

CLEARPATH



ClearPath
518 C St NE
Suite 300
Washington, DC 20002

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U.S. Nuclear Regulatory Commission
Washington, DC 20555

Subject: ClearPath Comments on Proposed Rule, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors" [Regulation Identifier Number RIN-3150-AK31; Docket ID NRC-2019-0062]

Dear U.S. Nuclear Regulatory Commission Staff:

Thank you for the opportunity to provide comments on Federal Register Notice "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors" (85 Fed. Reg. 71002).

ClearPath is a 501(c)(3) organization whose mission is to develop and advance policies that accelerate breakthrough innovations that reduce emissions in the energy and industrial sectors. ClearPath develops cutting-edge policy solutions on clean energy and industrial innovation, and collaborates with public and private sector stakeholders on innovations in nuclear energy, carbon capture, hydropower, natural gas, geothermal, energy storage, and heavy industry to enable private-sector deployment of critical technologies. ClearPath does not receive funding from industry.

While an active participant in both the Nuclear Energy Institute (NEI) and U.S. Nuclear Industry Council (USNIC) Part 53 working groups, as well as regularly meeting with nearly 10 non-governmental organizations and professional development organizations that are invested in the ongoing Part 53 rulemaking, the following comments are on behalf of ClearPath. ClearPath has attended multiple Nuclear Regulatory Commission (NRC) public meetings and, in a few instances, has made comments, but this is the first time ClearPath has formally submitted a letter on the Part 53 rulemaking docket. The timing of this letter is due to the staff publishing multiple subparts so the proposed rule language in Subparts A-F¹ can be considered holistically.

These comments are also influenced by my background as a former member of the NRC staff, my understanding of the license review process, and my understanding of the technologies of multiple reactor companies. Our comments consider how the Part 53 rule will impact license

¹ Rulemaking: Proposed Rule: Preliminary Rule Language for the Part 53 Rulemaking: Subparts A, B, C, D, E, and F -"Requirements for Operation"-10 CFR 53.820 and 53.830, and Part 73, "Physical Protection of Plants and Materials"-73.100, 73.110, and 73.120, Document Date June 2, 2021 (ADAMS Accession No. ML21148A062)

applicants and holders, as well as how the NRC staff will perform their review to comply with the regulations and make their reasonable assurance of adequate protection finding.

The main goal of Part 53 is to enable an efficient and effective licensing process for new reactor technologies. The rule needs to ensure safety, be practical and useful, and have the potential to unlock a variety of new nuclear technologies that can operate beyond electricity generation sources operated by utilities. This rule can also serve as a model internationally, which can open the international market for U.S. companies and support international safety and security standards. These are lofty, yet achievable, goals and the development of Part 53 is supported by bipartisan members of Congress and significant stakeholder resources. This rulemaking should be viewed as a once-in-a-generation opportunity to fundamentally reform the deployment of low-carbon nuclear power in the United States and even abroad.²

During the June 10, 2021³ Part 53 public meeting, the staff stated that they intend to focus on Part 53 topic-specific meetings to enable richer focused dialogue on specific issues. ClearPath supports this approach now that a significant portion of the proposed rule has been published and stakeholders can consider the totality of the draft rule language. This approach can also lead to meaningful collaboration between stakeholders.

Guiding Principles and General Recommendations

The following initial set of principles are broad, overarching, and based on the language in the Nuclear Energy Innovation and Modernization Act (NEIMA).⁴ They echo previous public comments made by multiple stakeholders, build off of each other, and influence the more specific comments below.

Reviewing the very first iteration of 10 CFR Part 50,⁵ the rule utilized by the first generation of commercial nuclear reactors, it is apparent that the rule was high level. Comparing that version and other early versions of 10 CFR Part 50 to today's version, there are significant differences, which are based on decades of operating experience and knowledge. During the development of Part 53, this experience shouldn't be forgotten or ignored. However, this operating experience needs to be leveraged in a technology-inclusive, risk-informed, and performance-based manner. Such an approach is fundamentally different from how Part 50 was developed over time, which incorporated deterministic, light-water reactor (LWR) centric language into the rule.

Technology-Inclusive

With dozens of advanced reactor designs looking to commercialize their technologies, it is imperative that Part 53 is technology-inclusive. This extends to not just licensing different reactor technologies, but also to different licensing approaches/methodologies, different approaches to reactor construction,⁶ and different end-use cases.⁷ Using straightforward language, inclusive definitions, and considering each line of the rule in the context of the balance of the entire rule can enable this objective.

² <https://clearpath.org/our-take/a-simpler-dedicated-pathway-for-advanced-nuclear-reactor-licensing/>

³ June 10, 2021 Part 53 Public Meeting Notice ADAMS Accession No. ML21152A183; Meeting Slides ADAMS Accession No. ML21148A059

⁴ <https://www.congress.gov/bill/115th-congress/senate-bill/512>

⁵ 21 FR 355, Jan. 19, 1956

⁶ For example, on-site construction, factory/modular construction, etc.

⁷ For example, electricity production, process heat, hydrogen production, desalination, etc.

Performance-Based and Risk-Informed

In addition to being technology-inclusive, through NEIMA, Congress directed the NRC staff to develop a risk-informed and performance-based regulatory framework. ClearPath strongly agrees with this approach, although the current implementation of these two concepts needs to be reconsidered. Overall, due to the need for the rule to be technology-inclusive, the rule *primarily* needs to be performance-based. Having clear and straightforward safety requirements will allow an applicant to know what information will be required to meet those requirements, as well as allow the staff to know when a design is “safe enough” by virtue of meeting the performance-based requirements. Thus, the rule being performance-based is a more important requirement than being risk-informed due to the aforementioned importance of the rule being technology-inclusive and able to accommodate the variety of advanced reactor designs that will justify safety in different ways. As will be discussed later in this letter, it is also important for the rule to be risk-informed, but the use of risk should be understood as a method or tool to inform compliance with performance-based regulations, and not the other way around.

Flexible Licensing Approaches/Methodologies

Part 53 also needs to be flexible, which will be enabled by a performance-based rule and requirements that allow different licensing approaches/methodologies and various safety cases to be acceptable. While it is understood that the staff wants to develop at least one set of guidance for a licensing approach/methodology that can meet the initial rule’s requirements, the rule itself should not be amenable to only a single licensing approach/methodology.

General Recommendations:

- Internally and externally rearticulate the NRC’s vision for Part 53 based on the rulemaking’s progress, internal and external feedback to date, as well as how it aligns with the intentions of NEIMA.
- Continue to publish rule text for review, including considering publishing multiple options of certain sections/topics. This may require additional staff perspectives and staff resources to ensure a diversity of options.
- Continue to schedule meetings on specific topics and seek diverse stakeholder feedback.
- Since each requirement should be directly correlated towards demonstrating reasonable assurance of adequate protection, for each new requirement developed for Part 53, justification should be provided for how it either reduces burden for applicants and licensees or is necessary to demonstrate safety.
- Be open to proposed rule language from other stakeholders, especially now that stakeholders can consider all of the subparts together.
- Consider feedback from international stakeholders, including international regulators that are familiar with nuclear energy but have different licensing approaches. This could include requesting representatives from CNSC, IAEA, and other international regulators to provide a separate analysis and/or a presentation at a future Part 53 public meeting.

Specific Comments and Recommendations

The following comments are focused on more specific aspects of the Part 53 draft rule text, or how the rule should be developed. They are influenced by the above principles.

A. The Role and Use of Risk

Over the past several months, a significant amount of dialogue has occurred during public meetings, as well as in comments submitted on the docket, related to the role and use of risk,

Probabilistic Risk Assessments (PRAs), and including similar language to the Qualitative Health Objectives (QHOs) in the Part 53 rule text. Several of these discussions stemmed from a lack of understanding for why the proposed rule included a version of the QHOs, which are currently Commission policy, or why the proposed rule language had such a heavy focus on PRA and included specific event frequencies. While the staff and industry have spent several years and significant resources developing the Licensing Modernization Project (LMP),⁸ it took several months from posting the initial Subparts B and C language for industry and other stakeholders to understand that the staff envisioned Part 53 to be LMP embodied in rule text. While there is certainly interest among some companies in using LMP under Parts 50 and 52, and an LMP-like⁹ process could be an acceptable methodology under Part 53, as written, Part 53 seems to only allow an LMP-like approach unless exemptions are required.

With the ongoing Part 50/52 alignment rulemaking,¹⁰ as well as the significant effort in developing LMP, it is reasonable to expect that some sort of PRA will be required for Part 53. The use of PRA and risk insights have been valuable tools in identifying issues that can be addressed to ensure the safety of operating reactors, and the decades of experience using these tools will continue to be valuable for the next generation of technologies. However, specifically including frequencies and the QHOs in the rule challenges the ability for a rule to be flexible. In addition, requiring a “leading” PRA¹¹ to be the only acceptable method limits the overall utility of the rule. While an LMP-like process may be the first approved methodology to meet Part 53, the rule language should be written to ensure alternative methods are considered.¹² Nonetheless, these concepts are still important, and the degree that tools like PRA will be used still ensures that the rule is risk-informed. Therefore, ClearPath does not support including specific frequencies or the QHOs in the rule text.

Instead, these frequencies and the QHOs should be included in guidance (or remain as Commission policy) for specific licensing methodologies that would be acceptable methods to meet the Part 53 rule language (similar to how LMP is an acceptable methodology for Parts 50 and 52 in accordance with Regulatory Guide (RG) 1.233). ClearPath notes that the Advisory Committee on Reactor Safeguards,¹³ USNIC,¹⁴ and NEI¹⁵ all have similar recommendations. The USNIC and NEI letters also proposed alternative rule language to address these topics, which should be reconsidered by the staff.

One concern with the term “graded” in “graded-approach” is that it can lead to thresholds of applicability. For example, during the May 27, 2021 NRC Advanced Reactor Stakeholder

⁸ Regulatory Guide (RG) 1.233, “Guidance for a 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”

⁹ This letter uses the term “LMP-like” because LMP was developed for Parts 50 and 52. Therefore, the use of LMP would have to be evaluated for use under Part 53.

¹⁰ Alignment of Licensing Processes and Lessons Learned From New Reactor Licensing (Docket ID NRC-2009-0196).

¹¹ NEI presented this concept during the June 10, 2021 Part 53 public meeting.

¹² During the June 10, 2021 Part 53 public meeting, NEI staff asked the NRC staff if the recent NuScale design certification review and the ongoing Oklo combined license review would be able to use Part 53 as Part 53 is currently written based on how those two applications use risk and PRA. This question is worth considering when developing the Part 53 rule text to ensure that the rule is technology-inclusive, performance-based, and risk-informed.

¹³ ADAMS Accession No. ML21140A354

¹⁴ ADAMS Accession No. ML21035A003

¹⁵ ADAMS Accession No. ML21042B889

Meeting,¹⁶ on slide 55, the staff were seeking input regarding criteria to determine when a graded PRA may be performed and listed “reactor thermal power.” This approach can lead to conclusions that only technologies like a microreactor could use a maximum credible accident type approach. While that may be how it is applied in practice, it shouldn’t be limited to such in the rule. Instead the rule should have performance-based requirements and a specific design’s application should justify how it meets those requirements. The role and use of PRA should be considered in the context of the license application and its content, and this will be done on a case-by-case basis. Furthermore, creating entry conditions to regulations that are dependent upon the use of a certain role of PRA can also limit the utility of the rule. Therefore, an application must be holistically reviewed to understand the safety case.

Finally, ClearPath agrees with the key points, conclusions, and recommendations stated in the public comment on Part 53 by Robin Martin,¹⁷ such as, “The endorsement of a particular analysis method prioritizes the method (PRA) over the design, rather than design over analytical methods.”

Recommendations:

- Revise the draft language to remove the specific frequencies and the QHOs.
- Ensure that the rule language does not preclude other licensing methodologies/approaches.
- Consider comments and proposed alternative rule language by the Advisory Committee on Reactor Safeguards, USNIC, and NEI.
- Develop a graded approach to PRA that is holistic, performance-based, and not solely dependent on deterministic requirements like reactor thermal power.

B. Flexible versus predictable licensing

During multiple NRC public meetings, the staff and some members of industry¹⁸ have commented on the seemingly opposing goals of having a flexible rule and a predictable rule. While we recognize this concern, these topics should not be treated as an either/or. Unlike the existing fleet of large LWRs that have multiple deterministic requirements in Parts 50 and 52, and decades of operating experience that has been incorporated into multiple RGs and NUREG-0800 (the Standard Review Plan or SRP), it is unlikely that the NRC can create a single licensing approach that is acceptable for all new reactor designs that will be proposed. Recognizing that these designs may present a variety of approaches to demonstrate their ability to meet the adequate protection standard, we believe this demonstrates why the rule must be flexible. Furthermore, the need for exemptions under Parts 50 and 52 creates a lack of predictability. Creating a new rule that minimizes the number of (or even need for) exemptions can provide increased predictability for both an applicant and the NRC staff.

As stated, because of the lack of decades of operating experience and associated guidance, the staff will not have the current predictability present in a large LWR review. That is why the staff and industry need to consider how to develop a predictable licensing process in other ways. The

¹⁶ Meeting Slides ADAMS Accession No. ML21146A347

¹⁷ Comment (26) of Robin Martin on PR-53 - Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (ADAMS Accession No. ML21081A197)

¹⁸ Some other members of industry also do not think that these are opposing goals. For example, USNIC stated during the May 5, 2021 Advisory Committee on Reactor Safeguards (ACRS) Meeting, “Preliminary Rule 10 CFR Part 53,” that “Predictability is having specific performance criteria that must be demonstrated, and every applicant must show that they meet the criteria that forms the basis for the staff findings of safety,” and “Flexibility is in the means of demonstrating the safety criteria are met, and needs to be a function of the technology and not rely on just LMP.”

first step to accomplish this is having a performance-based rule, which clearly states the acceptable requirements (e.g., dose limits). In addition, predictability needs to be created in other portions of the license review. One way to do this is through the actual review process, which is related to, but separate from, the licensing methodology used by an applicant. Setting clear review timelines, metrics, and milestones can provide certainty to both the applicant and the NRC staff. Improving regulatory processes such as audits¹⁹ will be paramount as well. In summary, flexibility can be addressed through how the rule is written, while predictability can be addressed through rule implementation and review processes.

The staff are expected to continue to use a “core team” concept for new reactor reviews. While one reason for this approach is to provide predictability for an applicant’s review costs, this approach will also continue to be extremely important for the NRC staff. Due to a lack of a non-LWR SRP,²⁰ the NRC cannot have an “all at once” or “office-wide” review similar to recent LWR design certification or Combined License (COL) reviews where individual staff members reviewed a few sections of the SRP and this fed into the overall safety finding. A core team can holistically review the entire license application in order to understand the licensing methodology/approach and the technical information that is necessary to justify safety.

In addition to continuing to utilize a core team approach, another step to increase predictability is looking at the different topics within a review, identifying those that are the most important (i.e., those topics that impact the rest of the review), and focusing on those topics first within the traditional Phased²¹ approach of a design certification (DC) or license application review. Many of these topics are similar to the topics covered in LMP, which is reasonable as those topics form the basis for an application, but this strategy is not solely applicable for applications that use LMP.²²

Early in a licensing review, the staff need to understand topics like licensing basis events (LBE) selection and how PRA is used as those topics directly impact the systems, structures, and component (SSC) classification. Then, once SSC classification is agreed upon, other staff can review more “deterministic” topics like the application of codes and standards, inspection requirements, operational programs, system performance, or other details that may be used to support the assurance of the SSC’s safety function(s). Having an “all at once” or “office-wide” review with NRC staff looking at topics like codes and standards or inspection requirements before having an understanding of the LBE selection, role of PRA, and importance to safety (or safety significance) of the SSCs would be a waste of both NRC staff and applicant resources.

One method to achieve this is to break up a review into multiple steps, in which the first step considers topics like Quality Assurance, LBE selection, SSC classification, and the role of PRA. To be practical, there also needs to be a clear outcome to that step, such as a draft Safety

¹⁹ While new reactors are generally expected to have less information in their final safety analysis report (FSAR) (i.e., on the docket) due to having less important to safety (or safety significant) systems, structures, and components (SSCs), they will still need to have adequate supporting information to justify what is in the FSAR. Audits provide a method for the NRC staff to review the supporting analyses that justifies why the information in the FSAR is what is required for safety. Therefore, processes such as audits will be even more important for new reactor reviews to allow the staff to make their reasonable assurance finding. The NRC should actively consider how to improve these processes within the context of developing Part 53.

²⁰ This letter is not advocating for the development of a non-LWR Standard Review Plan.

²¹ This is referring to the traditional 4 or 6 Phases for a DC or COL review.

²² The staff have proposed a similar concept as discussed in this paragraph for the Oklo COL application review, which is not using LMP, in order “to efficiently align on four key safety and design aspects of the licensing basis” (ADAMS Accession No. ML20149K616)

Evaluation Report (SER) with Open Items and ACRS Review²³ so that the preliminary safety finding that is the outcome of the first step can be used regarding subsequent review topics/areas. Overall, as the staff consider the Part 53 rule language, they should concurrently be considering how to improve the licensing review process to build in the predictability that will not exist due to the variety of reactor designs and approaches to justify safety.

Finally, as the staff develop Part 53, the staff should also consider how the rule would actually be implemented during a license review and during operation to ensure an efficient and effective license review and oversight (i.e., how the staff would meet all of the requirements that are mandated by the rule). For example, the current two-tier structure of the rule creates increased oversight on SCCs that may not be required to ensure adequate protection. This creates inefficiency and, most importantly, pulls both NRC staff and applicant resources away from focusing on items that are important to safety (or safety significant). In summary, the staff should remove the two-tier structure and consider how the rule would be implemented during both licensing and during operation to ensure that the rule is efficient and effective.

Recommendations:

- Draft the Part 53 rule's requirements to prioritize flexibility, recognizing that predictability can be better addressed through the review process.
- Consider how to develop predictability in the licensing process, including considering pre-application activities and recent review lessons learned²⁴ in the context of Part 53.
- Solicit input on the licensing process to help ensure predictable and efficient reviews.
- Consider and implement a multi-step approach described above for licensing reviews.
- Solicit input on reactor oversight to help ensure predictable and efficient oversight.

C. Review Guidance

Similar to improvements to the license review process itself, when developing the Part 53 rule language the staff should consider what acceptable guidance is needed, or consider what text that is currently proposed as rule language should instead be in regulatory guidance. For example, consider the proposed Integrity Assessment Program in draft Part 53.850. Due to the nature of high temperature reactor designs, and the impact of these high temperatures on materials and component integrity, a program like this seems reasonable. However, as currently proposed, this program would be applicable to *each licensee* that uses Part 53. For a light-water cooled small modular reactor that operates below the time-dependent temperature regime, a program like this may not be required for safety.²⁵ In addition, even for a reactor that operates at high temperatures, a program like this may not be required for safety based on the specific design of the reactor, the consequences of a specific component's failure, or an applicant's design choices (e.g., to replace components after a certain amount of time). Therefore, this program may not be needed at the level of detail that is prescribed in the rule for every application.

²³ Traditionally considered Phase 3 of a DC or COL Review

²⁴ ADAMS Accession No. ML21160A246

²⁵ Aspects of this program may be useful for license renewal or subsequent license renewal, but that is beyond the scope of what this program is proposing.

Furthermore, as written, this is a standalone program that may overlap with other operational programs such as the in-service inspection program, in-service testing program, maintenance rule, adherence to applicable design codes, or the proposed facility safety plan. The staff should consider how all of these operational programs fit together, as well as consider if the (inadvertent) prescriptive nature of portions of the proposed rule text may be more appropriate in regulatory guidance. Now that a large portion of the proposed rule text is published, it is easier to see how all of these requirements fit together. As such, the NRC should ensure that text is not overly prescriptive, redundant, or unclear. In some cases, this may require a revision to the rule's format, moving text out of the proposed rule into guidance, consolidating redundant language, and/or removing text that is unnecessary to ensure safety. Targeted table top exercises, like those that were performed during LMP, may also be useful.

Recommendations:

- Update the list of planned regulatory guidance that will be developed that was shared at an NRC public meeting²⁶ and ACRS meeting,²⁷ and include a more specific schedule for when this guidance will be prepared. In addition, actively develop the rule's Statements of Consideration and other supporting documentation.
- Hold a specific public meeting/workshop to solicit further industry comments on how review guidance can be developed, and how current rule language can be moved to review guidance.
- Evaluate the impact the proposed rule text would have on an actual NRC review (e.g. staff-hours and review duration), specifically what information that the staff would require to meet the requirements listed in the rule text. As part of this effort, we recommend performing table tops that look at generic and varied reactor designs to understand how the NRC would review certain portions of a design with the current draft text.
- Regarding inspection, oversight, and other operational programs, we recommend leveraging additional NRC staff with this expertise to ensure that rulemaking text is not overly redundant or overly burdensome for these topics.

D. The Use of Codes and Standards and Quality Assurance

ClearPath supports the NRC considering the use of alternative codes and standards, including quality assurance (QA) standards. While Part 53's QA requirements are likely to be similar to the existing 10 CFR Part 50 Appendix B, it is important that the specific standard or method to meet the QA requirements are not prescribed in the rule or guidance. Similarly, for design codes, based on the reactor's specific safety case, Part 53 and its associated guidance should allow an applicant to justify how a specific code meets the regulations or alternative performance-based commitments could be used in lieu of a certain code or standard. This directly relates to Part 53 being performance-based, as multiple different approaches would be acceptable to meet the regulatory requirements.

In order to provide regulatory certainty for both the NRC staff and applicants when Part 53 is finalized, the review and endorsement of additional standards of interest should happen concurrently with Part 53's development. The Commission is already budgeting and planning resources for when Part 53's Final Rule Package is expected to occur, so the NRC needs to proactively consider these topics for input into the budgeting and planning process. In order to

²⁶ ADAMS Accession No. ML21088A279

²⁷ ADAMS Accession No. ML21075A294

facilitate this, the NRC should leverage international standards, international operating experience, and other regulators' reviews and endorsements.

Recommendations:

- Conduct reviews and endorsements of additional standards of interest concurrently with Part 53 development.
- Consider the role that international standards and experience can play in Part 53.

Conclusion

ClearPath believes that incorporating these comments and recommendations will create a rule that is efficient and effective for both industry and the NRC. While the Commission set an ambitious timeline for completion of the rule, and the staff took on an ambitious scope of Part 53 to include construction through decommissioning, it is imperative that Part 53 is done correctly and the development of the rule does not negatively impact other advanced reactor reviews and activities.

Industry and other stakeholders are investing significant resources to ensure that this rulemaking results in a Part 53 that is useful. Focusing on what is necessary to justify safety, and building the rule around what is required to justify safety can ensure that the final rule will be something that industry will use. Considering guidance and the broader review process will also help with the development of the rule. Other industry efforts, such as TICAP and ARCAP,²⁸ while specifically focused on LMP, can also be useful to Part 53 to define the level of detail and specific topics that should either be in rule text or associated guidance. Finally, other industry or reactor developer reports that consider licensing improvements or alternative approaches to LMP should also be considered.

Thank you to the staff for their efforts, and thank you for the significant management and Commission involvement to ensure that this rule is transformational. Part 53 has the potential to enable the next generation of technologies, but that will only happen based on a truly meaningful collaborative effort.

Please do not hesitate to reach out for additional information or to discuss this letter. ClearPath looks forward to continued participation in the Part 53 rulemaking process.

Sincerely,

Nicholas McMurray
Senior Program Director, Nuclear Energy
ClearPath

²⁸ Technology-Inclusive Content of Application Project (TICAP) and Advanced Reactor Content of Application Project (ARCAP)