

Review of the Draft Proposed Part 53 Rule Language

December 6, 2022

Background

The foundation for 10 CFR Part 53 began in 1999 after the U.S. Nuclear Regulatory Commission (NRC) established a foundational policy for developing risk-informed, performance-based regulations.¹ Twenty years later, the Nuclear Energy Innovation and Modernization Act (NEIMA) of 2019 mandated these early aspirations be codified into a rule “to develop the expertise and regulatory processes to allow innovation and the commercialization of advanced nuclear reactors”² as defined in the Act and “to realize the environmental, economic, and national security benefits of these advanced nuclear technologies.”³ Specifically, NEIMA gave the NRC the following mandate:⁴

Not later than December 31, 2027, the Commission shall complete a rulemaking to establish a technology-inclusive, regulatory framework for optional use by commercial advanced nuclear reactor applicants for new reactor license applications.

Part 53 is the backbone of that regulatory framework. NEIMA further defines a technology-inclusive framework:

The term “technology-inclusive regulatory framework” means a regulatory framework developed using methods of evaluation that are flexible and practicable for application to a variety of reactor technologies, including, where appropriate, the use of risk-informed and performance-based techniques and other tools and methods.

In response to NEIMA, the NRC staff developed a rule development plan⁵ to achieve the milestones established by Congress. In November 2021, the Commission approved⁶ the NRC staff’s request for

¹ [Staff Requirements Memorandum for SECY 98-144](#), “White Paper on Risk-informed and Performance-based Regulation

² Public Law 115-439, January 14, 2019. <https://www.congress.gov/bill/115th-congress/senate-bill/512/text>, Section 2

³ *Id.* at p.2

⁴ Public Law 115-439, January 14, 2019. <https://www.congress.gov/bill/115th-congress/senate-bill/512/text>, Sec 103(a)(4).

⁵ See ADAMS Accession Number: ML20288A251.

⁶ See Proposed Rule. “Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors.” 86 FR 70423.

a nine-month extension “to address... significant areas of disagreement... identified by... stakeholders who are investing time and money to develop new reactor designs.”⁷ The NRC staff proposed a “novel, iterative process” to resolve those disagreements.⁸ Congress supported this extension to achieve alignment, writing, “We agree that reaching alignment with external stakeholders on the scope and details of the proposed rule is essential to ensure a better product.”⁹ Nevertheless, on February 4, 2022, members of Congress noted “NRC must be prepared to license and oversee the development and deployment of the designs” and requested the General Accounting Office (GAO) to “undertake a review to assess the NRC’s preparedness to review and approve applications for advanced nuclear reactor designs.”¹⁰

On September 30, 2022, the NRC staff submitted the current draft of Part 53 and other supporting documents in a rule package.¹¹ The package included the Statements of Consideration (which contains the NRC staff’s reasoning on various decisions), the two Frameworks (or licensing pathways), and other guidance documents. The comment period for the preliminary Part 53 rule language closed on August 31, 2022 — one month before the current draft of Part 53 was published. As such, stakeholders were not able to provide feedback on the most current version of the rule. The NRC staff has continued to revise the rule language since the public release of the rule package. One example is a change to the Alternative Evaluation for Risk Insights (AERI) entry condition at the ACRS meeting on November 2, 2022.

The Advisory Committee on Reactor Safeguards (ACRS) has been involved in the entire Part 53 development process. The ACRS has submitted five letters to the Commission commenting on Part 53. Most recently, the full committee convened to discuss the Part 53 draft rule language from November 1-4, 2022, which resulted in the fifth letter to the NRC Commission.¹² Overall, the committee deemed the draft text “adequate to solicit public comments.”¹³ Specifically, they found Framework A to be a viable framework that gives reactor developers a technology-inclusive and performance-based path for licensing.¹⁴ The ACRS withheld judgment on Framework B, saying

⁷ NRC ADAMS Accession Number: ML22040A354, p. 2.

⁸ *Id.* at p. 2

⁹ *Id.* p. 2

¹⁰ February 4, 2022, Letter to GAO

¹¹ NRC ADAMS Accession Number: ML22272A034.

¹² ACRS letter ADAMS Accession Number: ML22319A104.

¹³ *Id.* at Page 1.

¹⁴ *Id.*

that significant changes may still occur in that specific Framework as it continues to evolve.¹⁵ The Staff is not required to reply to comments from the ACRS or external stakeholders; however, the Staff has replied to ACRS comments¹⁶ and not stakeholder comments. The ACRS has brought up some of the issues raised in this Whitepaper. For example, the ACRS expressed reluctance about the inclusion of QHOs in the draft rule in its fourth letter to the Commission on Part 53.¹⁷

Major topics of concern

Quantitative Health Objectives (QHOs)

Quantitative Health Objectives (QHOs) have been included in the draft proposed Part 53 as a cumulative risk measurement since the NRC staff began developing proposed rule language. QHOs specify a threshold of risk relative to other accidents that the general population is exposed to, and cancer fatality risk from all other non-nuclear causes. The cause of cancer in the general population is not measurable in the short term with statistical confidence and, at best, difficult to measure in the long term^{18,19} As a result, QHOs are not a readily observable or ascertainable metric that could be utilized by licensees to monitor their radiation protection performance. Currently, QHOs are only safety goals intended to “provide guidance to the NRC staff on how the existing regulations may be modified, and on how new regulations should be considered;”²⁰ QHOs are not regulatory requirements. The Commission has, on several occasions, upheld and clarified that QHOs are to remain safety goals and are not to be included in regulations.²¹ Stakeholders, ACRS members, and even Commissioners have expressed concern about the inclusion of QHOs in the rule.

¹⁵ *Id.*

¹⁶ See “RESPONSE TO THE ADVISORY COMMITTEE ON REACTOR SAFEGUARDS, ‘FOURTH INTERIM LETTER ON 10 CFR PART 53 RULEMAKING LANGUAGE.’ ” ADAMS Accession Number: ML22249A073.

¹⁷ ADAMS Accession Number: ML22196A292 at Page 4.

¹⁸ For more information see: Stein, A. (2022, January 31). *Quantitative Health Objectives in a Performance-based Regulation*. Retrieved from

<https://s3.us-east-2.amazonaws.com/uploads.thebreakthrough.org/Whitepaper-Quantitative-Health-Objectives-in-a-Performance-based-Regulation.pdf>

¹⁹ This is further shown by the NRC’s abandonment of a National Academies study on this topic. Information on this study can be found on the NRC public website at:

<https://www.nrc.gov/reading-rm/doc-collections/fact-sheets/bg-analys-cancer-risk-study.html>

²⁰ SECY-00-0077, ADAMS Accession Number: ML003684288 at Page 4.

²¹ See, for example, SECY-00-0077 accessible at: <https://www.nrc.gov/docs/ML0036/ML003684288.pdf>

The NRC staff state that the inclusion of the QHOs in the rule is necessary to ensure that when the deterministic requirements in the existing frameworks are removed, the cumulative risk from the facility is below the safety goals. This is inconsistent with current practice compared to the NRC-endorsed LMP methodology for use with the existing Part 50 and 52 frameworks, from which Framework A of Part 53 was developed. The safety goals are not included in Part 50 or 52.

One ACRS member has proposed new surrogate goals for each type of reactor, as opposed to QHOs. However, this approach may reduce the efficiency of the licensing process because a surrogate metric would have to be developed and endorsed by the NRC for each design prior to submitting an application. Otherwise, the development of a surrogate metric would hold up the acceptance and review of that application. The development of design-specific surrogate metrics has the potential to increase review time and reduce regulatory predictability.

Facility Safety Program (FSP) in Framework A

The Facility Safety program would require biennial safety reviews of all new information to assess whether plant changes are required. The NRC staff continues to defend this new program claiming that it is a benefit to applicants. However, the industry worries that it circumvents back-fit protections and will continually force unwarranted operational standards and expectations for licensees. Stakeholders have requested on multiple²² occasions that the NRC staff clarify its position by providing a high-level example to illustrate how the FSP could be a benefit, but the NRC staff has not provided such an example.

As Low As Reasonably Achievable (ALARA)

Framework A and B require the design to achieve doses that are As Low As Reasonably Achievable (ALARA). In the past, ALARA has been an operational practice and not a requirement. ALARA is not a clear and defined performance metric. Framework B specifically defines ALARA as:²³

... as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety and other societal and socioeconomic considerations, and in relation to the use of atomic energy in the public interest.

²² See, for example, ADAMS Accession Number: ML22209A004 at Slide 16.

²³ Framework B. §53.4730(a)(11)(i).

This definition can be interpreted in various ways or change over time, creating regulatory uncertainty rather than reliability.²⁴ For example, in the past, regulators have revised the dollar value per person-rem used in ALARA assessments.²⁵

The language in Part 53 moves beyond considering ALARA as an operational practice by including design features. The draft states:²⁶

A combination of design features and programmatic controls must, to the extent practical, be based upon sound radiation protection principles to achieve occupational doses that are as low as is reasonably achievable....

This effectively subjects the entire plant design to a subjective ALARA requirement for which there is no finite standard. The NRC staff have stated that their intention is to apply ALARA in Part 53 the same way that it is applied in Parts 20 and existing licensing frameworks. However, the rule text states otherwise. The ACRS previously identified this subjectivity and expressed concern about “where does the designer stop?” in relation to adjusting design features to minimize dose. The ACRS asked the NRC staff how a developer could determine that this requirement is satisfied.²⁷ The NRC staff maintains that by allowing licensees to consider various societal and socioeconomic factors, the inclusion of ALARA would allow for greater flexibility.²⁸

Alternative Evaluation of Risk Insights (AERI)

The AERI methodology is contained in a regulatory guidance draft that was published in conjunction with the draft proposed Part 53.²⁹ The AERI methodology is intended to simplify the safety analysis by eliminating the need for a PRA for reactors that meet limiting entry requirements defined in Framework B. It is unrealistic to assume that a reactor would restart every year after annual bounding events. As currently drafted, AERI is impossibly conservative in terms of bounding event selection and event frequency, by assuming a bounding event occurs every year of operation. The staff state this assumption is used to eliminate reliance on PRA to

²⁴ Reliability is a Principle of Good Regulation.

²⁵ See ADAMS Accession Number: ML22053A025.

²⁶ Framework B. §53.4730(a)(3). Emphasis added.

²⁷ ADAMS Accession Number: ML22172A092 at p. 116-117

²⁸ ADAMS Accession Number: ML22272A036 at p. 39-40.

²⁹ ADAMS Accession Number: ML22272A045

justify a postulated event frequency. However, it is physically not feasible to have a bounding event at a reactor, repair or rebuild the reactor, and resume operation every year. Similarly, this frequency assumption contravenes NRC policy and practice. If a reactor experienced a bounding event, the NRC would likely take enforcement action and provide close oversight.³⁰ This level of oversight would continue until the NRC approves the reactor restart.

The one bounding event per year frequency is in contradiction with the calculations the staff provided in stakeholder meetings.³¹ These calculations assume one event, resulting in a maximum dose to an individual of 27.5 rem. If the frequency of one bounding event per year is used in AERI, the dose would be cumulative over the operational lifetime of the plant, resulting in a much greater dose and exceeding the prescribed risk threshold. For the calculations presented by the NRC staff to be mathematically correct, the AERI methodology would need to be revised to a frequency of one, not one per year.

Deterministic and prescriptive provisions

The Part 53 rule is mandated to be risk-informed and performance-based. A risk-informed performance-based approach would allow for different requirements and special treatment of safety systems and programs, depending on the risk significance of the hazard relative to a specific design.

However, some portions are deterministic and prescriptive. This is in part because large portions of the draft proposed Part 53 rule were either copied from Part 50 or 52, or reference sections of Part 50 or 52. Some examples of deterministic provisions can be found in the treatment of safety systems and components in design requirements. As part of the determination of reactor safety, a variety of hazards are considered (including incidents involving seismic activity, fires, and others). Some reactor safety systems and components are designed specifically for use in only one of the incidents above, yet these components must be protected from hazards or conditions during which that component is not needed. Additionally, deterministic requirements are present as design requirements, some of which are prescribed programs. For example, protection from multiple hazards must deterministically be designed to generally accepted codes and standards, address degradation due to aging, develop and protect functional design criteria,

³⁰ See Inspection Manual Chapter 0350

³¹ ADAMS Accession Number: ML22172A091 at p. 49-55

evaluation of defense in depth, and more. The ACRS expressed similar concerns that the deterministic requirements stating that this approach historically “...result in too many systems being classified as important to safety, but later found in the PRA to not have major risk significance.”³² The ACRS recommended optimizing the “safety footprint” in a design, which would have major benefits for both the licensee and the regulator by keeping the focus on risk-significant components.

Rule structure

The draft rule is currently designed with two separate licensing pathways. Framework A in the draft proposed Part 53 rule was designed to mirror the Licensing Modernization Project (LMP). LMP is intended to risk-inform the existing licensing frameworks, Part 50 and 52, not to innovatively design a new rule that is risk-informed and performance-based at the core. Framework A relies on the Probabilistic Risk Assessment (PRA) to evaluate risk. Many stakeholders have objected to the requirement of a formal PRA as unduly restrictive, not appropriate for all designs, and would not result in a safety benefit. Framework B is largely a duplication of Parts 50 and 52, but mostly technology-neutral. The NRC staff proposed the Alternative Evaluation of Risk Insights (AERI) to provide an option that satisfies the Framework B requirements without the need to perform a PRA.

Many stakeholders have indicated that a single framework that defines high-level performance objectives should be used, and the specific pathways in the NRC’s draft frameworks should be moved to guidance.^{33, 34} This will simplify and focus the rule on the criteria that licensees need to meet. This approach could provide additional flexibility by removing details that could preclude future innovations while still providing regulatory certainty. The NRC Staff has maintained that including more specific requirements in the rule improves predictability and that the rule is already sufficiently flexible and technology-neutral.³⁵

³² ACRS letter ADAMS Accession Number: ML22319A104.

³³ For example: Nuclear Energy Institute comment accessible at ADAMS Accession Number: ML22243A257.

³⁴ Franovich, R., Kadambi, N. P. (2022, September 20). *Former nuclear regulators propose an alternative approach to preliminary 10 CFR part 53*. The Breakthrough Institute. Retrieved December 8, 2022, from <https://thebreakthrough.org/press/release-former-nuclear-regulators-propose-an-alternative-approach-to-preliminary-10-cfr-part-53>

³⁵ See ADAMS Accession Number: ML22301A107.

The Draft Proposed Part 53 Does Not Satisfy Requirements in NEIMA

The Congress directed the NRC in NEIMA to develop a technology-inclusive regulatory framework that is risk-informed and performance-based. The NRC staff maintains that the proposed draft rule meets the mandate of NEIMA. However, the draft proposed rule does not sufficiently allow for innovation and commercialization. The nuclear industry says it is unlikely to use the draft rule, based on an anonymous survey done by the Nuclear Energy Institute and the U.S. Nuclear Industry Council.³⁶

The most recent draft proposed Part 53 text is not entirely technology-inclusive and is not fundamentally risk-informed or performance-based. In some areas, it is closer to risk-based than risk-informed because specific risk thresholds are set, and some requirements are not determined based on risk significance. The inclusion of QHOs is one example of how the draft proposed Part 53 is moving closer to risk-based than Part 50, and introducing requirements that are incompatible with a performance-based regulation.

Conclusion

The NRC staff was granted a 9-month extension to reach alignment with stakeholders. However, the NRC staff has not resolved stakeholder concerns about several key topics and acknowledges this fact by including questions in the draft rule to elicit public input on the concerns. The NRC staff has stated that it intends to send the draft rule, with the included concerns, to the Commissioners to receive direction. As it stands, the draft of Part 53 requires further improvements to ensure that the vision of NEIMA is fulfilled.

³⁶ NRC ADAMS Accession Number: ML22130A523, Slides 52-95.