RULEMAKING ISSUE

NOTATION VOTE

RESPONSE SHEET

TO: Tomas E. Herrera, Acting Secretary

FROM: Chair Hanson

SUBJECT: SECY-23-0021: Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31)

Approved __X__ Disapproved ____ Abstain ____ Not Participating ____

COMMENTS: Below ____ Attached __X__ None ____

Entered in STAR
Yes __X__
No ____

Signature
Christopher T. Hanson

Date 10/30/2023

Chair Hanson's Comments on SECY-23-0021, "Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors"

The Commission has an opportunity in Part 53 to set the NRC up for success with a reactor regulatory framework that is both innovative in its approach and in keeping with the agency's long history of safe and reliable regulation. Congress, industry, and the public expect a strong, independent NRC to continue to perform its public health and safety mission as the nuclear landscape changes and novel technologies arise. I see several overarching imperatives for this rule, including assurance of regulatory predictability, commitment to technology inclusivity, incorporation of risk-informed approaches, and maintenance of stakeholder confidence. The NRC can and should create a rule that supports innovation by both the regulator and the industry and while it provides reasonable assurance of adequate protection of the public. It is the responsibility of the Commission to give clear direction so that the staff can proceed with the rulemaking process and continue to incorporate critical stakeholder feedback that will make this framework successful.

The staff led a complex task of developing an all-encompassing, technology-inclusive rule for regulating future nuclear power plants while providing unprecedented levels of stakeholder engagement. Never has the agency engaged so early and so extensively with stakeholders. Rule language was shared openly and transparently, and the agency was met with feedback from multiple, different, and often conflicting perspectives. This has provided the Commission with a profound record of information that will help shape the direction of the agency's approach. While not every comment and consideration can ultimately be included, the rulemaking process is designed to allow the agency to proceed with critical input from entities seeking to use the framework in the future.

Background

Before turning to the substance of the proposed rule, I want to recognize the fortitude and commitment of the NRC staff in the face of unprecedented, withering, and, frankly, largely unmerited outside criticism. The staff was tasked with incorporating divergent feedback from stakeholders while adhering to Commission direction both in the form of past Commission Policy Statements and more recent Staff Requirements Memoranda (SRM) directly tied to the current rulemaking effort. Many of the decisions made by the staff with regard to the overall approach operate within the confines created by the extensive history that predates the current effort.

I reprise an abridged version of the history here to add context for the staff's proposal. The evolution of Advanced Reactor Policy at the NRC spans the better part of three decades. The staff does not set the policy of the agency, and they should not be chastised for following direction from the Commission. Despite the narrative that I have heard throughout this process, this was not a "blank sheet of paper" effort by the NRC staff—they respected long-standing Commission policy and direction on several issues that are now drawing ire from stakeholders. It is the Commission's responsibility to consider the framework that the staff has developed in light of this history and stakeholder input and ultimately provide responsive direction.

The Commission officially set the course for this rulemaking after passage of the Nuclear Energy Innovation and Modernization Act (NEIMA) (Public Law No: 115-439). But well before then, the Commission had started to look at probabilistic approaches for the identification of

licensing basis events as part of technology-inclusive licensing.[1] This trend toward incorporating probabilistic approaches into the agency's decision-making was based on longstanding Commission policy.[2] Shortly before I joined the NRC, the Commission unanimously approved the staff's recommendation to proceed with the use of a methodology incorporating probabilistic approaches as part of its implementation of NEIMA.[3] In its direction, the Commission specifically reminded the staff to closely adhere to agency policy, noting "[i]n its work on the regulatory framework for advanced reactors, the staff should continue to recognize that the Commission's established policy on the application of the safety goals and safety performance expectations provides an acceptable minimum safety standard for new reactors." Most recently, the Commission, during my tenure, expressed such confidence in the trajectory of the staff's approach to developing the rulemaking based on the established probabilistic methodology used in the Licensing Modernization Project that it directed the staff to forgo the Advanced Notice of Proposed Rulemaking process and proceed to develop the proposed rule currently before us.[4]

Summary of Policy Decisions

The staff proposes many strong attributes of a modern risk-informed regulatory framework and I approve the overarching rationalist approach in Framework A. However, there are several issues within the proposed rule that need course-correction before publication for further stakeholder feedback, which I briefly summarize here and fully explain below.

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[1] *See, e.g.*, SRM-SECY-03-0047, "Policy Issues Related to Licensing Non-Light-Water Reactor Designs" (approved the staff recommendation to modify the Commission's guidance to allow the use of a probabilistic approach in the identification of events to be considered in the new designs, provided there is sufficient understanding of plant and fuel performance, and deterministic engineering judgment is used to bound uncertainties). *See also*, SRM-SECY-06-0007, "Staff Plan to Make a Risk-Informed and Performance-Based Revision to 10 CFR Part 50" (approved the staff recommendation to issue an Advanced Notice of Proposed Rulemaking on approaches for making technical requirements for power reactors risk-informed, performance-based, and technology neutral).

[2] The 1986 Safety Goal Policy Statement presented an objective articulation of "how safe is safe enough" in terms of likelihood and individual health effects. It recognized the importance of severe accidents in regulatory decision-making and enabled the use of PRA for risk-informed regulation.

The 1986 Advanced Reactor Policy Statement (updated in 2008) expressed the view that advanced reactors "will provide enhanced margins of safety and/or use simplified, inherent, passive, or other innovative means to accomplish their safety and security functions."

The 1995 PRA Policy Statement encouraged increased use of risk-informed approaches within the agency; stating that the "use of PRA technology should be increased in all regulatory matters to the extent supported by the state of the art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy."

[3] SRM- 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." This effort led to the publication of Regulatory Guide 1.233 endorsing the industry-led Licensing Modernization Project, that could be implemented under the existing regulatory framework in parts 50 and 52.

[4] SRM-SECY-20-0032, "Rulemaking Plan on 'Risk-informed Technology-Inclusive Regulatory Framework for Advanced Reactors.'"

- I disapprove the inclusion of a second, structuralist framework (Framework B) similar to the frameworks currently captured in Parts 50 and 52. This additional framework adds unnecessary complexity and does not fit cleanly within Part 53. The staff should preserve its work on Framework B and consider it in another part of the Code of Federal Regulations after outreach to stakeholders.
- Codification of the quantitative health objectives is not warranted, and the staff should consider an alternative method of requiring development and use of a cumulative risk standard as part of Framework A.
- The agency's standard of "as low as reasonably achievable" for radiation protection should not be incorporated into design requirements because it does not properly account for the protection provided by Part 20 requirements during operation.
- The requirements for the facility safety program are burdensome and not necessary for Part 53.
- As recommended by several stakeholders considering the use of the new framework, the manufacturing license provisions should address fuel loading at manufacturing facilities in the proposed rule.
- Additional clarity is needed regarding how security events are to be considered for emergency planning zone sizing evaluations.
- Finally, Part 53 should reference Appendix B to Part 50 for quality assurance requirements.

The staff should make conforming changes to the proposed rule text, regulatory analysis, *Federal Register* notice, and any associated guidance to be consistent with the direction below before proceeding with the rulemaking process.

Part 53 Structure and Approach

Framework A

<u>The Advantages of a Rationalist Approach to Defense-in-Depth</u>

A regulatory framework based on a rationalist approach to defense-in-depth, implemented using risk-informed, performance-based principles and methods, can support effective and efficient regulatory approaches.[5] A rationalist approach applies probabilistic information to evaluate uncertainties and determine what measures should be taken to compensate for those uncertainties. In contrast, a structuralist approach relies on multiple barriers and strategies in the design and operation of a facility to compensate for uncertainties.

Parts 50 and 52 largely embody the structuralist view of defense-in-depth and are implemented with prescriptive and deterministic requirements. They continue to serve the Commission and the public well, but here we have an opportunity to codify a regulatory framework based entirely on a rationalist approach, implemented with risk-informed, performance-based requirements.

Currently, rationalist approaches are used in the Part 50 and 52 frameworks to focus isolated requirements on risk significance. For example, 10 CFR 50.69 and the risk-managed technical specification program reduce unnecessary conservatisms and provide operational flexibility through risk-informed requirements. In some cases, rationalist approaches have led to the

[5] ACRS letter to Chairman Jackson, "The Role of Defense in Depth in a Risk-Informed Regulatory System," May 19, 1999.

addition of requirements, as in the case of the station blackout rule in Part 50, which improved safety by considering the risk significance of an accident sequence previously thought to be bounded.

In Part 53 Framework A, the staff developed a logical and coherent risk-informed, performance-based framework, which allows applicants and licensees to justify an appropriate regulatory footprint throughout the plant life cycle from design and construction to operation. The rationalist framework implemented with PRA would allow both the regulator and applicant to focus on matters that are truly risk and safety significant. This is a substantial change for the NRC—but one that is steeped in history and experience to ensure continued protection of public health and safety.

PRA as the Backbone of Part 53

I also want to address the use of PRA as integral to Part 53 and the NRC's overall regulatory scheme for advanced reactors. In my view, the use of a well-established risk and reliability methodology such as PRA provides the regulatory confidence that will allow considerable flexibility in design, licensing, and operation. Quantitative understanding of risk-significance informed by PRA can provide the basis for regulatory approval and in turn, predictability for applicants and licensees.

However, some stakeholders are opposed to placing PRA in such a prominent role in the new regulatory scheme. There seems to be a perception that PRA development for advanced reactors will be too costly and outweigh its potential benefits. This line of reasoning does not reflect what we currently know about PRA development. PRAs for the simpler designs expected of many advanced reactor developers will likely be much less complex and therefore less costly to develop than PRAs developed for traditional large light water reactors. This line of criticism also focuses too heavily on the initial cost of developing a PRA to support licensing, and not enough on the cost savings associated with a well-defined and predictable regulatory pathway or the potential long-term benefits of developing a PRA for subsequent licensing actions.

Some stakeholders also argue that the lack of relevant operating experience for advanced reactors makes the use of PRA as a basis for Part 53 uncertain. I am not convinced that this argument has merit. PRAs with limited operating experience have been developed and used to improve safety. This was true of the original WASH-1400[6] and has been a consistent trend throughout the history of PRA. PRAs have always used generic data, including input from non-nuclear sources. Established guidance addressing PRA uncertainties is available and remains applicable. Much success was found in development of the non-LWR PRA standard, which involved extensive outreach to help ensure its usefulness. Several prospective advanced reactor applicants using the Part 50 framework are currently leveraging the Licensing Modernization Project, a PRA-based methodology that served as a precursor to the staff's development of Part 53.

With that said, I recognize that some industry stakeholders may perceive PRA standards as daunting. And I believe this hesitancy is based on a concern that the NRC staff will impose standards strictly and methodically without due consideration of the design at hand. PRA

[6] "Reactor Safety Study: An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants," WASH-1400, U.S. Nuclear Regulatory Commission, October 1975. WASH-1400 was a major step forward in the development and refinement of accident risk quantification and established the fundamental paradigm for all subsequent PRAs.

acceptability is determined through a holistic approach. In its current PRA reviews, the staff does not use the high-level and supporting requirements in industry consensus PRA standards as a punch list of acceptability. The implementation of Part 53 should be no different. The staff should continue to ensure appropriate flexibility in the approach to implementation of the PRA-led licensing pathway.

Industry stakeholders have also expressed concerns regarding the amount of PRA information that may be required to be submitted on the docket. As proposed, Part 53 will require applicants to include a summary of the PRA and risk insights necessary to support the NRC staff's safety findings. I agree with the staff's approach that additional detail supporting the PRA need not be submitted but should be available to the NRC staff for its review.

The staff continues to develop detailed implementation guidance that will assist applicants in understanding the scope and level of detail in the PRA that will be required for their design, as well as areas of flexibility. While there will inevitably be growing pains as the new framework comes into use for the first time, I am confident that Framework A anchored by PRA methods is the right path forward for the agency, the industry, and the public.

Ensuring Regulatory Predictability

I want to place special emphasis on the importance of providing sufficient detail in regulation to ensure predictability. An undefined rule would undermine many of our Principles of Good Regulation—efficiency, clarity, and reliability particularly—in the licensing and regulation of advanced reactors. The NRC conducts its regulatory activities to ensure reasonable assurance of adequate protection of public health and safety. If a goal for the rulemaking is efficient licensing, the rule must be structured in a way that allows the agency to reach its reasonable assurance finding in a consistent and predictable way. Lack of specificity in the rule also threatens to cause significant issues for enforcement. Further, the burden on inspectors to understand licensing bases that vary significantly from plant to plant would put tremendous strain on the agency and result in a weakened system of accountability and safety.

The idea that any approach is possible but no one approach is acceptable with certainty is antithetical to reliable regulation. Guidance is not regulation, and full-sail reliance on it is unworkable and not in the public interest. Not only does it create considerable consistency and enforcement concerns for the agency, but the NRC has an obligation to the public to clearly communicate the bases for its safety findings. Without an adequately structured rule, the standards applied in safety evaluations will be less transparent, and the public will have difficulty understanding the staff's reviews. This could also introduce litigative risks undermining efficient licensing and deployment of advanced reactors. The rule must ensure regulatory predictability and support the agency's ability to explain its safety determinations to the public it serves.

Framework B

Framework B Does Not Fit in Part 53

Notwithstanding the potential benefits of using a rationalist framework early in the rulemaking process, some stakeholders expressed concerns that not all applicants plan to develop and use PRA to the extent contemplated in the rule. Responding directly to this feedback, the staff developed a technology-inclusive version of Parts 50 and 52 within Part 53 called Framework B. This structuralist framework would require traditional design techniques such as the use of principal design criteria, the single failure criterion, and PRA in a confirmatory role.

Framework B also includes improvements such as the Alternate Evaluation for Risk Insights (AERI) concept that would allow an alternative risk evaluation to a PRA and the risk-informed seismic option.

I recognize the staff for their efforts in developing Framework B and appreciate their responsiveness to stakeholder concerns. However, a Part 53 with two fundamentally different regulatory philosophies unnecessarily adds complexity, duplicates requirements, and creates multiple sets of regulatory terminologies. In my view, the Commission directed the staff to develop Part 53 using a rationalist approach implemented with risk-informed, performance-based requirements in response to NEIMA. Framework A fulfills this direction and should stand alone.

Development of Options Paper for Framework B

To address stakeholder requests for a more traditional defense-in-depth approach, the staff should develop an options paper for the Commission to consider different applications for the staff's work on Framework B. This could include consideration of a technology-inclusive rulemaking to codify what is now known as Framework B in a different part of the Code of Federal Regulations, or it could take the form of improvements to currently existing Parts 50 and 52. This paper should consider the experience and insights gained through the Part 53 rulemaking process and include innovative concepts such as AERI and risk-informed seismic design. The paper should also incorporate relevant lessons learned from near-term advanced reactor experience evaluating the applicability of Part 50 and 52 requirements. Finally, as part of this effort, the staff should explore ways to improve compatibility with international safety standards such as use of common terminology. The staff should develop this paper within one year and propose timelines for potential future efforts that will cause neither a delay in the ongoing Part 53 rulemaking effort nor undue complications in ongoing advanced reactor licensing activities under Parts 50 and 52.

Areas of Specific Direction

Standard for Cumulative Plant Risk

An appropriate regulatory standard for cumulative plant risk should be included in a performance-based rule such as Part 53. Given the considerable flexibility Framework A provides with respect to design and operation, such a standard in the regulation will provide reasonable assurance of adequate protection with regard to overall consideration of risk in the design. This includes proper accountability of the potential for events to exceed the design basis.

The staff recommends codifying Quantitative Health Objectives (QHOs) as the cumulative risk standard in Part 53, and there has been considerable debate as to whether codification is appropriate. The QHOs are a well-established part of NRC policy and have enabled the use of PRA and risk-informed regulatory approaches for decades (e.g., Regulatory Guide 1.174, Reactor Oversight Process). They maintain consistency with the Licensing Modernization Project methodology and previous efforts to develop a technology neutral framework (e.g. NUREG-1860). Codification of QHOs in the rule would not preclude the use of surrogate methods, the most regularly used approach to cumulative risk in past applications that leverage current frameworks.

Yet I understand the challenges that would result from codifying QHOs in the rule rather than retaining them as policy. Since 1986, the QHOs have represented the base standard for agency consideration of cumulative risk despite not being codified. Enshrining the QHOs as the exclusive metric for establishing a cumulative risk standard in Part 53 may introduce an unnecessarily inflexible requirement where a broader standard could be used to meet the same need.

I therefore conclude that the QHOs should not be used as the exclusive cumulative risk standard in the new framework. Instead, I propose that the rule require applicants to define a cumulative plant risk metric that will ensure an acceptable level of radiological risk to the public. The QHOs will continue to act as the agency's base standard through the 1986 Safety Goal Policy Statement, and applicants will not be precluded from using the QHOs as part of their design. To ensure that this requirement does not introduce uncertainty with regard to agency acceptability, I propose that the rule language require the metric to have been previously approved by the NRC. This will avoid a scenario in which an applicant proposes a methodology that the staff finds unacceptable late in the application process. This is not to say that the metric must be approved by the NRC before Part 53 is effective; rather the methodology should be approved before an application is submitted. Applicants can leverage topical reports and the NRC endorsement process to assure that their cumulative risk standard meets the NRC's requirement.

Therefore, the staff should revise Part 53 to require applicants and licensees to define a cumulative plant risk metric, previously approved by the NRC staff, that ensures an acceptable level of radiological risk to the public. Further, the staff should clarify in the preamble that this risk metric is intended to be at least as protective as the Commission's approach described in the 1986 Safety Goal Policy Statement.

Finally, I want to address the concern from some industry stakeholders that the NRC may treat the cumulative risk metric as an instantaneous "speed limit" and take enforcement action if it is exceeded. This is not the purpose of a cumulative risk metric, which is intended to be a licensing requirement that facilitates integrated decision-making during operation. The staff should revise the preamble or the rule language as appropriate to remove any ambiguity that the cumulative risk metric will be enforced as a real-time risk monitor.

Design Requirements for ALARA

Consistent with the Commission's policy on advanced reactors, developers are encouraged to consider ALARA at the design stage of the project. However, I find requiring consideration of ALARA at the design stage to be unnecessarily burdensome because it does not consider the interface of Part 20 requirements and operational programs. To a large extent, it is up to designers and operators to determine who ultimately bears the burden of meeting those requirements. Reasonable assurance of adequate protection is assured through the application of ALARA and other Part 20 requirements at the operational stage. While it benefits designers and operators to consider ALARA early in the process, I see no need to enshrine a design requirement to do so. Therefore, the staff should delete ALARA-related design requirements from Part 53.

Facility Safety Program

The staff proposes a facility safety program, which is a risk-management program to assess new knowledge that may affect the facility risk profile, such as operating experience and updated hazard information, on an ongoing basis. The program would require licensees to take appropriate risk-reduction measures, if necessary. Currently, the NRC carries out much of this responsibility through the agency's Generic Issues Program and other regulatory processes. The proposed facility safety program would effectively shift this burden to the licensee.

Conceptually, given the risk assessment infrastructure that will be required of licensees using the new framework, requiring licensees to assume responsibility for some of the NRC's Generic Issues Program has some appeal. In particular, the staff has noted the potential efficiency of dealing with new issues through this approach and for agency cost savings if a significant number of licensees materialize in the future.

However, I find the overall cost effectiveness of the proposal to be uncertain, and the potentially extensive effort required of licensees to develop, implement, and maintain the program at the front end raises concerns. The NRC will continue to review changes to external hazards and leverage insights from operating experience to provide the necessary mechanism for reasonable assurance of adequate protection. Therefore, the staff should remove the proposed requirements associated with the facility safety program from Part 53.

Fuel Load Provisions for Manufactured Reactors

In an earlier iteration of the draft proposed Part 53, the staff included specific provisions that would allow fuel load into the reactor at the manufacturing facility, including requirements for criticality prevention and details for the content of an application. The staff subsequently decided to remove these provisions from the draft rule and elected to elicit stakeholder feedback on the topic. I understand the novel issues associated with factory fuel loading and staff's preference to obtain additional stakeholder feedback on the matter before including specific provisions in the rule. However, several microreactor designers seek regulatory clarity on this issue and I see the benefits of using the public comment mechanisms of the proposed rule to continue the conversation. Therefore, the staff should include factory fuel load provisions in the draft proposed rule and incorporate any information or feedback received through its interactions with stakeholders.

Consideration of Security in Emergency Preparedness

Emergency preparedness is the last line of defense for protecting public health and safety. The NRC, industry, and other stakeholders acknowledge that security is a critical part of emergency preparedness. I see a connection between the physical security requirements in Part 53 and the final emergency preparedness rule for small modular reactors and other new technologies (EP rule).[7] The EP rule includes provisions for scalable emergency planning zones (EPZs) based on radiological risk, but it does not explicitly address how security events are to be considered. For future reactors, security events may not always be bounded by the radiological safety analysis. Therefore, the staff should work with stakeholders to develop appropriate guidance for addressing security events in EPZ sizing evaluations.

[7] Staff Requirements Memorandum - Affirmation Session - SECY-22-0001: Rulemaking: Final Rule: Emergency Preparedness for Small Modular Reactors and Other New Technologies, August 14, 2023.

Quality Assurance/Appendix B

Finally, I agree with Commissioner Caputo's approach to addressing quality assurance requirements in Part 53. Referencing Part 50 Appendix B in lieu of including a nearly identical set of requirements in Part 53 is appropriate. This would avoid unnecessary duplication of requirements and minimize impacts on nuclear suppliers that may provide safety-related equipment or services to Part 53 applicants and licensees. Therefore, the staff should provide appropriate revisions to Appendix B and Part 53 consistent with this direction.