Part 53 Rulemaking: Selected Topics

NRC Public Meeting
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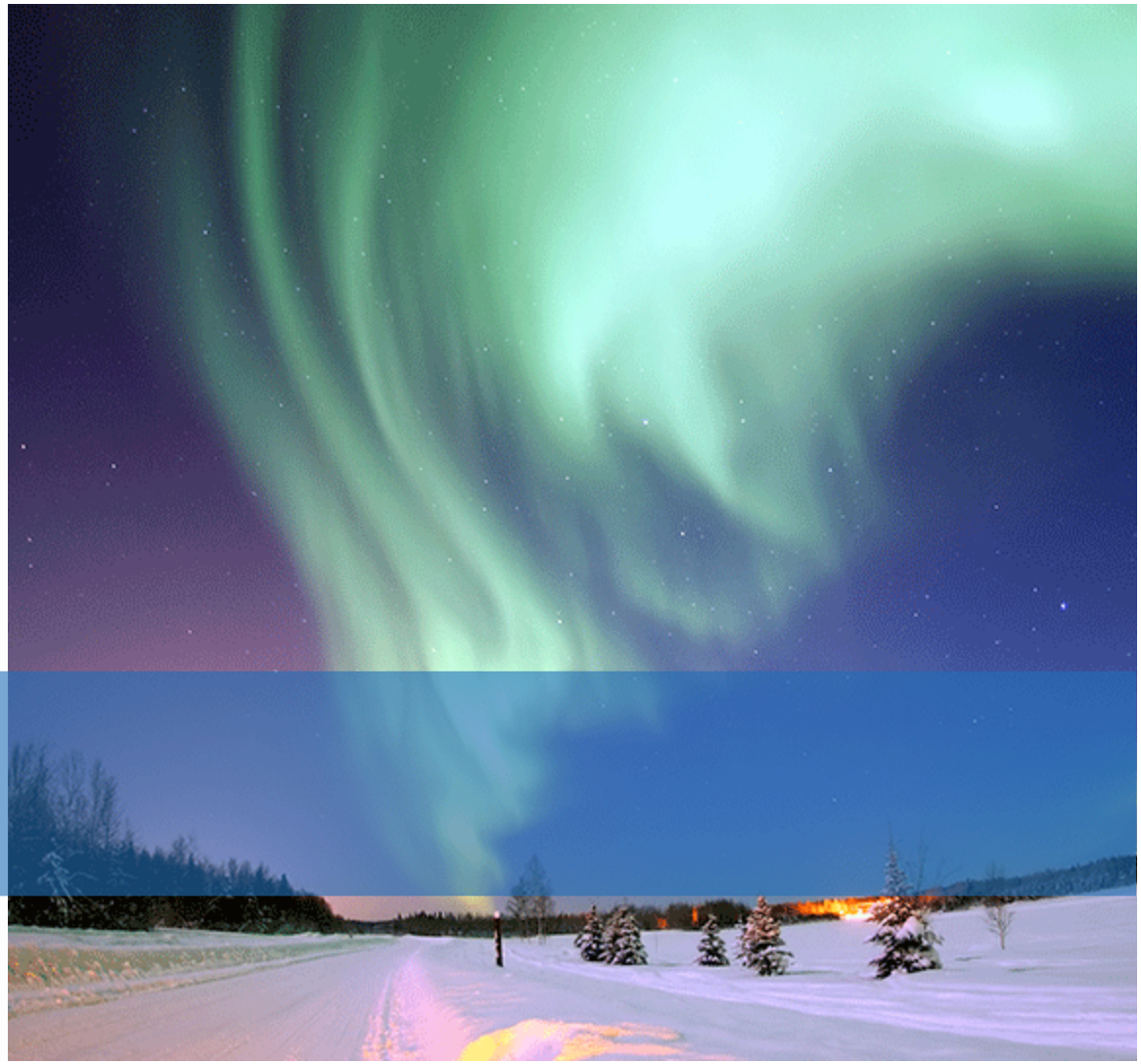
Marc Nichol, NEI
Senior Director, New Reactors



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General Approach

Overall Part 53 Framework (1/3)

- The NRC staff is working hard, and Part 53 includes some new and beneficial approaches that should be available to all licensing approaches
  - For example: the technology-inclusive requirements for safety functions, design criteria and design features
- We appreciate the helpful clarity improvements to Part 53 made to-date
  - Eliminating two-tier structure, and appropriate treatment of normal operations
  - Overlapping, redundant and duplicative QA requirements
- We look forward to engaging on other improvements as they are shared
  - Manufacturing license options, operations, security
- However, Part 53 still includes significant regulatory burden as compared to Parts 50/52, and that burden does not result in any increase in safety
  - To be discussed today: QHOs, treating BDBE like the design basis, ALARA, facility safety and other programs
  - Not mentioned by the NRC: new safety standards, increased regulation of non-safety related SSCs, streamlining siting requirements

Overall Part 53 Framework (2/3)

- NRC first proposed leading/enhanced-only PRA framework in October 20, 2020 rule text
  - NEI advocated for a single framework that allows a range of PRA uses in October 21, 2020 letter
  - Of concern was QHOs in the rule (will be discussed in detail later this meeting)
- NRC reinforced leading/enhanced-only role in December 18, 2020 rule text
  - NEI provided more details on why this is problematic in December 23, 2020 letter
  - Of concern was **details** of PRA requirement (a requirement **for** a PRA was acceptable)
- NRC first proposed options for those that don't want to use leading/enhanced PRA around February 2021
  - NRC said other uses of PRA can use Part 50/52
  - NEI expressed concerns with that approach

Overall Part 53 Framework (3/3)

- NRC is currently pursuing two frameworks under Part 53
  - Framework A remains the enhanced/leading-only PRA role
  - Framework B allows the traditional/supporting PRA role
  - NRC has said Framework B, based on Part 50, will not include elements of Framework A, e.g., performance-based design requirements, that industry believes are the beneficial improvements in Part 53 and are equally applicable for all uses of PRA
  - NRC has said it does not know what, if anything, will be similar between Framework A and B, perhaps not even QA requirements
  - NEI remains concerned about the viability of a two framework approach is less efficient and could result in more challenges than a single-inclusive framework
- NEI and USNIC provided comments on 11/5/21 on how a single framework can be created to enable a full range of PRA use consistent with industry design and analysis
  - This approach would require only minor changes to the requirements for QHOs and PRA
  - A single framework would provide more regulatory stability and require substantially less resources to develop and implement
- We do not know why the NRC is not pursuing a single framework approach, or why a two framework approach is perceived to be better

Quantitative Health Objectives

Quantitative Health Objectives

NRC Response to Industry Communicated Concerns

NEI Concern / Recommendation	First Identified	NRC Response
1. NRC has not provided a basis for why not keeping QHOs in the Policy statement is not acceptable.	11/18/20 (verbal)	None (NRC Question today)
2. Part 50/52 do not have QHOs in the rule (they apply as policy statement), and thus there is already an acceptable alternative performance-based metric.	11/18/20 (ppt)	None (NRC Question today)
3. Increases regulatory uncertainty by establishing requirements without specifying the consequence limits (i.e., dose for immediate fatalities and latent cancers). The dose limits are only known to be located in the MAACS code, and may not even be in the documentation of the software.	12/23/20 (ltr)	None
4. Reduces regulatory stability since changes to consequence limits (i.e., risk for immediate fatalities and latent cancers) will now be regulatory limits instead of policy goals.	1/7/21 (ppt)*	None
5. Is counter to Commission's intent that the QHOs are goals, and not limits.	1/7/21 (ppt)*	None
6. Not having consequence limits, and the complexity of demonstrating the QHOs are met, increases licensing risk. The PRA itself may need to be included in the licensing basis and be subject to NRC review.	1/7/21 (ppt)*	None
7. Changes to societal risks can result in changes to the requirements that can force changes to the facility design.	1/7/21 (ppt)*	None
8. Analyses and calculations related to demonstrating the QHOs are met are now used for legal compliance with requirements. The PRA itself may be subject to contentions by intervenors, leading to protracted and riskier licensing reviews.	1/7/21 (ppt)*	None
9. Risks a revision to the QHOs. The NRC discontinued its efforts circa 2000 to update the safety goals so that improvements can be more significant and incorporate experience with risk-informed decision making.	1/7/21 (ppt)*	None
10. Including QHOs in the rule would result in Part 53 being inconsistent with the PRA policy statement (to not treat them as requirements) and the approach in Parts 50/52.	1/7/21 (ppt)*	None

*Provided afterwards in writing in letter dated 2/11/21.

QHO's / Top-Down Approach

NRC Response to Industry Communicated Concerns

- NRC's slides do not appear to consider our input on this issue
  - Input to NRC questions provided since 10/21/20
  - NRC has not explained the lack of response to NEI concerns or recommendations
- NRC's slides appear to imply basis for QHOs in the rule is that there is no other alternative:
  - QHOs are not in the rule for Parts 50/52 - acceptable alternatives already used
- NEI and USNIC provided comments on improvements needed to the top-down approach in November 5, 2021 letter
  - These requirements (safety functions, design criteria and design features) are applicable whether or not QHOs are in the rule, and for all roles of the PRA
  - Part 53 functional design criteria (FDC) are functionally the same as principal design criteria (FDC/PDC) in Part 50, and the definitions are virtually identical
  - FDC/PDC should be after safety function and before design features

Beyond Design Basis Events

Beyond Design Basis Events

NRC Response to Industry Communicated Concerns

NEI Concern / Recommendation	First Identified	NRC Response
1. The NRC should provide an assessment of other options to address BDBE.	12/23/20 (ltr)	None (NRC Question today)
2. The NRC should continue to address BDBE through requirements for mitigation, rather than establish new risk-based requirements.	2/11/21 (ltr)	None (NRC Question today)
3. If the NRC addresses BDBE with a risk-based metric, does this mean that a mitigation requirement is no longer needed?	1/7/21 (verbal)	None
4. If BDBE are included in the design basis then they are no longer “beyond” design basis, and this is a dramatic increase in NRC regulatory control resulting undue regulatory burden.	11/5/21 (ltr)	None
6. Design features and SSCs needed to mitigate BDBEs should be part of the licensing basis, but not treated in the same manner as addressing the design basis events.	11/5/21 (ltr)	None
7. NRC’s application of downstream requirements (e.g., safety functions, design criteria, design features), effectively includes BDBE in the design basis.	11/5/21 (ltr)	None
8. NRC’s Part 5X (now Framework B) also treats BDBE as part of the design basis, increasing regulatory burden without an increase in safety.	11/5/21 (ltr)	None
9. Including BDBE in the design basis is not consistent with the current regulatory treatment of BDBE through mitigation, or the recent NRC rulemaking (SRM-SECY-15-0065).	11/5/21 (ltr)	None
10. Including BDBE in the design basis would be less performance-based and flexible than the Part 50/52 approach, and would discourage innovative solutions.	11/5/21 (ltr)	None
11. Part 53 requirements do not achieve NRC staff intent (stated at Commission briefing on 12/9/21) to not treat BDBE as design basis.	12/17/21 (ppt)	None

Beyond Design Basis Events

NRC Response to Industry Communicated Concerns

- NRC's slides do not appear to consider our input on this issue
  - Input to NRC questions provided since 12/23/20
  - NRC has not explained the lack of response to NEI concerns or recommendations
- NRC's slides appear to imply basis for treating BDBE as design basis is that there is no other alternative:
  - Parts 50 and 52 use mitigation to address BDBE
- NRC's slides appear to imply that treating BDBE as design basis is consistent with Parts 50/52:
  - We disagree with the NRC's legal interpretation that Parts 50/52 treat BDBE as design basis
  - We disagree that guidance for LMP should be codified in the rule language
- It is not clear that NRC's justification for BDBE as design basis is consistent with NRC staff statements to the Commission on December 9, 2021

As-Low-As-Reasonably Achievable

As-Low-As Reasonably Achievable

NRC Response to Industry Communicated Concerns

NEI Concern / Recommendation	First Identified	NRC Response
1. ALARA should not be a design requirement, but should remain an operational consideration consistent with NRC policy and current requirements.	11/18/20 (ppt)	None (NRC Question today)
2. ALARA requirements already exist in Part 20, and Part 53 does not need to increase the scope of ALARA requirements. It is sufficient to point to Part 20.	1/7/21 (ppt)*	None (NRC Question today)
3. The dose limits are already stringent and protective of public health and safety, and a "safer than safe" standard will drive up costs of compliance without any benefit to safety.	1/7/21 (ppt)*	None
4. In reviewing the AEA, there is no nexus between ALARA and statutory requires for applying it to the design requirements, and the Commission policy 56 Fed. Reg. 23359, 23366 (May 21, 1991) is clear that the concept is intended to be an operating principle, and doing so would go beyond what is in place for operating reactors.	1/7/21 (ppt)*	None
5. Part 53 ALARA requirement for design (applying to the entire design) is not consistent with 50.34a (applying only to equipment to control releases).	12/17/21 (verbal)^	None
6. If the NRC believes 50.34a requirements must be in Part 53, then the requirement should be copied as-is, and not modified to be a requirement with broader reach.	12/17/21 (verbal)	None
7. ALARA requirements are not consistent with past Commission decisions. Part 53 ALARA requirements clearly expand scope of ALARA in design.	12/17/21 (ppt)	None
8. Part 53 requirements do not achieve NRC staff intent (stated at Commission briefing on 12/9/21) to not elevate ALARA to a design requirement.	12/17/21 (ppt)	None
9. It is unclear how an ALARA requirement for design can even work. How do you decide good is good enough? How do you account for cumulative regulatory burden?	12/17/21 (ppt)	None

*Provided afterwards in writing in letters dated 2/11/21. ^Transcript available: ML22024A447.

As-Low-As-Reasonably Achievable

NRC Response to Industry Communicated Concerns

- NRC's slides do not appear to consider our input on this issue
  - Input to NRC questions provided since 11/18/20
  - NRC has not explained the lack of response to NEI concerns or recommendations
- NRC's slides appear to imply that ALARA as a design requirement is consistent with Parts 50/52:
  - We disagree with the NRC's legal interpretation that Part 53 design requirement for ALARA is consistent with past Commission decisions
  - We disagree that staff review practices under Part 50 should be codified into requirements, especially when they are inconsistent with current requirements
- It is not clear that NRC's justification for ALARA as a design requirement is consistent with NRC staff statements to the Commission on December 9, 2021

Facility Safety Program

Facility Safety Program

NRC Response to Industry Communicated Concerns

NEI Concern / Recommendation	First Identified	NRC Response
1. A Facility Safety Program (FSP) does not have any precedent in the U.S. and would increase regulatory burden that the NRC imposes on the industry.	1/7/21 (ppt)*	None
2. The FSP requires periodic reviews to modify the plant, and would reduce regulatory stability by circumventing the back-fit rule.	1/7/21 (ppt)*	None
3. The NRC has not characterized the benefits (e.g., efficiencies) of an FSP, either to the NRC or the industry. The NRC stated the driver (more smaller plants) but has not clarified why a different approach is necessary to achieve regulatory efficiencies, nor what those efficiencies would be.	1/7/21 (ppt)*	None
4. While the NRC offered a potential benefit to industry in terms of more efficient licensing, we are skeptical that the NRC staff would be able to adapt their review practices to achieve the envisioned benefits.	1/7/21 (ppt)*	None
5. The NRC has not stated which current requirements or regulatory burden would be avoided by use of a FSP.	1/7/21 (ppt)*	None
6. Industry would need to have confidence that benefits to the industry outweigh the increased burden in order to use a rule with the FSP requirement. If the NRC intends to pursue this requirement, then they should demonstrate that the benefits to industry clearly outweigh the burden.	1/7/21 (ppt)*	None
7. The NRC should also provide examples that demonstrate how past operating experience would have been more efficiently addressed for licensee that met the proposed facility safety program requirements.	1/7/21 (ppt)*	None
8. NRC should remove FSP, as it duplicates many other programs.	11/5/21 (ltr)	None

*Provided afterwards in writing in letter dated 2/11/21.

Facility Safety Program

NRC Response to Industry Communicated Concerns

- NRC's slides do not appear to consider our input on this issue
  - Input to NRC questions provided since 1/7/21
  - NRC has not explained the lack of response to NEI concerns or recommendations
- We believe NRC initially presented the FSP as an idea they were considering
  - To gather stakeholder perspectives to evaluate whether this approach should be pursued
  - We identified our concerns and questions and clarified that clear benefits and examples should be provided
- NEI, and many others, recommended Part 53 not include an FSP, since it would add regulatory burden, and that burden would not increase safety
- NRC slides appear to imply that Part 53 will include an FSP, the question is about details of the requirements
  - After more than a year: We still do not understand what benefits the NRC believes the FSP provides, nor how those benefits are demonstrated through examples that show an FSP is better than current approach

Other Topics

NEI Input Provided To-Date

Many hundreds of pages of comments, produced through thousands of hours of effort, since August 2020

Formal Comments and Papers Submitted to NRC

1. "Comprehensive Industry Comments on NRC's Rulemaking on TIRIPB Regulatory Framework for Advanced Reactors" Joint NEI/USNIC November 5, 2021 (ML21309A578)
2. "NEI Paper on Licensing Approaches for the NRC's Rulemaking on TIRIPB Regulatory Framework for Advanced Reactors." September 28, 2021 *(ML21274A070)*
3. "NEI Comments on the Preliminary Language for the Physical Security and Cyber Security Requirements included in the Proposed TIRIPB Regulatory Framework for Advanced Reactors Rule," August 31, 2021 (ML21244A331)
4. "NEI Paper on Manufacturing License Considerations for Part 53, TIRIPB Regulatory Framework for Advanced Reactors" July 16, 2021 (ML21197A103)
5. "Unified Industry Position on the NRC's Rulemaking on TIRIPB Regulatory Framework for Advanced Reactors" NEI and 18 other signatories July 14, 2021(ML21196A498)
6. "Industry's Concerns about NRC Proposed Approaches to Part 53, and Alternative Discussion Draft for the NRC's Rulemaking on TIRIPB Regulatory Framework for Advanced Reactors" February 11, 2021 (ML21042B889)
7. "NEI Input on the NRC Rulemaking on, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors" December 23, 2020 (ML20363A227)
8. "NEI Input on the NRC Rulemaking Plan on, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors" October 21, 2020 (ML20296A398)

Presentations at NRC Meetings

1. "*Industry Perspectives on Part 53,"* December 17, 2021 ACRS – Joint presentation NEI/USNIC. Topics include: QHOs, PRA, ALARA BDBE
2. "Part 53 – NEI Perspectives," December 9, 2021 Commission Briefing. Topics: Key Issues, Path Forward, Stakeholder Engagement
3. "*Part 53 Programs*," and "*Change Control – 53.1322*," September 15, 2021.
4. "Role of the PRA," August 26, 2021.
5. "*Manufacturing Licenses*," June 10, 2021, at NRC Part 53 meeting (starting slide 62)
6. *"Part 53 Graded Approach to PRA,"* May 27, 2021.
7. *"Part 53,"* April 8, 2021. Part 53 meeting. Topics: Subpart C (slide 75), Subpart E: Construction and Manufacturing
8. *"Part 53 Rulemaking – NRC ACRS Meeting,"* March 17, 2021. Topics includes: Vision and Goals, Fundamentals of Part 53, NEI Discussion Draft – Alternative Part 53 Rule Language, Safety, Design and Analysis, High-Level rule language, ALARA, Security, Siting, QA, PRA, DID, QHOs, Quantitative Frequencies, and Facility Safety Program.
9. "*Construction Permit Guidance*" (NEI slides 18-31, Stakeholders meeting), February 25, 2021
10. *"Part 53 Rulemaking,"* February 4, 2021. Topics include: Vision and Goals, Success Criteria, NRC Regulatory Functions, Key Concepts, Key Regulatory Guidance, Safety, Design and Analysis, and Siting. (ML21032A045, slides 9 to 13, 34 to 36, 41 and 42, 50 to 52, 78 and 79)
11. *"Part 53 Rulemaking,"* January 7, 2021 (slide typo indicates 2020). Topics: Safety Objectives and AEA Standards, Two-Tier Criteria, ALARA, QHOs, Quantitative Frequencies, and Success Criteria. (ML21006A000, slides 55 to 69)
12. *"Part 53 Rulemaking,"* November 18, 2020. Topics include: Safety Criteria, Objectives and AEA Standards, ALARA, Safety Paradigm. (ML20318A007, slides 37-45)
13. "*Part 53 Rulemaking*," August 20, 2020. Topics: Objectives, QA, Role of PRA, (ML20232D114, slides 121-127)

Need for Timely, Explicit and Meaningful NRC Response to Significant Adverse Comments (1/2)

Topic	NRC First Proposed	Industry First Identifies Concern	NRC Provides Basis	NRC Response to Significant Concerns
Single flexible framework	10/20/20	10/21/20	None	None
Quantitative Health Objectives	10/20/20	10/21/20	3/29/22	None
Beyond Design Basis Events	12/18/20	12/23/20	3/29/22	None
As-Low-As- Reasonably Achievable	10/20/20	11/18/20	3/29/22	None
Facility Safety Program	12/18/20	1/7/21	3/29/22	None
Safety standards	03/21/21	4/8/21	None	None

- Industry has been timely in providing input to the rule so that it can meet the schedule
  - Time from NRC release to NEI feedback: 1 to 21 days (not accounting for year end holidays)
  - Provided detailed comments with basis for substantive concern, proposed viable alternative approaches and alternative rule language, and explained why the alternatives are better, and provided
- Industry does not understand the NRC perspectives on industry's comments
  - Time from NRC proposed approach to providing a basis: 467 to 525 days, still waiting for some issues
  - Time from NEI concerns to meaningful NRC response: still waiting
  - NRC's responses to concerns: "We already decided this is how Part 53 will be" sometimes saying it was decided years ago, "you don't understand what we're doing," "wait until you see the next subpart, it will be better

Need for Timely, Explicit and Meaningful NRC Response to Significant Adverse Comments (2/2)

- We believe NRC approach to Part 53 is not on a path to success
  - Few, if any, potential applicants have expressed a desire to use Part 53 due to substantial concerns
  - Benefits of Part 53 are outweighed by an unjustified substantial increase in regulatory burden
  - Approaches that potential applicants believe make Part 53 nonviable have not been meaningfully modified
- Stakeholder engagement process is not achieving a common understanding of Part 53
  - Stakeholders do not understand NRC's response to our significant adverse concerns that challenge the fundamental premises of the approaches
  - Stakeholders do not understand why the NRC does not adopt proposed alternative approaches that commenters believe would protect the public health and safety more efficiently and with more clarity and predictability
  - Stakeholders are spending significant resources to reiterate their substantive concerns with the rule due to the lack of understanding of NRC's response to concerns and proposed alternatives
- The Part 53 schedule extension should be used to achieve a common understanding
  - Congressional clarification on the intent and goals of NEIMA would help align expectations (industry believes efficiency and technology-inclusive are highest priority, appears NRC puts risk-informed as highest priority)
  - Alternative approaches should be evaluated for areas with substantial concern to determine which best achieves the goals of NEIMA, and the results of the evaluation should be provided to stakeholders
  - A detailed comment response document should be provided for significant adverse concerns so stakeholders understand the NRC's perspective on those concerns, whether changes are made to address them, or whether the NRC disagrees that the concern warrants an alternative approach

