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**Subject:** [External\_Sender] U.S. Nuclear Industry Council Comments on NRC's Rulemaking on "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors" (RIN-3150-AK31; NRC-2019-0062)  
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**ATTACHMENT CONTAINS THE COMPLETE CONTENTS OF THE USNIC PART 53 LETTER**

15 July 2021

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:** U.S. Nuclear Industry Council Comments on NRC's Rulemaking on "*Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors*" (RIN-3150-AK31; NRC-2019-0062)

Dear Mr. Tappert:

The Nuclear Regulatory Commission (NRC) is developing 10 CFR Part 53 to establish a much-needed technology-inclusive, performance-based, and risk-informed regulatory framework for new nuclear reactors in accordance with the direction of the Nuclear Energy Innovation and Modernization Act (NEIMA). The attached letter provides the perspective of the U.S. Nuclear Industry Council (USNIC), and the USNIC Part 53 Task Force, on selected topics related to the ongoing Part 53 rulemaking. USNIC represents approximately 80 companies engaged in nuclear innovation and supply chain development, including advanced nuclear reactor developers, manufacturers, engineering and construction companies, utilities, and service providers.

USNIC asks that senior level NRC leaders work with the NRC staff to craft a rule that meets reasonable assurance of adequate protection and enables the deployment of advanced reactors in an efficient process without creating new, unnecessary requirements.

**U.S. Nuclear Industry Council (USNIC)  
Part 53 Letter to U.S. Nuclear Regulatory Commission**

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Director, Division of Rulemaking, Environmental, and Financial Support  
Office of Nuclear Material Safety and Safeguards  
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Dear Mr. Tappert:

The Nuclear Regulatory Commission (NRC) is developing 10 CFR Part 53 to establish a much-needed technology-inclusive, performance-based, and risk-informed regulatory framework for new nuclear reactors in accordance with the direction of the Nuclear Energy Innovation and Modernization Act (NEIMA). This letter provides the perspective of the U.S. Nuclear Industry Council (USNIC), and the USNIC Part 53 Task Force, on selected topics related to the ongoing Part 53 rulemaking. USNIC represents approximately 80 companies engaged in nuclear innovation and supply chain development, including advanced nuclear reactor developers, manufacturers, engineering and construction companies, utilities, and service providers.

Stakeholder Engagement

USNIC commends the hard work undertaken by the NRC staff on the Part 53 rulemaking activities and applauds the departure from historical rulemaking practices that has permitted the staff to release multiple iterations of preliminary language to solicit stakeholder comments.

USNIC has been actively engaged in participating in NRC Part 53 public meetings, and attending NRC staff briefings to the ACRS and the Commission on Part 53 language and process. Previously, USNIC offered written alternative language to Subparts B and C (ADAMS Accession No. ML21035A003 provided 3 February 2021)<sup>1</sup>. USNIC also has provided input with slides, verbal comments, and other submissions about various elements of the rule, including draft Subparts A, B, C, D, E and F. Many industry comments have focused on removal of expanded scope beyond what is required in parallel portions of Part 50 and 52. USNIC emphasizes that the rule should not expand regulatory requirements for advanced reactors that qualify to use Part 53 without providing the supporting technical basis for the expansion. The NRC – not the industry – bears the responsibility for demonstrating the basis for any new requirements.

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<sup>1</sup> <https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML21035A003>

USNIC supports the recent stakeholder letter, “Unified Industry Position on the NRC’s Rulemaking on *Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors*,” dated July 14, 2021, which was co-signed by USNIC, the Nuclear Energy Institute (NEI), and a number of USNIC and NEI member companies.

### Results of USNIC Survey on Part 53

At the end of June 2021, USNIC conducted a survey of U.S. advanced nuclear reactor developer companies.<sup>2</sup> A usable Part 53 is important to the U.S. advanced reactor industry. Results of this survey relevant to the Part 53 effort are summarized below.

Survey Question	Advanced Developer Response
<i>How important is a usable Part 53 (that is flexible enough and without undue regulatory burden) to the U.S. Advanced Reactor Industry?</i>	
Essential for longer-term deployment of commercial Advanced Nuclear Reactors in the U.S. (i.e., industry may not survive without appropriate Part 53)	44%
Important for deployment of commercial Advanced Nuclear Reactors in the U.S.	30%
Desirable for deployment of commercial Advanced Nuclear Reactors in the U.S.	17%
Not critical as we can work within existing regulatory framework	9%
Not that important	0%
<i>How satisfied are you with the usefulness of Part 53 based on current language and explanations provided by the NRC?</i>	
Excellent	0%
Very satisfied	0%
Somewhat satisfied	41%
Somewhat dissatisfied and substantial changes are necessary	36%
Very dissatisfied	5%
Not helpful at all so far	18%
<i>Comment on Part 53 timing:</i>	
Would accept a delay in the development of Part 53 to ensure it meets the needs of industry and the regulator	71%
Prefer development of Part 53 on its current schedule	29%
<i>Comment on planned approach regarding the role and use of PRA:</i>	
Use of significant PRA input (similar to Licensing Modernization Project (LMP))	35%
Use of medium PRA input (similar to existing regulatory framework)	24%
Use of minor PRA input (similar to maximum credible accident approach)	29%
Another licensing methodology approach	12%

<sup>2</sup> Part 53 data presented (as of 2 July 2021) is from end of June 2021 USNIC Advanced Nuclear Survey that included responses from 17 USNIC members that are advanced nuclear developers and 7 non-USNIC members that are advanced nuclear technology developers.

Results of 2021 USNIC Advanced Nuclear survey are expected to be presented at the August 2021 NRC Advanced Reactor Stakeholders public meeting.

### Lack of a Roadmap and Clarity on Expectations of Safety

USNIC thinks the Part 53 process could be improved by having a clear written statement of the expectations, structure and objectives of the rule. That statement would provide reasons underlying what the NRC is attempting to accomplish in the rule, including purpose and intent of Part 53, and how they meet the intent of NEIMA. Without such a document, it is difficult to align on the key concepts and the reasons supporting them.

Additionally, there needs to be greater clarity regarding the Agency's expectation of how the rule will align with the requirement for reasonable assurance of adequate protection. This could be incorporated in Statements of Consideration, or perhaps in Subpart A language of Part 53 or as a separate formal supporting letter.

### Perspective on Rule Development

USNIC recognizes that the NRC at times may hear different opinions about aspects of the rule from different industry organizations and non-governmental organizations. However, industry is unanimous in wanting a rule that is useful, efficient, technology-inclusive, and risk-informed. Given the variety of technologies and broad nuclear industry interest, it is expected that there are some differences of views on how to achieve a useful, flexible, and efficient rule. USNIC will continue to work with developers, electric utilities, public interest organizations, other U.S. government agencies, and international organizations to establish consensus when possible.

On the topic of application of Consensus Codes and Standards, USNIC is encouraged by the openness for alternative approaches to satisfy, for instance, requirements similar to 10 CFR Part 50 Appendix B, and hopes that the openness to using alternative consensus codes and standards (rather than narrowly relying on a single acceptable code or standard) will apply to other topics. For example, the use of ISO Standards (e.g. 9001) could allow greater innovation and reduce excessive oversight cost.

Regarding the topic of security, the graded approach to security is thoughtful and consistent with the intent of Congress for Part 53. However, Part 73 modifications and guidance will be critical for a successful approach. NRC should reconsider the proposed entry criteria in draft §53.830(a)(2)(i), recognizing that in a recent public meeting NRC staff said no company could probably meet their current entry criteria. Furthermore, modifications also are needed in §73.100 to reflect the Part 73 Physical Security for Advanced Reactors rulemaking (forward progress on which is also critical).<sup>3</sup>

While USNIC supports the LMP-based guidance as an acceptable approach to meet regulatory requirements, USNIC also supports the use of other approaches to meet Part 53. USNIC's survey results show only 33% of developers plan to use the LMP approach at this time, and

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<sup>3</sup> [Federal Register :: Physical Security for Advanced Reactors](#), Docket ID: NRC-2017-022

many others are undecided. It is imperative that Part 53 does not preclude the use of other approaches in preparing the licensing basis for advanced reactor designs. This includes consideration for approaches that would make U.S. reactor designs easier to export, including those evaluated by the Canadian Nuclear Safety Commission, United Kingdom's Office for Nuclear Regulation, and the Nuclear Energy Agency. It is essential that Part 53 not establish requirements in a way that could inhibit, for example, future reciprocity agreements between UK, Canada, and U.S. nuclear regulatory agencies. This should include approaches that lean on historically acceptable methods of demonstrating safety, similar to the Maximum Credible Accident approach.

Lessons learned from recent applications and from pre-application engagements prior to finalization of the draft text of Part 53 should be incorporated to the maximum extent practicable to ensure the broadest scope of realistic design types and licensing approaches for advanced reactors are fully considered.<sup>4</sup>

Industry stakeholders have a common goal that regulating under Part 53 will be less burdensome over the lifecycle of activities (i.e., licensing, construction, operations, oversight) than regulating under the existing Parts 50 and 52. Part 53 must endeavor to be flexible and inclusive, and this should be accomplished through performance-based, rather than prescriptive, requirements. However, some of the NRC's preliminary Part 53 requirements are prescriptive and overly detailed, and we encourage the NRC to consider options to make language more performance-based where appropriate.

USNIC recognizes that urgency to complete Part 53 should not come at the expense of achieving the goal of creating a rule that will be used and useful. While the rule should proceed as expeditiously as possible, our 2021 survey results indicate over 70% of developers would accept a delay in issuing Part 53 if it means ensuring it meets needs of industry and the regulator.

USNIC has been consistent in voicing concerns with the current proposed rule language.<sup>5</sup> Several important topic areas are highlighted in greater detail below.

### Key Stakeholder Input on Topics of Interest within the Current Part 53 Language

#### *Probabilistic Risk Assessments*

The requirements for and application of Probabilistic Risk Assessment (PRA) is a complicated topic and one that is of utmost importance to USNIC members. We appreciate that NRC has shown more flexibility to allow an array of advanced reactor developers to take different licensing approaches. A graded PRA approach makes sense;<sup>6</sup> however, implementation guidance will be essential for understanding how the

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<sup>4</sup> Lessons Learned letters from industry include: ML20357A001 from Oklo, ML21050A431 from NuScale, and ML20353A393 from Nuclear Energy Institute

<sup>5</sup> 1 June 2021 NRC preliminary rule language

<https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML21148A062>

<sup>6</sup> Advisory Committee on Reactor Safeguards (ACRS) May 30, 2021 interim report to NRC Chairman on Preliminary Proposed Rule Language for 10 CFR Part 53, p. 2 & 5; ACRS is encouraged by the NRC's revision to the PRA

rule will be satisfied. USNIC understands that NRC and NEI are working on draft guidance. The development of satisfactory PRA guidance is essential to providing a useful and efficient rule. USNIC further understands that the NRC is actively considering a regulatory framework for advanced reactors using PRA in a supporting role, and considering how NRC might grade the scope and content of the PRA itself based upon several variables including the licensing stage, reactor design, and specific role of PRA in an application. The graded PRA approach also could be incorporated in future iterations of the non-light water reactor PRA standard currently being reviewed by NRC for endorsement.

PRA insights are important to the design of nuclear facilities in that they can identify capabilities and functions of systems to successfully mitigate off normal events. USNIC believes that, depending on the licensing process chosen, the design detail may not be sufficiently mature for the application of a PRA as currently required by the preliminary rule language. More specifically, a fully developed full scope PRA at the beginning of the licensing process may not be possible for applicants seeking a Construction Permit, may be unnecessary to demonstrate reasonable assurance of adequate protection for applicants seeking an Operating License or Combined Operating Licenses (OL/COL) for some licensing approaches, and is well beyond PRA requirements set forth in Part 50/52. For first-of-a-kind advanced reactor design the PRA must grow and mature with the design.

In the USNIC 2021 survey of advanced nuclear developers, for the question regarding the role and use of PRA, almost half plan on using only minor PRA input or an alternate licensing approach. In an alternative, a developer using LMP may use PRA consistent with the existing regulatory framework in terms of what goes into the application. Future discussion will be required as NRC presents a graded PRA approach, recognizing only a minimal PRA may be appropriate, particularly at the construction phase.

Part 53 should allow a variety of roles and uses of the PRA that are practical for the applicant's design and licensing approach, and PRA use should be at the discretion of the applicant. The term "graded PRA" is used for either a leading or confirmatory process, where the depth or completeness of the PRA is proportional to the estimated risk (the lower the risk, the less PRA needed). Part 53 should allow the PRA to be used in either a "leading" role (as established in NEI 18-04) or "confirmatory/supporting" role that has been found acceptable and historically used in the NRC approval of previous Part 52 applications. USNIC appreciates that NRC staff no longer seem to be using a PRA supporting a "risk-informed" process to require PRA in a leading role, and recognize many designs plan to use PRA in a confirmatory role. NRC has licensed reactors in the past with PRA used in a confirmatory role (e.g., AP1000, without using LMP) and the

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requirements and pursuit of a graded approach to PRA. They note that more work is needed in this area and offer some points for NRC's consideration. They express the goal of the graded approach to PRA is to enable flexibility in allowing multiple approaches; and are focusing on the main purpose of the PRA to provide a systematic search of events.

NRC should allow for both “leading” and “confirmatory/supporting” roles of the PRA in Part 53.

#### *ALARA*

USNIC members recognize ALARA (As Low as Reasonably Achievable) has been a tenet of sound radiological safety practices. Furthermore, USNIC members intend to continue those safety practices. However, the preliminary Part 53 language changes the means by which ALARA is implemented from one of a good practice to one of purported central importance for design criteria, and risks unreasonably broadening the definition of “safety related.”

As constructed, the language of the rule has no practical endpoint for additional measures, and it is left to negotiation between the NRC and the designer as to how much is good enough. The preliminary rule language is an example of where the rule is not efficient and does not improve safety because the safety objective for normal plant worker safety is already set by a different regulatory section within the rule. This leads to ambiguity. To address these concerns, Part 20 could be referenced rather than new provisions incorporated in the Part 53 rule as part of design criteria. Also the inclusion of ALARA as a mandate in the rule could result in further confusion beyond just NRC licensing proceedings under Part 53 as individuals attempt to provide a concrete definition for the term. USNIC looks forward to the NRC removing the unnecessary ambiguity of this provision in the next version of the draft rule language.

#### *QHOs*

Quantitative Health Objectives (QHOs) are not needed in the rule for making a safety case that a design provides reasonable assurance of adequate protection. The QHOs are used to establish acceptable radiological consequence criteria for events that are outside of the design basis of a facility. Further, if the QHOs are not met, then the staff expectation is that additional measures be provided to reduce the radiological consequences to within the QHO values. This is an expansion of scope of Part 53 beyond the parallel requirements in Part 50 and 52, because the construction of the preliminary language is such that the so-called Beyond Design Basis Events are actually within the design basis for the facility because of the provision to add additional measures that further reduce the radiological consequences of Beyond Design Basis Events if the QHOs are not met.

In addition, there is no NRC guidance as to how the assessments against the QHOs are to be performed nor guidance on the acceptable regulatory values that are to be used in the assessments. Surrogate criteria prescriptively based on LWR technology (and therefore incorporation of the QHOs) without a simplified metric would require each designer to develop their own surrogates and subsequently defend them. This potentially sets another moving target in review space. In the recent USNIC 2021 survey, 64% of companies did not feel QHOs were appropriate for inclusion in Part 53.

Furthermore, the current preliminary language suggests that the QHOs will have to be recalculated on some periodic basis as an ongoing requirement during the operations of the plant. If QHOs are required for making a safety case, the NRC should instead rely on approved plant programs to assure continued compliance once the design demonstrates that the QHOs are met. It is unclear why mitigative strategies for responding to Beyond Design Basis Events would be insufficient. For example, the NRC has accepted a coping time of 72 hours as sufficient for LWRs to bring additional onsite or offsite resources to bear on mitigating Beyond Design Basis Events. For advanced technologies with coping times much longer than the 72 hours, it seems unreasonable to establish a higher regulatory burden than the regulatory philosophy adopted for LWRs without a strong safety reason or evidence that offsite capabilities would not be sufficient.

Finally, the use of QHOs in the Safety Goal Policy statement provides the same benefits as having them in the rule and avoids the potential for unintended consequences. Also, there is no advantage in using the NUREG-1860 approach for integrated risk.

### *Quality Assurance*

Regarding QA, we are encouraged by the openness to alternative approaches to satisfy requirements similar to 10 CFR Part 50 Appendix B without narrowly relying on a single acceptable code or standard. Use of ISO Standards (e.g. 9001) could allow greater innovation, and reduce excessive oversight cost. Level of quality of commercially available components may meet and exceed prior “nuclear standards” without the need for the overly burdensome reporting requirements. Use of multiple consensus standards would allow more vendors in the supply chain, which should drive up quality and reduce costs.

### *Subpart F*

Some new programs (e.g. the Facility Safety program (53.890) and the Integrity Assessment Program (53.850)) appear, as written, to be redundant. These sections seem intended to include programs like the maintenance rule, inservice inspection (ISI), and inservice testing (IST) programs.

NRC staff stated in spring 2021 that Subpart F would enable significant reduction in operational burden as compared to Parts 50/52, based on increased regulatory burden in Subparts B and C. However, having now seen many portions of Subpart F, these benefits are not clear. The preliminary Subpart F language seems to result in increased regulatory footprint (burden), a limit on flexibility, and no enhancement to safety in comparison with Parts 50/52.

### *Decommissioning*

The staff should consider delaying the development and inclusion of the decommissioning portion of Part 53, or just including specific decommissioning requirements that are applicable at the initial licensing stage. This would allow the NRC and industry to focus their resources on the more near term portions of licensing (e.g., construction and operation) to ensure these portions of the rule are available sooner. Also, it would allow the NRC to complete its long-delayed decommissioning rulemaking and factor that information into Part 53.

### *Defense in Depth*

We appreciate that Defense in Depth (DID) is an important design philosophy in supporting an adequate safety case. We suggest that the rule allow sufficient flexibility for applicants to demonstrate how DID is provided. This should allow use of programmatic controls as an alternative to additional equipment.

### *Two tiers*

NRC staff proposed two tiers in the safety criteria (currently §§53.210 and 53.220). The USNIC position from the first draft was that the two tiers were unnecessary to ensure safety and were confusing. This view was recently supported by the recent letter report from ACRS<sup>7</sup> that found “no value in the two-tiered approach to safety requirements.” USNIC agrees with ACRS and still believes that the two tier safety criteria should be removed.

### *Reasonable Assurance of Adequate Protection*

In the most recent version of the proposed rule, the NRC changed the safety objective away from “reasonable assurance of adequate protection” to “a standard of immediate threat to public health and safety.” Such a change was made with little explanation or rationale for why the standard for safety was changed from the adequate protection standard that has served the NRC well since the early 1960s. Absent additional explanation, USNIC believes reasonable assurance of adequate protection must remain as the standard for safety.

### Going Forward

USNIC believes the NRC needs to articulate a clear vision and outline a roadmap for what is necessary for safety and how that translates into the rule – then engage with stakeholders to achieve approaches that demonstrate compliance with the safety requirements.

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<sup>7</sup> Advisory Committee on Reactor Safeguards, May 30, 2021 interim report to NRC Chairman on Preliminary Proposed Rule Language for 10 CFR Part 53, p.1

USNIC urges the staff to consider that higher level standards and simplicity could benefit the process. One size does not fit all – therefore, there needs to be a reasonable balance among predictability, prevention of imposing unnecessary burden, and flexibility, and all these attributes are possible using risk-informed, performance-based requirements. It is possible to have predictability in having specific and clear performance criteria for meeting the risk to the public that must be demonstrated, and flexibility in the means of demonstrating that these safety criteria are met.

The rule should enable the deployment of advanced technologies and should not impose burdens currently beyond Part 50 and 52 without providing the supporting technical basis for the expansion. More importantly, NRC bears the responsibility for demonstrating why new requirements are needed. It should not be the industry’s responsibility to demonstrate why new requirements should not be included.

In closing, USNIC asks that senior level NRC leaders work with the NRC staff to craft a rule that meets reasonable assurance of adequate protection and enables the deployment of advanced reactors in an efficient process without creating new, unnecessary requirements.

If you have questions regarding the above comments, please contact Cyril Draffin, Senior Fellow, U.S. Nuclear Industry Council ([cyril.draffin@usnic.org](mailto:cyril.draffin@usnic.org)).



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