or deployment models helps illustrate the immense scope of the Part 53 framework. The new Part 53 rule should be able to effectively and efficiently license a wide variety of use cases such as:

- Prototype 1000 MWe liquid-fueled molten salt reactor
- First of a kind (FOAK) 20 MWth TRISO-fueled high temperature gas reactor (HTGR)
- Manufacturing License for a 1 MWe heat pipe microreactor that would not be refueled but moved to a interim storage location at the end of its operational life
- Combined Operating Licenses for ten 20-MWe co-sited HTGRs
- Ten Construction Permits/Operating Licenses for a sodium fast reactor developed to support repowering of an existing coal power plant site
- Manufacturing License for a transportable microreactor that can be operated at multiple sites
- Standard design certification or standard design approval for FOAK or Nth of a kind (NOAK) reactors
- Construction Permit/Operating License for a Generation 3+ large light water reactor

Comparing and contrasting these different use cases for a single proposed regulatory framework reveals two important characteristics of a new Part 53 regulatory framework:

- Consistent performance-based requirements could provide a consistent level of safety for both existing reactors and advanced reactors with a range of fundamentally different safety approaches. A large liquid fueled reactor and a micro heat pipe reactor have few technical similarities to regulate but consistent performance-based requirements would provide a common set of requirements for both applicants and the regulator.
- The new regulatory framework should provide regulatory flexibility for novel FOAK reactors but enable predictability for subsequent standardized reactors. FOAK reactor licensing questions will differ significantly from NOAK reactor licensing questions and a new regulatory framework should accommodate both.

Satisfying these characteristics leads to two important insights about the safety analyses that should be performed under a new regulatory framework:

- Applicants should be able to choose how risk information is used to support the licensing of their technology. Reactors without significant operating experience may not be able to effectively utilize certain risk-informed methods to produce useful risk insights. Applicants may choose to use largely deterministic methods to demonstrate compliance with regulatory requirements and would not need detailed risk evaluation methods to develop simple but adequate risk insights.
- Applicants should be able to choose the methods used to demonstrate compliance with performance-based regulatory requirements. Applicable methods for demonstrating reactor safety will vary significantly based on the level of regulatory detail that applicants use to demonstrate compliance with performance-based safety requirements. A holistic approach to licensing that considers not just licensing and construction, but how operational programs and oversight are utilized, can also address inherent uncertainties present in the licensing process while providing reasonable assurance of adequate protection.

These characteristics and insights lead us to two framework requirements for a new Part 53 rule:

- A rule must achieve predictability through a clearly defined review process and not through design requirements, analysis methods, or operational programs. The small number of the example use cases provided above highlight that there are likely no common design features, analysis methods, or operational programs that are appropriate for all possible technologies licensed under a Part 53 rule. Developing predictability through design, methods, or programs will be infeasible so a focus on a clear review process should be a critical feature for rule predictability.
- A rule must enable applicants and staff to readily incorporate lessons learned for licensing that improve regulatory effectiveness and efficiency in between formal rulemaking activities. Staff must be empowered and encouraged to make evolutionary changes to guidance or processes to improve process effectiveness. Furthermore, staff need to be empowered and encouraged to have the ability to make a safety finding despite uncertainties in some areas if adequate technical justification is present in other review areas to support a finding of reasonable assurance of adequate protection. Clear communication of process changes, regulatory decisions, and changes to guidance can improve processes and help ensure predictability of a new rule.

This discussion and requirements now provide a conceptual framework for a successful Part 53 rule that meets the underlying needs for a new Part 53 regulatory framework. Part 53 must be a technology-

inclusive rule with clear regulatory processes that enable applicants to select the design features, analysis methods, and operational programs that demonstrate compliance with technology-inclusive, risk-informed, and performance-based regulatory requirements.

The rule framework should enable flexibility for reactor developers, owners, operators, and utilities with novel technologies, but provide more predictable but optional prescriptive regulatory requirements (at the cost of flexibility) for applicants that seek a more predictable licensing process. The rule would also allow advanced reactor technologies to satisfy the NRC's mandate to provide reasonable assurance of adequate protection. While the rule framework would initially be a revolutionary change from the existing paradigm of nuclear reactor licensing in Part 50 and Part 52, it should still enable regulatory evolution by efficiently incorporating lessons learned and best practices into regulatory processes as applicants and staff gain experience with the design, siting, construction, commissioning, and operation of advance nuclear power plants. This conceptual framework meets stakeholder needs, but this conceptual model should be reconciled with the current draft rule and process to help determine next steps.

Innovations and challenges in the proposed Part 53 draft rule text

NRC staff's proposed draft rule text is largely an evolutionary step forward from existing regulatory frameworks and follows initial industry-led efforts on advanced reactor licensing. While the proposed draft rule is not currently structured to provide the significant regulatory framework changes needed for innovative licensing of advanced reactors, it is a highly commendable first effort at solving a highly constrained regulatory development challenge. This proposed draft rule contains several provisions that point to NRC staff's ability to create more revolutionary regulatory pathways:

- The proposed draft rule text proposes performance-based regulatory requirements that are technology inclusive. Regulatory requirements (such as off-site public dose exposure) are inclusive of all advanced reactors and enable a uniform safety comparison between existing and new nuclear facilities. The extension of these requirements in the rule to acute (e.g., accidental release), chronic (e.g., routine releases), and cumulative hazards (e.g., integrated release risk) represent a comprehensive development of performance-based requirements.
- The rule's multiple pathways (Part 53 Framework A and Framework B) demonstrate the importance of allowing different regulatory methods to meet uniform risk-informed and performance-based regulatory requirements even though they use prescriptive methods and programs which may limit the regulation of some reactor technologies.
- The ability to use different types of risk information (an LMP-like methodology for a risk-leading license application or the Alternative Evaluations for Risk Insights (AERI) method) can facilitate the selection of licensing pathways that are more effective for a specific advanced reactor applicant.

While the proposed draft rule contains some regulatory innovations, the overall draft rule is still limited based on its overreliance on existing regulatory frameworks and paradigms. While the two proposed pathways are performance-based and largely eliminate the prescriptive design-based regulatory requirements in Part 50 and Part 52, they still achieve predictability by prescribing the methods and programs for demonstrating compliance with performance-based regulatory requirements. Thus, the use of prescriptive methods and programs limits the rule's applicability for at least some advanced reactor developers. Licensing would still be possible under Part 53 for any advanced reactor design (similar to advanced reactor licensing under Part 50 and 52), but would still require exemptions from prescribed

methods and program requirements instead of exemptions from prescribed design requirements. The draft rule relies on performance-based quantitative health objectives (QHOs), but demonstrating compliance with QHOs as a regulatory requirement necessitates detailed and extensive risk assessments that may be infeasible for novel technologies or applicants that use deterministic methods to demonstrate compliance with other regulatory requirements.

Overall, the proposed draft rule text falls short of the conceptual framework needed for a new Part 53 regulatory framework for advanced reactors. Schedule constraints, at least in part, led NRC staff to leverage existing regulation as the basis for Part 53, creating an evolutionary rule instead of developing a revolutionary rule that meets the underlying intent of NEIMA. While the proposed draft rule makes important advances in terms of use of performance-based requirements, multiple regulatory pathways, and varying uses of risk information, the new required prescriptive analysis methods and operational programs limit the rule's potential applicability and effectiveness. The proposed draft rule will provide some regulatory framework improvements from the existing regulatory frameworks in Part 50 and Part 52 by eliminating prescriptive design requirements, but it is unclear if the additional prescriptive analysis method and operational program requirements will result in a net efficiency gain for applicants. Refocusing the proposed draft rule text to meet a clear objective and understanding of what an ideal Part 53 rule would accomplish is critical to ensuring the rule development process can converge on a usable regulatory framework for advanced reactors.

Rethinking the Part 53 rulemaking direction

The Nuclear Innovation Alliance (NIA) believes that a process-based approach to Part 53 with multiple approaches, licensing methods, and operational programs can enable a Part 53 rule that meets all stakeholder needs and provides for a predictable performance-based, technology-inclusive, and risk-informed regulatory system for advanced reactors that protects public health and safety. The basis for the Part 53 rule should be uniform performance-based regulatory requirements that create a standard and consistent basis for evaluating advanced nuclear technology and enable applicants to select the methods used to demonstrate compliance with the regulatory requirements. A consistent regulatory basis helps ensure consistent regulatory treatment of nuclear technology under different frameworks, and directly links regulatory approvals with the NRC's statutory mission of "reasonable assurance of adequate protection".

Regulatory predictability can be developed through design requirements, method requirements, program requirements, or process requirements. Use of design, method, or program requirements can create barriers to the efficient and effective regulation of the wide range of technologies included in Part 53. Use of a clear regulatory process, therefore, can introduce regulatory predictability more generally by having clear stages for review and timely decisions on approval or changes. This process, however, has limitations since it can require duplicative and redundant reviews if applicants are demonstrating reactor compliance using well established designs, methods, or programs or if applicants are seeking subsequent licenses for a standardized design.

Optional predictability can be added to the advanced reactor licensing process by enabling use of pre-approved regulatory pathways in guidance to demonstrate compliance with the performance-based requirements. Regulatory approval of optional prescribed methods and programs can provide specific predictable licensing pathways without restricting flexibility or requiring regulatory exemptions for other applicants. Framework A and Framework B proposed by NRC staff in the draft rule text are virtually complete as optional pathways that would align with the needs of some potential applicants and provide

regulatory certainty, but are not necessarily suitable or optimal for all applicants. These first two regulatory frameworks are the first of a virtually unlimited set of methods or programs that an advanced reactor applicant could use to demonstrate that their design meets the technical and social requirements for nuclear power plant operation. Thus in NIA's view, Framework A and Framework B should be two options applicants could pursue, but they should not be the only options for licensing advanced reactors without use of regulatory exemptions. Subsequent regulatory guidance, technical reports, or additional formal rulemaking could be used by applicants or staff to detail and codify acceptable methods or programs for licensing that would provide additional regulatory certainty.

NIA believes that this process of making evolutionary changes to regulatory documents or processes based on regulatory and industry experience is critical to the long-term success of the Part 53 rule. As advanced reactors are constructed and operated, develop new use cases, and move from demonstration reactors to standardized commercial offerings, applicants and regulators can adapt their development and review of applicants under this proposed regulatory framework. Evolution of regulatory precedent and development of optional regulatory pathways would create more efficient and effective pathways for advanced reactor licensing. Enabling evolutionary changes within a transformative rule helps balance the needs of a variety of stakeholders and complements the natural iteration of regulatory frameworks as we gain operational experience with the novel technologies.

NIA's proposal leverages existing NRC staff work on prescriptive pathways while also enabling the applicants to take higher-flexibility but lower-certainty pathways to demonstrate that their technology meets the uniform performance based regulatory requirements. Additional details on NIA's proposal for a revised Part 53 regulatory framework can be found in NIA's November 2021 comment on the Part 53 rulemaking: https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML21321A284