

RULEMAKING ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: Carrie M. Safford, Secretary

FROM: Commissioner Crowell

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

Approved X Disapproved X Abstain Not Participating

COMMENTS: Below Attached X None

Entered in STAR

Yes X

No

Signature

Commission Crowell’s Comments on SECY-23-0021, “Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31)”

Introduction

The NRC is at an inflection point in its regulatory posture for licensing nuclear reactors. The agency has a long and well-established history of licensing nuclear reactors and successfully overseeing their safe operation. However, as we look ahead, the next generation of nuclear power reactors will be very different from our existing fleet of large, light-water reactors. Recent advancements in nuclear technologies have set the stage for a new generation of nuclear power reactors utilizing non-light-water technologies and advanced fuels, with smaller, more compact reactor designs and enhanced safety features. Helping fuel this evolution in nuclear technology and engineering is the growing recognition that expanded nuclear generation capacity will be an essential component of achieving our collective energy security and carbon-reduction goals—both in the U.S. and globally.

Indeed, Congress has recognized and supported the impending commercialization of new and advanced reactors in its passage of the Nuclear Energy, Modernization, and Investment Act of 2019 (NEIMA),¹ and in subsequent legislation to incentive deployment of new nuclear reactors, including the 2022 Inflation Reduction Act² and recent infrastructure investment legislation.³

As a result, the nuclear industry has signaled its intention to seek new licenses for the design, manufacturing, construction, and operation of new, advanced reactors before the end of this decade and beyond. Therefore, it is incumbent upon the Nuclear Regulatory Commission to be fully prepared to handle this anticipated influx of reactor applications based on new, novel nuclear technologies and designs. To succeed, the agency must quickly transition to providing a more modern regulatory model that can effectively accommodate licensing a variety of new reactor technologies and designs with significant differences from the current operating reactor fleet. Thus, it is at this juncture that we, the Commission, have both the opportunity and responsibility to enable the transformation of the NRC’s regulatory framework for a new age of nuclear reactor licensing. This is no small task. To meet this moment, the NRC must establish a modern, technology-inclusive regulatory framework for advanced reactors that is clear, usable, and efficient, while maintaining the NRC’s long record of success in protecting public health and safety.

First, I want to acknowledge the incredible effort by the NRC staff to develop a comprehensive, technology-inclusive, risk-informed, and performance-based draft proposed rule for Commission consideration. The process used for the development of this rulemaking package was as novel, challenging, and complex as the substance of the rule text itself. The staff’s development and public issuance of preliminary proposed rule language on an iterative basis enabled an unprecedented level of stakeholder engagement, and offered a transparent window into how the NRC goes about its work. I thank the NRC staff, industry, non-profit organizations, and members

¹ Nuclear Energy Innovation and Modernization Act, Pub. L. No. 115-439 (2019).

² Inflation Reduction Act of 2022, Pub. L. No. 117-169 (2022).

³ Infrastructure Investment and Jobs Act, Pub. L. No. 117-58 (2021).

of the public for engaging in this process and for their genuine dedication and helpful input on this rule.

I appreciate the Chair's acknowledgment in his vote of the challenges the NRC staff faced throughout the preliminary proposed rule development, while adhering to the NRC's principles of good regulation and long-standing Commission policy on numerous issues that were of significant concern to stakeholders. I understand stakeholders did not always feel heard, particularly when the NRC staff was at times unable to respond in real time to the input received or did not agree with proposed changes. I can see why this process yielded some frustration, and there are many lessons to be learned from this novel rulemaking process. However, I do think the early and frequent engagement on this important rule was valuable. I hope that the NRC will continue to build upon its wealth of rulemaking knowledge and will continue to enhance and refine its public engagement procedures.

Overview

My colleagues helpfully outlined in their respective votes the many decades of relevant technical and regulatory history, so I will not reiterate that history here. However, I do think it is important to further highlight recent actions that set the stage for the NRC undertaking this rulemaking to modernize its reactor licensing framework. First and foremost, in 2019, Congress passed NEIMA, directing the NRC to develop a "technology-inclusive, regulatory framework" for new reactor license applications. NEIMA defines "technology-inclusive, regulatory framework" as one that is "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." Acknowledging this direction from Congress, the NRC staff developed a draft proposed rule that utilizes probabilistic, innovative approaches, in tandem with traditional, deterministic approaches. Following the passage of NEIMA, the Commission approved the staff's rulemaking plan for Part 53 to build upon ongoing advanced reactor licensing activities such as the industry-led Licensing Modernization Project (LMP).⁴ Since then, the tides have changed, and support for using the LMP to inform Part 53 has waned. However, I see value in retaining key elements of this approach, with several modifications that I address below.

In addition, I agree with Commissioner Wright that the NRC staff should take another look at the status of other NRC advanced reactor rulemakings, guidance development, and licensing activities, given the time that has passed since the draft proposed rule arrived at the Commission. The staff should take a holistic look at these activities and their schedules, identify key attributes (e.g., differences in scope, applicability, objectives), analyze any possible inconsistencies or areas of overlap, and provide an overview to the Commission. In doing so, the staff should provide monthly CA briefings regarding their progress on implementing the direction provided in the Staff Requirements Memorandum. I also appreciate Commissioner Caputo's thorough and extensive editing, as well as Commissioner Wright's novel, high-level thinking—I encourage the NRC staff to review and consider their proposed edits and table of typographical errors and inconsistencies, as appropriate. Lastly, the NRC staff should provide the revised proposed rule to the Commission at least ten business days prior to its submittal to the Office of the Federal Register for publication.

⁴ Staff Requirements – SECY-20-0032 – Rulemaking Plan on "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)".

The timing of this rulemaking is critical to establishing a successful path for timely review of new reactor designs. While the NRC has established it can license advanced reactors today under the existing Part 50 and 52 frameworks, doing so would necessitate numerous exemptions from certain requirements that are generally not applicable to non-LWRs. Similarly, using existing regulatory pathways for advanced reactors will likely require time-intensive, case-by-case reviews of individual applications that would forgo regulatory predictability, stability, and efficiency.

Unfortunately, time is a luxury we have precious little of. The dual imperatives of enhancing energy security while rapidly reducing carbon emissions demand we move expeditiously and thoughtfully. The international community is likewise moving quickly to expand low-carbon nuclear energy capacity—in both developed and developing nations, and in many nations looking to build nuclear power capacity for the first time. The United States has long been viewed by many in the international community as the “gold standard” of safely regulating civilian nuclear power plants. But to maintain U.S. leadership in nuclear technology and regulation, while maximizing the economic benefits of expanding global nuclear power production, we too must move quickly. The NRC will be critical to overall U.S. success—and a major first step is developing a thorough, well thought out, predictable, and, perhaps most importantly, usable rule for new reactors. As such, I approve the NRC staff’s overall approach with several clarifications and changes set forth below. The staff should also revise the proposed rule preamble and associated draft guidance and make other conforming changes as necessary to implement the clarifications and changes set forth below.

Structure and Approach for Part 53 Frameworks A and B

I appreciate the staff’s efforts to develop a comprehensive rule offering a broad, holistic approach intended to accommodate distinct performance-based and deterministic licensing pathways, otherwise known as Frameworks A and B, respectively. While this construct made logical sense as a starting point, in developing a dual framework approach the draft proposed rule quickly became excessively large and, at times, unwieldy and unnecessarily complex. This outcome stood in contrast to what many stakeholders, including Congress, expected. Part 53 must provide a flexible, clear, efficient, and technology-inclusive means for licensing new and advanced reactors while ensuring safety and security. Likewise, my goal for Part 53 is to establish a useable technology-inclusive rule for applicants that will eventually become the preferred licensing process for advanced reactors. While I appreciate the extensive work that went into developing a deterministic pathway in a short period of time in response to previous stakeholder interest in a more traditional licensing approach, I acknowledge the subsequent stakeholder feedback that a single framework is preferred.⁵ As Commissioner Caputo pointed out in her vote, the Advisory Committee on Reactor Safeguards (ACRS) expressed the same concern over the complexity of the dual frameworks.

Therefore, I join Chair Hanson and Commissioner Caputo in finding the two-framework approach overly complex, and in need of rethinking. For these reasons, Framework B should be removed from the proposed rule. Instead, in the interest of retaining the significant and useful

⁵ Breakthrough Institute, “The Nuclear Regulatory Commission Should Consider Stakeholder Consensus on Part 53 Major Topics,” Nov. 2, 2023. <https://thebreakthrough.org/issues/energy/the-nrc-commission-should-consider-stakeholder-consensus-on-part-53-major-topics> (hereinafter referred to as “BTI 2023 letter”).

work that went into drafting Framework B, the staff should develop an options paper for the Commission to consider placing Framework B in a different part of the Code of Federal Regulations, such as using Framework B when undertaking future rulemakings to make technology-inclusive improvements to Parts 50 and 52. At least one option should consider the legal and technical extent to which such provisions could be located in guidance and the regulations refocused to be higher-level performance requirements. This paper should consider the experience and insights gained through the Part 53 rulemaking process and include innovative concepts such as the alternative evaluation for risk insights (AERI) and risk-informed seismic design. The paper should also incorporate relevant lessons learned from near-term advanced reactor licensing experience evaluating the applicability of Part 50 and 52 requirements. The staff should also explore ways to address compatibility with international safety standards such as use of common terminology. The staff should develop the paper within one year and should 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.

Regulatory Predictability

Identifying the appropriate balance between regulatory flexibility and certainty is an age-old debate for regulators. I acknowledge the logic behind Commissioner Wright's proposal to move significant portions of the rule into guidance, and, while I would retain more specificity, I similarly propose to streamline and simplify many aspects of the proposed rule. Specifically, as described below, I support flexibility, such as allowing an applicant to propose their own cumulative risk metric for certain types of licensing basis events. However, while I agree that guidance is the backbone of implementing NRC regulation, regulatory predictability is vitally important to avoid time-intensive, case-by-case licensing reviews and to ensure enforceability. Strategically incorporating regulatory predictability for key elements of Part 53 will likely facilitate a more efficient review process for NRC staff. For example, regulatory direction will help avoid instances where the NRC staff, in review of a proposed design, is challenged, or unable, to make a safety determination because certain fundamental design information was not required by rule, only non-binding guidance. While this can be overcome through other mechanisms for engagement with an applicant, doing so on a case-by-case basis will likely be less straightforward and efficient than adopting requirements for fundamental safety information into the underlying regulation. Similarly, without requiring applicants and licensees to perform and maintain an evaluation of licensing basis events, the NRC may have difficulty obtaining such an evaluation, and an even harder time reviewing an application to make a safety determination without such an evaluation.

By striking a strategic balance of regulation versus guidance in Part 53, a more efficient license review process can be achieved. This would be accomplished by establishing regulatory predictability for fundamental safety information while avoiding an overly burdensome rule through development of comprehensive guidance to facilitate an efficient, informed application review process that still prioritizes adequate protection of public health and safety. While the NRC could start with a blank slate and codify regulations in the future on an ongoing basis, I believe the agency has a sufficient understanding today of basic safety elements appropriate for inclusion in all reactor applications to adopt such requirements directly into the proposed rule. I believe such a strategic, blended approach is exactly what Congress intended in NIEMA when

directing the NRC to establish a modern, efficient, technology-inclusive rule for commercial advanced nuclear reactors.

Furthermore, I agree with Chair Hanson's vote that such a balance would benefit the public interest through preserving key opportunities for public engagement and maintaining an appropriate level of accountability and transparency in NRC decision-making. Below, I work to strike the right balance to afford maximum flexibility, while also ensuring public confidence, regulatory predictability, and enforceability. From this starting point for Part 53, the NRC can continue to learn and further refine its licensing frameworks.

Use of Probabilistic Risk Assessment

In 1995, the Commission issued a policy statement that encouraged the use of probabilistic risk assessment (PRA) methods for nuclear regulatory activities.⁶ The Commission stated that it believed that the use of PRA should be implemented in a consistent and predictable manner to promote regulatory stability and efficiency, and 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. The Commission also explained that PRA methods have been applied successfully in several regulatory activities and have proved to be a valuable complement to deterministic engineering approaches. I likewise believe that PRA methodology can be implemented in a consistent and predictable manner for new and advanced reactors that will continue to promote regulatory stability and efficiency as well as enhance safety. The staff's proposal is consistent with the Commission's PRA policy—the proposed rule would increase the use of PRA while maintaining a complementary role for traditional deterministic approaches and consideration of defense-in-depth.

Part 53 presents a new opportunity for risk-informing licensing and oversight of new and advanced reactors. The use of risk insights and quantitative understanding of risk information from a PRA, in combination with other generally accepted approaches for systematically evaluating engineered systems, would allow for a holistic approach to risk. Nonetheless, it should be recognized that the development of new PRA methodologies for advanced designs could be different from the current state-of-the-art practices utilized for traditional large light-water reactor designs. The NRC must embrace the evolution of such practices as it gains more experience over time with the Part 53 licensing process.

Indeed, Congress articulated this expectation when it directed NRC to develop a "technology-inclusive regulatory framework," which Congress defined to mean "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.*"⁷ Risk-informed techniques necessarily integrate both probabilistic and deterministic methods—in other words, risk-informed regulations look at both the *probability* of an event and its possible consequences. I believe a solely deterministic, qualitative method of performing and applying a risk assessment would be inconsistent with Congress's direction in NEIMA.

⁶ Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement, 60 Fed. Reg. 42622, Aug. 16, 1995.

⁷ Pub. L. No. 115-439 § 3(14) (emphasis added).

That said, I acknowledge concerns raised by some stakeholder that the use of PRA for advanced reactors could, in the near-term, be burdensome and present uncertainties due to current knowledge and data gaps with new designs, availability of sufficient data, and initial lack of operating experience.⁸ Industry stakeholders have expressed concerns regarding the amount of PRA information that may be required to be submitted on the docket. As proposed, Part 53 would require applicants to include a summary of the PRA and risk insights necessary to support the NRC staff's safety findings. To further address this concern, the staff must allow for broad flexibility in determining the appropriate PRA scope, level of detail, and use of "realistic approaches" in future applications.⁹ I understand this presents a challenge for both the agency and the applicant. This use of PRA necessitates an understanding of the strengths and limitations of the models and uncertainties. As with the current practice, the staff should continue to use appropriate flexibility in its evaluation of PRA in a licensing application. The idea of scaling the scope of the PRA with the design is described in existing guidance such as the LMP, which states in relevant part:

The scope and level of detail of the PRA models align with the state of definition of the design, the safety design approach, and systems design concepts. As the design matures and more design information becomes available for different types of risk evaluations, the scope of the PRA can be broadened to address other plant conditions and progressively confirm the plant capability to meet safety objectives.

Given the simple systems, inherent characteristics, and minimal possible public health hazards expected of many non-LWR designs, especially those with low power levels, the PRA complexity necessary to support decision-making and an application should be much less complex than for operating LWR plants.¹⁰

The LMP further explains, in relevant part, "as the design matures, the scope and level of detail of the PRA is expanded, and it is used to help support design decisions along the way."¹¹ I support this understanding of scaling PRA scope and technical adequacy, also known as "fit for purpose,"¹² and I believe this idea of an iterative and appropriately scoped PRA should be carried into Part 53.

The PRA should continue to be a key element of the new Part 53 regulatory framework. However, consistent with the statements above from the LMP, the staff should develop or expand PRA guidance or the preamble for Part 53, as appropriate, to provide appropriate clarity and flexibility in determining PRA acceptability and to assist applicants and the NRC staff in determining the appropriate detail in the PRA that would be required for a Part 53 application.

⁸ See, e.g., NEI Public Comment on Part 53 Preliminary Proposed Rule Language, Feb. 11, 2021 (ML21042B889).

⁹ See SECY-23-0021, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," Mar. 1, 2023, Enclosure 4, at 47.

¹⁰ Nuclear Energy Institute (NEI), NEI 18-04, Rev. 1, "Risk-Informed Performance-Based Technology-Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," issued August 2019, at 23 (referred to as the "Licensing Modernization Project" and endorsed by NRC Regulatory Guide 1.233, Rev. 0, June 2020).

¹¹ *Id.* at 19.

¹² *Id.* at 23 ("Reactor designs with small radionuclide inventories, few SSCs, and inherently safe responses to upsets may employ simple, yet fit-for-purpose PRAs"); see also NRC Regulatory Guide 1.247, "Acceptability of Probabilistic Risk Assessment Results for Non-Light-Water Reactor Risk-Informed Activities," Mar. 2022 (for trial use).

The staff should apply the “fit for purpose” and “minimal PRA” concepts from sources such as the LMP in the Part 53 PRA guidance. This guidance should not only allow for the use of current PRA methodologies as set forth in existing NRC-approved standards and practices but should also allow for new PRA approaches (“newly developed methods”) consistent with the design and features of advanced reactors, which will likely utilize less-complex designs and incorporate new passive safety systems. This is a significant departure from the existing reactor fleet and therefore the PRA guidance should accommodate more straightforward and reliable PRA modeling methods.

I recognize that Framework B was intended to provide the deterministic approach that, along a risk-informed continuum, would allow for the use of more qualitative, deterministic inputs. I believe a rule that fully accommodates both deterministic and quantitative approaches could only be written at such a high level that it will ultimately be unworkable and fatally deficient in regulatory predictability, accountability, and enforceability. So, recognizing that Framework A relies on the PRA to inform most of the risk insights in the rule, it is important to also understand that there is still a role for deterministic information in Part 53—in a supporting role to the probabilistic analysis, as well as in the evaluation of defense-in-depth and design basis accidents, among other examples. To that end, the proposed rule language in section 53.450(b) would allow for the use of the “PRA in combination with other generally accepted approaches for systematically evaluating engineered systems.” The staff should further clarify in guidance the manner and extent to which deterministic, bounding, qualitative approaches to risk insights may be used in combination with quantitative, probabilistic approaches in Part 53.

A Cumulative Risk Metric

The staff proposes two safety criteria, one that would apply to design basis accidents (DBAs) and another that would apply to licensing basis events (LBEs) other than DBAs. These two safety criteria would fit into a larger framework of performance standards in the proposed rule’s integrated decision-making process. The staff proposes that the safety criterion for LBEs other than DBAs would serve to establish connections among human actions, the design of safety-related structures, systems, and components (SSCs), programmatic controls, and a broader set of potential internal and external hazards and would also address certain defense-in-depth matters. This criterion would not apply to the evaluation of DBAs, but rather would solely apply to LBEs other than DBAs and the SSCs that support such events. In this way, the rule would limit the scope and application of this criterion to certain events but would integrate the evaluation of this criterion into the broader Part 53 safety framework.

The staff proposes to codify a specific cumulative risk metric as the safety criterion for LBEs other than DBAs, based on the quantitative health objectives (QHOs) described in the NRC’s policy statement, “Safety Goals for Nuclear Power Plant Operation,” dated August 4, 1986 (51 FR 28044), as corrected and republished August 21, 1986 (51 FR 30028) (Safety Goals Policy Statement). As stakeholders have articulated, this would amount to a codification of existing Commission policy.

Some stakeholders have raised concerns about whether this codification of Commission policy is necessary. While I understand these concerns, I would also have concerns if an applicant or licensee could not satisfy existing Commission policy, which ensures that new reactors attain

the same level of safety as current reactors.¹³ Put another way, if an applicant is going to meet the QHOs regardless, there may not be a significant difference between codifying the QHOs by rule versus retaining them as policy. Given the value of regulatory certainty, I understand the reasoning behind the NRC staff's proposal to codify.

Stakeholders also highlight that Parts 50 and 52 did not include a specific cumulative risk measure but rather addressed this issue via policy, implying that Part 53 would be more burdensome in this regard. In practice, Parts 50 and 52 do not need a codified cumulative risk measure because those frameworks instead rely on a system of deterministic, prescriptive requirements that, taken together, provide the safety case. By contrast, Part 53 would be performance-based, and thus, for example, would not prescribe specific types of events that plants must be able to withstand. For this reason, I believe promulgating high level safety standards for Part 53 is both necessary and prudent, while preserving appropriate flexibility for applicants to define their LBEs and characterize their SSCs in a manner that demonstrates the high-level standards are met.

I recognize the challenge is not whether a safety criterion is necessary in this context, but rather the identification of the appropriate specificity and type of criterion to adopt. The ACRS helpfully weighed in on this point, stating in its November 2022 letter on Part 53, "There are limitations of the existing [QHOs] to fully capture the value and risk of nuclear technologies and the large uncertainties associated with evaluating individual and societal risk. This could inhibit flexibility and opportunities for more innovative approaches as the regulator and applicants learn from new nuclear technologies and associated missions."¹⁴ Subsequently, in the June 9, 2023, Commission meeting, ACRS Member Dr. Petti articulated a slightly different approach, stating that incorporating QHOs in the rule text would not establish a more stringent safety level, but instead would provide advanced reactors ample margin to meet the goals.¹⁵ Dr. Petti further stated, "the argument for putting it in the rule has more to do with having a metric to assure an equivalent level of safety to what's there in 50 and 52. That, without it, there's a hole, and the staff might feel compelled to put in additional requirements that could be—well, that could be more difficult to make a technology neutral as such."¹⁶

Another concern some stakeholders raised is that demonstrating satisfaction of the cumulative risk measure on an ongoing basis would be challenging, if not impossible. On this point, I agree with the Chair that the cumulative risk measure is not a "speed limit" but rather is intended to be a licensing requirement that facilitates integrated decision-making during operation. I further agree that the staff should revise the preamble, or the proposed rule language itself, as appropriate, to remove any ambiguity that the cumulative risk metric will be enforced as a real-time risk monitor.

That said, and as stated previously, I believe the most important element of establishing a cumulative risk metric is striking the appropriate balance of regulatory flexibility and

¹³ Policy Statement on the Regulation of Advanced Reactors, 73 Fed. Reg. 60612, Oct. 14, 2008.

¹⁴ ACRS, Nov. 22, 2022, letter report, "Final Letter on Draft 10 CFR Part 53 Rulemaking Language" (ML22319A104).

¹⁵ Commission meeting transcript, June 9, 2023, at 59 (ML23171B031).

¹⁶ *Id.* at 60.

predictability, while also ensuring we meet our public health and safety mandate. While other cumulative risk measure ideas have been explored at great lengths, there is no perfect answer in this regard—for example, defining surrogate risk metrics for every design would be challenging, as stakeholders recently and consistently noted.¹⁷ Thus, in the effort to balance regulatory flexibility and clarity, I agree with all three of my colleagues that including the QHOs in the proposed rule as a sole risk metric is not prudent at this time. Instead, I agree with the Chair that the rule should require applicants to define a cumulative plant risk metric that will ensure an acceptable level of radiological risk to the public, and that the rule language should require the metric to have been previously reviewed or approved by the NRC. I further agree that the staff should clarify in the preamble that this applicant-defined risk metric is intended to be consistent with the Commission’s safety approach as described in the 1986 Safety Goals Policy Statement.

However, one key pitfall of this applicant-defined approach is the potential to inadvertently undermine important opportunities for public engagement. Defining a specific, high-level cumulative risk measure by rule would afford the public an opportunity to comment on the proposed metric and require the NRC to consider such comments. In contrast, under this applicant-defined approach, an applicant would likely use a topical report or similar guidance document to submit a risk metric, which under current NRC procedures would not afford the public an opportunity for comment. Instead, the first official opportunity for public engagement on the risk metric would be when the applicant submits its application and the NRC issues the notice to the public of an opportunity to intervene, which provides for participation in an adjudicatory process rather than the more familiar and less burdensome public comment process. Since the risk metric is of great significance in the NRC’s evaluation of a reactor design’s LBEs that are not DBAs, this lack of up-front public engagement gives me significant pause, particularly in the context of preserving and expanding the “social license” to safely regulate and operate commercial nuclear reactors. Additionally, not having a high-level risk metric codified into regulation potentially opens the risk metric to adjudication on every license application—because guidance documents are not covered by the restriction on challenging NRC rules and regulations concerning reactor licensing in adjudicatory proceedings.¹⁸ This could subject both the agency and applicant to resource-intensive adjudicatory proceedings to resolve safety contentions that intervenors may file on the risk metric, and therefore necessitate resolution on a case-by-case basis through administrative and judicial adjudicatory proceedings.

I see several possible remedies to resolve many of these concerns. First, the NRC could issue for public comment the proposed applicant-defined cumulative risk metric. While this isn’t required by the Administrative Procedure Act because these would be guidance documents,¹⁹ this approach would nonetheless provide an important opportunity for the public to weigh in on the risk metric. Second, the NRC could voluntarily, as a matter of best practice, hold public meetings with the public and applicant to discuss the cumulative risk measure that would be used for evaluating LBEs that are not DBAs in the design. Third, the NRC could voluntarily adopt a practice of codifying, retroactively after an application is processed, the cumulative risk metrics previously utilized in Part 53 licensing so that future applicants could utilize those risk metrics and the public could then participate via public comment. This approach could be similar to the design certification process but would be limited to creating a codified repository of approved cumulative risk metrics for use by future Part 53 applicants. Lastly, another solution could be to codify the QHOs as an optional, alternative cumulative risk metric that an applicant

¹⁷ BTI 2023 letter at 7.

¹⁸ 10 CFR § 2.335.

¹⁹ Administrative Procedure Act, 5 U.S.C. § 553(b) (1946).

could use instead of defining their own metric. This option has the benefit of providing the public an opportunity to comment on the QHOs in this rulemaking outside of the adjudicatory process.

I acknowledge that each of these options has benefits and challenges. Weighing each, I come out in favor of a combination of several of the above options—the staff should both hold a public meeting and also issue for public comment all licensee-submitted cumulative risk metrics and associated draft NRC safety evaluations or other guidance documents that would be used to review or approve a cumulative risk metric. In this way, the guidance would benefit from transparency and public input, similar to how the NRC’s regulatory guides are treated, which also undergo public notice and comment. While not codified, and therefore not shielded from litigative risk, I believe this approach strikes the appropriate balance of regulatory flexibility and clarity, without undermining public engagement and safety. In addition, I believe the NRC needs to codify cumulative risk metrics over time once the agency and industry have licensing experience with cumulative risk metrics as applied in Part 53 licenses. I envision that this library of codified Part 53 cumulative risk metrics could be placed in an appendix that might look something like the collection of codified design certifications in Appendix E to Part 52. The staff should evaluate how this future codification could be executed. Finally, the staff should define the term "cumulative risk metric" in the Part 53 proposed rule to facilitate a common understanding of this foundational concept.

ALARA

The principle that offsite releases and doses to plant employees should be “as low as is reasonably achievable” (ALARA) is enshrined in NRC regulations in 10 CFR Part 20. These operational requirements are incorporated in the draft proposed rule in 10 CFR 53.260(a) and 53.270(a). I am encouraged that each of my colleagues preserve the applicability of these Part 20 standards to licensees under Part 53.

In my view, the use of ALARA should be consistent with its use in 10 CFR Parts 50 and 52. To that end, the staff should retain in the proposed rule the requirement for applicants, including, for example, applications for design approvals or design certifications, to demonstrate how effluent releases will be limited consistent with 10 CFR 50.34a.

While I agree with the Chair in general that ALARA for offsite releases is best addressed through requirements for operations, it is important for both the NRC and the public to have confidence that an approved design will have the capability to support operational controls that, taken together, will keep offsite doses ALARA.

Facility Safety Program

The staff drafted a proposed requirement for a Facility Safety Program (FSP) under Subpart F of Part 53 requiring licensees to periodically assess possible changes in plant risks, including risks from external events, and, when appropriate, considering risk-reduction measures. The program would provide operational flexibility for licensees to manage facility risk.

Specifically, the proposed Part 53 FSP would require the licensee to periodically assess possible risk-reduction measures considering technology changes, economic costs, operating experience, and new or revised hazard information. The proposed FSP would be a departure from the current practice under Parts 50 and 52, in which the NRC staff monitors the magnitude

of external hazards and addresses information showing an increased hazard with affected licensees. In contrast, the FSP proposed in Part 53 would require each licensee to proactively identify and address such information.

The staff explains that, when fully considered as part of an overall regulatory regime, the FSP could enhance NRC oversight programs. As a helpful example, the staff explains that the FSP could help resolve difficult technical issues in initial licensing via assurance from the routine licensee assessments under the FSP. To that end, while the FSP would require additional effort by licensees, the staff believes it would also provide more flexibility in addressing changes to a facility's risk profile than is available under current processes. In other words, in "optimizing" the NRC's oversight programs, the FSP would enable the NRC to scale back its evaluation of external hazards, effectively transferring some portion of that evaluation to the licensees. Additionally, the staff explains that the proposed FSP requirements would present an opportunity to leverage insights from the PRA.

Keeping in mind this understanding of the staff rationale for including an FSP in the draft proposed rule, I now turn to stakeholder concerns. Some stakeholders have stated that the FSP would increase the regulatory burden the NRC imposes on industry while also duplicating existing safety programs, and therefore it is both unhelpful and unwarranted. Presumably, these stakeholders prefer the current approach, in which the NRC reviews possible changes to external hazards, possible insights from operating experience, and other factors potentially affecting risk during plant operation.

I acknowledge that there is a majority among my colleagues to remove the FSP. I am not opposed to this per se. However, I do have concerns that eliminating the FSP sends the wrong signal to the public and may impact the "social license" of nuclear power reactors if not managed carefully. On this point, it is important to highlight that removal of the FSP in Part 53 does not mean that the NRC or licensees will no longer be required to evaluate and act on new hazards or risk information. Instead, applicants and licensees will be treated using the same approach used in Parts 50 and 52—licensees would be responsible for updating their PRAs and performing risk assessments as a result of new information. Meanwhile, the agency would continue to evaluate risks and hazards to ensure safety remains at the forefront. To this end, the staff should explain in the preamble how, with the elimination of the FSP, the NRC will continue to perform adequate and appropriate oversight of external hazards, consistent with the approach currently in Parts 50 and 52. Likewise, the staff should also clearly explain how other requirements included in the proposed Part 53 capture ongoing evaluation of external hazards evaluations and updates to risk information that otherwise would have been addressed by the FSP. This additional language is important to clarify for the public that "facility safety" is still sufficiently addressed in the proposed Part 53 even if the "facility safety program" as included in the draft proposed rule is eliminated.

Given the important substance and optics related to the FSP, the staff should revise the *Federal Register* notice to include a specific question for public comment asking whether including the FSP as an optional approach in the rule, or possibly moving some or all of it into guidance, would be valuable as an option for future Part 53 applicants versus deleting the FSP entirely.

Factory Loading of Fuel in Manufactured Reactors

The staff's draft proposed rule would solicit valuable feedback from all interested stakeholders on the subject of manufacturing licenses for reactors that are pre-loaded with fuel at the

manufacturing facility, including low-power nuclear physics testing on the fueled reactor, with the goal of providing requirements for such licenses in the final rule. I support the staff's intention of addressing this important issue in the rule, but I agree with the Chair and Commissioner Caputo that the staff should develop these provisions for inclusion in the proposed rule, rather than defer this step to the final rule stage. The public comment process would benefit from having a concrete proposal from the staff included in the proposed rule text. In doing so, I note that the staff will shortly be submitting a notation vote paper to the Commission on regulatory issues related to microreactors, which will provide an additional opportunity for the Commission to provide specific direction on how fuel load and low-power testing may best be accomplished under a manufacturing license.

Consideration of Security in Emergency Preparedness

In the final rule, "Emergency Preparedness for Small Modular Reactors and Other New Technologies, (SMR/ONT EP rule),²⁰ the NRC provided an alternative emergency preparedness framework for non-large light-water reactors that allows for scalable sizing of the emergency planning zone (EPZ). That rule does not specifically address how security-related events should be considered in sizing of the EPZ. As the Chair and Commissioner Caputo each point out in their votes on the Part 53 proposed rule, the assumption that the consequences of security events will be bounded by those of non-security radiological safety events may not always hold for advanced reactors. Accordingly, I agree with my colleagues that the staff should address the consideration of security-related events through harmonization of this rulemaking with the SMR/ONT EP rule, including the development of appropriate guidance for addressing security events in EPZ sizing evaluations. This is important to do for a variety of reasons, not the least of which includes building and maintaining public trust, particularly in communities that may be hosting a commercial nuclear reactor for the first time.

Quality Assurance

The draft proposed rule includes a set of quality assurance requirements in Part 53 that are largely identical to those in Appendix B to Part 50. I agree with the Chair and Commissioner Caputo that this duplication is at best unnecessary, and at worst could place additional burden on suppliers to Part 53 applicants and licensees. The staff should instead make conforming changes to Appendix B and Part 53 as necessary to apply the existing requirements to applicant and licensees utilizing the Part 53 framework.

Safety Objective

The staff proposed high-level safety objectives in draft proposed Section 53.200. In principle, I understand the need for overarching objectives for the rule. I also appreciate the staff's rationale for not incorporating the specific language from the AEA into the safety objectives in Part 53, in order to avoid defining "adequate protection" through the individual safety requirements in Part 53. I respectfully disagree with stakeholder comments that the adoption of the draft proposed safety objectives would be inconsistent with the AEA—in all NRC regulations, the

²⁰ "Emergency Preparedness for Small Modular Reactors and Other New Technologies," 88 Fed. Reg. 80050, Nov. 16, 2023.

agency implements its statutory authority in Sections 182 and 161 of the AEA, and in doing so must be consistent with its statutory authority but need not recite the statutory language. High-level safety objectives are no different.

That said, I believe the regulatory structure in Part 53, Framework A, is complete without the safety objectives in draft proposed Section 53.200—the performance standards in Subpart B and other safety requirements throughout the proposed rule, taken together, would be sufficient, if met, for the NRC to make the findings required to grant an application for a utilization facility under the AEA. The language in Section 53.200 is thus not necessary and could add confusion regarding its nexus to the AEA. Therefore, the staff should remove draft proposed Section 53.200.

Conclusion

It is important to recognize that we are still in the early stages of this process. Adjustments and improvements can still be incorporated. As the immediate next step, the agency will finalize the Commission's direction to the staff for issuance of the proposed rule, before providing a public comment opportunity and responding to all public comments, and issuing a final rule for adoption. In this vote, I have attempted to articulate my best thinking on this complex, historic NRC undertaking. Moving ahead, we will all gain new, valuable insights and lessons learned that we must find ways to acknowledge and incorporate as part of regulatory best practices. I look forward to working through these issues with my colleagues, reviewing public comments, and discussing further with both internal and external stakeholders, as we move through the subsequent rulemaking stages. And even after the final rule is issued, the NRC must continue to learn and grow as it gains experience working with applicants using this new framework. History will judge our success or failure collectively. I look forward to doing my part to facilitate our collective success.