UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, DC 20555 - 0001

May 30, 2021

The Honorable Christopher T. Hanson
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: PRELIMINARY PROPOSED RULE LANGUAGE FOR 10 CFR PART 53, "LICENSING AND REGULATION OF ADVANCED NUCLEAR REACTORS," INTERIM REPORT

Dear Chairman Hanson:

During the 685th meeting of the Advisory Committee on Reactor Safeguards (ACRS), May 5 - 7, 2021, we reviewed preliminary draft language for the proposed rule for Title 10 of the *Code of Federal Regulations* (10 CFR) Part 53, "Licensing and Regulation of Advanced Nuclear Reactors." We wrote our first letter, dated October 21, 2020, on the proposed rulemaking during our 678th meeting in September 2020. Our Future Plant Designs Subcommittee also reviewed this matter during meetings on January 14, February 18, March 17, and April 22 and 28, 2021. We had the benefit of discussions with representatives of the NRC staff and other stakeholders. We also had the benefit of the referenced documents.

CONCLUSIONS AND RECOMMENDATIONS

1. The overall structure of Subparts A through I provides a logical framework for the rule. It is complete with respect to topics that must be covered and addresses the lifetime of a power reactor. It will be helpful to all applicants and to the NRC staff.

2. A coherent and detailed explanation of the integrated intent of the rule and its associated design-specific guidance should be developed as soon as possible and enshrined in the rule itself.

3. Subpart B, "Technology-Inclusive Safety Requirements," is coming together, but we would like to offer a few specific comments and see some further improvements:

    a. To this point in the development, we find no value in the two-tiered approach to safety requirements. Alternative integral risk criteria to the Quantitative Health Objectives (QHOs) should be investigated.

    b. Desired flexibility to address the broad range of technologies and power levels is provided by establishing high-level safety criteria that must be assured in top-down fashion as the applicant identifies needed lower-level safety functions. This allows novel technologies to make their safety case specific to their designs, while still precluding release of radioactive materials from the facility.

c. The rule should include a set of over-arching general principles in one place (Subpart B) that would apply to any reactor concept.

d. The rule should state that safety analyses must demonstrate that for normal operation and Anticipated Operational Occurrences (AOOs) all safety related barriers to release are maintained.

e. The rule should state that safety analyses must demonstrate that Design Basis Accidents (DBAs) achieve and maintain a safe, stable, and subcritical condition.

4. Subpart C, “Design and Analysis Requirements,” is generally in good shape.

   a. The requirement for risk-informed analysis is appropriate if the use of Probabilistic Risk Assessment (PRA) is approached in a graded fashion commensurate with the potential consequences and the simplicity of the design.

   b. The requirements for selection and analysis of DBAs must be clarified.

   c. The rule eliminates single failure criteria but needs to define the process that replaces it.

5. The two recommendations in our first letter report on 10 CFR Part 53 of October 21, 2020, still apply: for novel designs with uncertainties due to incompleteness in the knowledge base, systematic searches for hazards, initiating events, and accident scenarios should be required; and a licensing pathway including additional testing and monitoring akin to prototype testing should be available.

BACKGROUND

As the NRC staff continues to prepare for regulating a new generation of advanced reactors, the efforts of the staff have now progressed to developing a proposed rulemaking for licensing advanced reactors using a technology-inclusive, risk-informed, performance-based approach. This effort is directed by the United States (U.S.) Congress in the Nuclear Energy Innovation and Modernization Act (NEIMA), Public Law 115-439.

The staff submitted SECY-19-0017, “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,” to the Commission for approval to implement this new approach for advanced reactor licensing. The Commission approved the staff approach in staff requirements memorandum (SRM) SRM-SECY-19-0017, dated May 26, 2020.

The staff submitted a Rulemaking Plan to the Commission in SECY-20-0032, providing a schedule and planned resources for the rulemaking, following the direction provided in NEIMA. In the rulemaking plan, the staff asked the Commission for permission to forego the normal first step in rulemaking, the Advanced Notice of Proposed Rulemaking, and go directly to the proposed rulemaking stage. In consideration of the preliminary work undertaken by the staff to this point, the rulemaking plan also asked for permission to proceed with a series of stakeholder meetings, including with the ACRS, as a substitute for the information that would be obtained from comments at the notice of proposed rulemaking.

The Commission approved the staff's plans in the Rulemaking Plan in SRM-SECY-20-0032, dated October 2, 2020. Following the directions in SRM-SECY-20-0032, the staff immediately embarked on drafting proposed rulemaking language. The staff is presenting proposed draft language for 10 CFR Part 53 in sections at stakeholder public meetings being held approximately once a month, followed by a presentation of the same sections to the ACRS Future Plant Designs Subcommittee about a month later.

During the 678th meeting of the Committee, September 9 - 11, 2020, we reviewed the staff white paper entitled, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors." In our letter report dated October 21, 2020, we included the following conclusion and recommendations:

1. The staff's proposed approach for developing the Title 10 of the *Code of Federal Regulations* (10 CFR) Part 53 rule is viable.

2. The staff should ensure that applicants compensate for novel designs with uncertainties due to incompleteness in the knowledge base by performing systematic searches for hazards, initiating events, and accident scenarios with no preconceptions that could limit the creative process.

3. The rule should provide a pathway for licensing prototype facilities, when uncertainties in the knowledge base and lack of operating experience suggest that additional testing and monitoring are needed.

DISCUSSION

Overview

This rulemaking is proceeding with a unique approach. In lieu of presenting a regulatory basis document, the staff is having regular meetings with stakeholders and this committee to discuss the preliminary rule language, as it is being developed. For us, this means that we are watching and participating in a work in progress. It is not surprising that individual members question parts of the preliminary language. It is also not surprising that there is a general feeling of discomfort when many details are not in the text and when the staff is as yet uncertain about what design-specific guidance will be needed and when it will be developed. We are gaining confidence as the text is refined.

The rule is intended to be applicable to a wide variety of fission reactor designs and possibly fusion reactors. To allow for this flexibility, details that might have been expected in the rule are reserved for guidance documents. The staff is trying to develop high level principles that can be implemented via design-specific guidance documents. However, in the absence of the full suite of guidance documents, an explanation is needed of the relationship between the rule and the guidance. In addition, there are many examples of subjective language that can lead to regulatory uncertainty. For example, some stakeholders have expressed concern that As Low As Reasonably Achievable (ALARA) and defense-in-depth, while in principle good practices, are too subjective to be included in 10 CFR Part 53. Also, failing to adopt particular consensus standards in the rule raises concern that there are no actual requirements, which makes the rule appear incomplete. It will be difficult to support a rule if the plan for its implementation is not transparent. This could be done in the usual way through the statements of consideration. However, given the departure from the approach in traditional NRC rulemaking and the need for

applicants and regulators to fully understand the integrated intent of 10 CFR Part 53 and its associated guidance, it would provide more confidence if the explanation is enshrined directly in the rule, probably in Subpart A. The sooner this is done, the sooner general support for the rule can develop.

Our comments focus on Subparts B and C. We will address additional Subparts, as they mature. A final section raises issues involving other Subparts to alert the staff to areas where we expect substantial interaction.

Subpart B, "Technology-Inclusive Safety Requirements"

The language of Subpart B has been evolving as the staff discusses the general approach for safety with stakeholders and our members. The discussion is much improved over previous drafts. The staff is still considering alternative presentations, and we look forward to continuing discussions with stakeholders and the staff. While many of us are becoming comfortable with the structure and logic of Subpart B, other members and many stakeholders would have approached it much differently. A variety of opinions can be found in the transcripts of our meetings.

While the staff has clarified their discussion substantially, we find little value in having two-tiers, both of which are required. Having the second tier tied to the Commission's QHOs memorializes direct application of the QHOs, which can be difficult. The established subsidiary goals for the QHOs were based on results from a number of light-water reactor (LWR) PRAs that will not be appropriate for specific advanced technologies. The staff should consider alternative measures of integrated risk, such as those investigated in NUREG-1860[1].

The staff's exposition of safety functions and fundamental principles of safety is based on a top-down analysis of the functions that need to be met to preclude the release of radioactive materials from the facility. A key underpinning of 10 CFR Part 53 is the need for flexibility in meeting safety requirements. The designer, applicant, and regulator desire such flexibility to address the broad range of advanced reactor technologies and power levels under consideration. Such flexibility has been posited to pose unnecessary regulatory uncertainty given the high-level nature of the requirements. However, more prescriptive requirements will limit flexibility and may not be applicable for all advanced reactors.

The staff implemented flexibility by establishing safety criteria that must be satisfied to assure protection of the public and workers. A primary safety function, "limiting the release of radioactive materials," is identified, but the applicant must develop additional safety functions that support the primary safety function, to meet safety criteria. How those additional supporting safety functions are defined, as well as the specific design features (or combinations thereof) and programmatic controls to implement them, will depend on the advanced reactor technology and associated design. The primary and additional safety functions must be maintained during normal and accident conditions throughout the plant lifetime.

[1] For information in NUREG-1860 on licensing basis event selection, integrated risk, and subsidiary risk objectives see Chapter 6 and Appendix C; for information on QHO surrogates see Chapter 3 and Appendix D.

We support the additional flexibility offered by this approach. It promotes technology inclusiveness and minimizes exemptions that might be required if a detailed list of safety functions were enumerated within the rule. During our discussions, staff clarified that assurance of the primary safety function requires sufficient integrity of radionuclide retention barriers for functional containment performance criteria to be met. The staff should revise the proposed rule text to include this clarification and expand the list of candidate additional safety functions to include independently "control reactivity."

The preliminary language of 10 CFR Part 53 emphasizes implementation of defense-in-depth. Defense-in-depth, when used in combination with risk-based tools, is a powerful means to systematically assess the design and identify weaknesses that need to be bolstered by either reducing the frequency of specific off-normal events (through improvements in system reliability, redundancy and diversity) or minimizing the consequences with additional structures, systems, and components (SSCs). This systematic examination should result in a balanced approach for safety implementation in the design, providing additional protection where necessary. It also provides a mechanism for establishing when sufficient defense-in-depth is achieved. In particular, this approach is critical for advanced reactor designs that have never been built, preventing ad-hoc adoption of safety criteria that may be of little substantive value.

We have had a continuing dialog with the staff on the question of design criteria—should the general design criteria (GDC) of 10 CFR Part 50, Appendix A, be included in the rule; should the advanced reactor design criteria (ARDC) of Regulatory Guide (RG) 1.232 be included? Because the rule is to apply to a wide range of technologies, certain of the GDCs and ARDCs may not apply to all and some additional ones could be needed. We are reaching a consensus that, as a minimum, the rule should include a set of over-arching general criteria that would apply to any reactor concept, something like the generic ARDCs 1-5. While some of these are already scattered throughout the Subparts, they should be presented as a set in one place in Subpart B. The process described by the staff in our April meeting that should lead the applicant to something close to the GDCs/ARDCs must be reduced to text and included in the rule. There also is general agreement that safety analyses must demonstrate that for normal operation and AOOs all safety related barriers to release are maintained. Also, the rule should state that safety analyses must demonstrate that DBAs achieve and maintain a safe, stable, and subcritical condition.

Subpart C, "Design and Analysis Requirements"

We agree with the requirement for risk-informed analysis. However, the use of PRA should be approached in a graded fashion, scaled to the potential consequences of accident scenarios. This will require developing guidance on how to select an appropriate depth of analysis. A risk assessment is represented by the complete set of triplets $<S_i, L_i, C_i>$, i.e., the scenario S_i (what can go wrong?), the likelihood L_i, and the consequences C_i. Experience has shown that one can scale the analysis effort by bounding the likelihood and consequences with simplified analyses but failing to perform a complete search for initiating events and scenarios will always underestimate the risk, possibly to a catastrophic degree. We have discussed in previous letters the importance of providing guidance for a structured, systematic search starting with no preconceptions that could limit the creative process. Although the staff has added language offering alternative risk-informed processes to Subpart C, they should continue the effort to clarify a graded PRA and other approaches.

The selection rules for licensing basis events and DBAs in § 53.450(e) and (f) need to be stated or there should be a reference to appropriate guidance such as RG 1.233 and NEI 18-04.

Otherwise, there is no defined meaning to these terms. Alternatively, the explanation of the relationship between the rule and its guidance and a description of how the process is to work (Recommendation 2) should clarify the requirements of the rule. Likewise, the meaning of 'deterministic' and 'conservatively' in § 53.450(f) "Analysis of design basis accidents" must be clarified. If a PRA is performed, the identification of DBAs by a process similar to that described in NUREG-1860 and NEI 18-04 provides a way to select safety-related SSCs and demonstrate that each DBA, using only safety-related SSCs, meets established safety criteria. In this process, the results of the PRA are recalculated modeling all non-safety-related SSCs as failed and using estimated failure rates including uncertainty for the safety-related SSCs (rather than assuming the most limiting single failures as described in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition" (SRP), Chapter 15). Without a PRA, lack of the application of the single failure criterion to the analyses described in Chapter 15 of the SRP could substantially erode safety. It is possible that this problem can be addressed if effective system reliability requirements are specified. Because the language in the rule is currently vague in this area, we would like the staff to brief us on new and existing tabletop exercises to demonstrate and clarify the process.

Issues and Questions for the Future

As we progress through the language in all Subparts of the rule, there are a number of issues members have already identified that we will want to discuss with the staff. These include:

- Will there be a regulatory guide on mechanistic source term? Existing guidance may not be directly applicable to some reactor concepts.

- How will the forms of licenses [construction permit (CP), combined operating license (COL), Early Site Permit (ESP), operating license (OL)…] be included in the rule and what will be the requirements during each phase of the licensing process? How much design information will be required at each phase of the licensing process?

- How will the equivalent of the general design criteria be addressed?

- Defense-in-depth and quality assurance are important concepts and should be kept in one place, up front, rather than being distributed through other Subparts or buried in guidance. Will this be the case?

- How will external and internal hazards be applied in the rule—on a per-module, per-facility, or per-site basis? What if there are existing facilities on site? What if there are multiple licensees?

- How will microreactor transportation to and from the site be addressed, including the impact on siting considerations if a licensed facility for defueling spent microreactors is not available?

SUMMARY

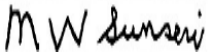
This rulemaking, given the almost real-time interactions with stakeholders and the ACRS and the multitude of expectations, presents the staff with a very difficult challenge. We find their ability to graciously accept comments from all sources and to seek resolution of competing requests commendable. The draft preliminary language is progressing at a fast pace.

However, the associated design-specific guidance that should be issued jointly with the rule will be difficult to keep on-track. Describing the needed guidance and setting priorities on the order in which documents should be developed will help clarify the relationships between rule and guidance. Bringing a discussion of the relationship between the rule and guidance into the rule itself would increase confidence in the suitability of the rule language and how the process would work in practice.

We have made a few specific recommendations, but generally agree with the direction the rule is taking. We look forward to continued interactions with the staff, as they refine the language of the rule.

We are not requesting a formal response from the staff to this letter report. We expect the staff will discuss the issues raised in this letter report during our continuing series of monthly Subcommittee meetings.

Sincerely,



Signed by Sunseri, Matthew on 05/30/21

Matthew W. Sunseri
Chairman

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