From:	TRUE, Doug
To:	Dorman, Dan
Cc:	Zobler, Marian; Roberts, Darrell; Haney, Catherine; Lubinski, John; Tappert, John; Beall, Bob; Veil, Andrea; Taylor, Robert; Shams, Mohamed; Reckley, William; Khanna, Meena; NICHOL, Marcus; Cyril Draffin; Jeff Merrifield (jeff.merrifield@pillsburylaw.com)
Subject:	[External_Sender] Comprehensive Industry Comments on the NRC's Rulemaking on 10 CFR Part 53, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," (Docket ID NRC-2019-0062)
Date:	Wednesday, August 31, 2022 4:56:28 PM
Attachments:	08-31-22_NEI_USNIC Comprehensive Comments NRC Part 53.pdf

THE ATTACHMENT CONTAINS THE COMPLETE CONTENTS OF THE LETTER

August 31, 2022

Mr. Dan Dorman
Executive Director of Operations
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Comprehensive Industry Comments on the NRC's Rulemaking on 10 CFR Part 53, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," (Docket ID NRC-2019-0062)

Submitted via Regulations.gov

Dear Mr. Dorman:

The Nuclear Energy Institute (NEI)[1], the U.S. Nuclear Industry Council (USNIC)[2], and our members want to express our appreciation for the Nuclear Regulatory Commission's (NRC) efforts, over the course of the last 2-3 years, in developing a new licensing framework for advanced reactors, commonly referred to as the Part 53 rulemaking, as outlined by statutory requirements in the Nuclear Energy Innovation and Modernization Act (NEIMA) and subsequently, the Commission direction in SRM-SECY-20-0032. While a significant effort has been made by the NRC staff to develop Part 53 rule language and elicit stakeholders' perspectives, the current preliminary rule is unlikely to provide the foundation needed to enable the scale of nuclear deployment that the U.S. needs to meet energy, environmental, climate, economic and national security goals.

We look forward to working with the staff to answer any questions or provide additional context on the comments that we have provided. If you have questions concerning our input, please contact Marc Nichol at NEI at mrn@nei.org, or Cyril Draffin at USNIC at cyril.draffin@usnic.org.

Sincerely,

Doug True
Sr. VP and Chief Nuclear Officer
Nuclear Energy Institute

Jeffery Merrifield
Chair, Advanced Nuclear Working Group
U.S. Nuclear Industry Council

[1] The Nuclear Energy Institute (NEI) is responsible for establishing unified policy on behalf of its members relating to matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect and engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations involved in the nuclear energy industry.

[2] The United States Nuclear Industry Council (USNIC) advances the development and implementation of new nuclear technology and services, and the American supply chain, globally. USNIC's members include 80 organizations engaged in nuclear innovation and supply chain development, including technology developers, manufacturers, construction engineers, key utility movers, and service providers.

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Dear Mr. Dorman:

The Nuclear Energy Institute (NEI)[1], the U.S. Nuclear Industry Council (USNIC)[2], and our members want to express our appreciation for the Nuclear Regulatory Commission's (NRC) efforts, over the course of the last 2-3 years, in developing a new licensing framework for advanced reactors, commonly referred to as the Part 53 rulemaking, as outlined by statutory requirements in the Nuclear Energy Innovation and Modernization Act (NEIMA) and subsequently, the Commission direction in SRM-SECY-20-0032. While a significant effort has been made by the NRC staff to develop Part 53 rule language and elicit stakeholders' perspectives, the current preliminary rule is unlikely to provide the foundation needed to enable the scale of nuclear deployment that the U.S. needs to meet energy, environmental, climate, economic and national security goals.

The critical concerns that industry has with the current form of Part 53 are related to NRC proposed requirements that increase complexity and regulatory burden without any increase in safety and reduce predictability and flexibility through the inclusion of prescriptive details that are typically found in guidance.

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The success of Part 53 will be measured by whether it efficiently enables the licensing and operation of safe advanced reactors at a rate and scale necessary to support U.S. decarbonization needs. Since many designs will first be licensed under Parts 50 and 52, Part 53 must demonstrate a degree of efficiency that encourages applicants to switch regulatory frameworks.

At a high level, the six most significant industry concerns and proposed resolutions are embodied in the following six topics. While industry has comments to improve many other areas within Part 53, it is believed that the NRC would need to address all of the following six areas to create a viable Part 53.

Industry Concern	Proposed Solution
1. Two frameworks (Framework A and Framework B) increase complexity and decrease clarity and predictability. The two frameworks are only necessary because prescriptive details found in guidance were elevated to rule text.	Create Part 53 as a single framework that allows a flexibility for the licensing basis and PRA approaches, consistent with the flexibility already available in Parts 50 and 52, while including the technology-inclusive benefits of Framework A, such as performance-based requirements for safety functions. This would require less time and resources to develop than a two-framework approach, and result in a rule that is clearer and more predictable.
2. Incorporating the Quantitative Health Objectives (QHOs) in the rule text as a performance metric, rather than continuing to apply as a Policy Statement, unnecessarily introduces new and unforeseen challenges, since the already included dose limits create sufficient performance standards to protect the public health and safety.	Remove the QHOs from the rule language, and recognize that the dose criteria provides sufficient performance-metrics. Conformance with the QHOs can be confirmed consistent with the current Commission Policy Statement. NRC should rely on the existing safety standards which have a long history of interpretation and understanding. Remove the prescriptive details for the specific uses of the PRA, rather relying on risk-informed approaches that can be described in guidance. This would be consistent with other risk-informed regulations such as the Maintenance Rule (50.65) and risk-informed special treatments (50.69).
3. Making ALARA a design requirement is inconsistent with the current approach to	Delete the requirement for ALARA as a design requirement, since ALARA is already addressed

using ALARA as an operational consideration and creates a subjective performance criteria. This increases burden without increasing safety.	in applicable Part 20 requirements, or at a minimum change the rule text to match existing Part 50 requirement wording, and do not subject the entire plant design to meet ALARA (as the Part 53 requirements currently do).
4. Including Beyond Design Basis Events (BDBE) in the design basis (protect and withstand) increases burden without increasing safety and is inconsistent with the Commission decision on the Mitigation of Beyond Design Basis Events Rulemaking.	Address BDBEs consistent with Parts 50 and 52 by creating a more technology-inclusive and performance-based mitigation requirement.
5. The new Facility Safety Program (FSP) in Framework A duplicates most other programs required by the NRC, would require biennial safety reviews, and would circumvent backfit protection. The FSP would result in a significant increase in regulatory burden without increasing safety.	Delete the requirement for the FSP in Framework A, since it is not necessary to protect the public health and safety.
6. Creating new terminology that establishes safety standards that are not consistent with the Atomic Energy Act and results in a proliferation of redundant programs. This increases burden without increasing safety.	Change the safety standards in 53.200 to be consistent with the Atomic Energy Act, which are also used in Parts 50 and 52, as well as all other NRC Parts. Eliminate the programs that are redundant with programs that are carried over from Parts 50 and 52. Use consistent terminology for regulatory concepts that are also found in Parts 50 and 52, while making changes to the details, to be more technology inclusive, performance-based and risk-informed.

The industry has worked diligently to review and analyze the current state of the entire Part 53 framework. Our goal, as stated in past public forums, is a framework that is used and useful. Our collective comments herein are an effort to shape a successful framework.

Addressing these six most significant industry concerns to achieve a regulatory framework that achieves a similar level of safety as Parts 50 and 52 more predictably, clearly, and efficiently, would result in a Part 53 that is more likely to be used by potential applicants. The details of the industry concerns and proposed solutions on these and many other topics are included in the following:

- Explanation of The Six Significant Industry Concerns – See Attachment A

- Framework A Detailed Comments – See NEI and USNIC Letter dated November 5, 2021 (ML21309A578). It is noted that NRC's second iteration of Framework A (released May 2022) addresses a few of the more minor concerns identified by industry, but there are many more concerns that remain unaddressed and the second iteration also introduces new concerns.
- Framework B Detailed Comments – See Attachment B
- Comments on Operations Requirements – Framework A (Subpart F) and Framework B (Subpart P) – See Attachment F
- Comprehensive List of Industry Comment Submissions and Presentations on Part 53 Rule Language – See Attachment E
- Comments on DG-1413, "Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants" – See Attachment C
- Comments on DG-1414, "Alternative Evaluation for Risk Insights (AERI) Framework" – See Attachment D

At this critical juncture of the closing of the preliminary proposed rule stage, it is incumbent on all stakeholders to reflect upon the progress made to date, milestones reached, and the strategic direction that is needed from this point forward, to achieve the efficient and useable Part 53 rule that is needed.

We encourage the NRC to continue engaging stakeholders, with a focus on responding to these critical concerns before the next formal phase of the rulemaking process – issuance of the proposed rule in summer 2023. The volume and need for multiple attachments for our comments reflects the complexity of the NRC preliminary rule text, which could create barriers to public understanding. Our comments, especially those requesting a single framework, are intended to simplify the rule, which would also make it more accessible to the public. It is our hope that these comments can be used to inform the finalization of the proposed rule, such that Part 53 moves towards a usable rule that enables the vast deployment of advanced nuclear.

We look forward to working with the staff to answer any questions or provide additional context on the comments that we have provided. If you have questions concerning our input, please contact Marc Nichol at NEI at mrn@nei.org, or Cyril Draffin at USNIC at cyril.draffin@usnic.org.

Sincerely,

Doug True	Jeffery Merrifield
Sr. VP and Chief Nuclear Officer	Chair, Advanced Nuclear Working Group
Nuclear Energy Institute	U.S. Nuclear Industry Council

Attachment A - Explanation of Significant Industry Concerns
Attachment B - Framework B Detailed Comments
Attachment C – Comments on DG-1413, "Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants"
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Attachment F – Comments on Operations Requirements – Framework A (Subpart F) and Framework B (Subpart P)

Cc: Ms. Marian Zobler, General Counsel, NRC
Mr. Darrell Roberts, DEDO, NRC
Ms. Catherine Haney, DEDO, NRC
Mr. John Lubinski, NMSS, NRC
Mr. John Tappert, NMSS, NRC
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Ms. Andrea Veil, NRR, NRC
Mr. Rob Taylor, NRR, NRC
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Mr. William D. Reckley, NRR/DANU/UARP, NRC
Ms. Meena Khanna, NRR/DRA, NRC

Attachment A: Explanation of Significant Industry Concerns

The purpose of this attachment is to provide more details regarding the industry's six most significant concerns summarized in the comment cover letter.

In a recent survey of our NEI and USNIC members (slides #52 to 95 from NRC meeting on May 11, 2022 – ML22130A523), 18 of 21 respondents indicated that they are not likely to use Part 53, though some of those *might* consider using it *if* it is demonstrated to be more efficient than Parts 50 and 52. The large majority of members see significant increases in complexity and unnecessary burden in Part 53 without a commensurate increase in safety. Many recognized that in a few areas the NRC's proposed Part 53 language did offer benefits not available with Parts 50 and 52, for example the NRC's proposed performance-based security requirements and technology-inclusive requirements for safety functions, design features and design criteria. However, the list of concerns with Part 53 is nearly three times as long as the list of benefits, with these concerns being the subject of this comment letter. Furthermore, many believe that the NRC is not pursuing numerous innovations in Part 53 that could greatly enhance its value, such as streamlining the review process, or better integrating safety, security, emergency planning and siting. As a result, very few believe that Part 53, in its current form, meets the goals for promoting regulatory stability, predictability, clarity, efficiency and usefulness.

Decreased Regulatory Clarity, Predictability and Flexibility

Two of the major concerns with the rule language relate to the clear potential for decreased regulatory clarity, predictability and flexibility and the lack of any associated regulatory benefits.

1. **Two Frameworks**

   The NRC has now released both of the separate and distinct dual frameworks for Part 53 (Framework A & Framework B). We have long advocated for a single framework as the approach to Part 53 that provides more clarity, simplicity, and efficiency (see November 5, 2021, letter from NEI and USNIC, ML21309A578). The NRC staff's decision to create Framework B, which largely replicates significant portions of Parts 50 and 52, further complicates Part 53 and does not address industry's concerns. While we remained open to dual frameworks (provided at least one represented a viable framework for regulating advanced reactors), we have since evaluated both Framework A and Framework B and do not believe either are a better alternative to the existing Part 50 and 52.

   Parts 50 and 52 both enable a wide range of licensing approaches through the use of a single framework. However, Part 53 has established two frameworks in order to permit the same range of licensing approaches allowed by a single framework in Parts 50 and 52. In Part 53, Framework A is established for licensing approaches based upon a PRA-led licensing basis, for which only the Licensing Modernization Project, which was recently endorsed by the NRC and has never before been approved for an actual application, is the only known approach. Part 53 Framework B is established for a PRA-confirming licensing basis, for which all recent new reactor applications submitted under Part 52 would qualify. Part 53 does not currently allow both PRA-led and PRA-confirming approaches to be used under a single framework (as they can both be used today under the single frameworks in Parts 50 and 52), because the NRC has included in rule text prescriptive details about the licensing methodologies, which historically are only included in guidance. Thus, the ostensible need for two frameworks is a direct result of including unnecessary detail in the rule language. In reviewing both Frameworks A and B, we have concluded that Framework A includes many enhancements in the areas of being technology-inclusive, risk-informed and performance-based (that are not dependent upon the licensing approach used), while Framework B is largely the same as Parts 50 and 52. Therefore, we recommend that the NRC pursue an approach to develop Part 53 in a way that would make Framework A viable for all licensing approaches, rather than continue to pursue dual frameworks. Not only does a single framework provide the most clarity and predictability, it would also be the most efficient and require fewer resources to develop. Further, many stakeholders have noted the sheer size and complexity of the NRC's dual framework preliminary proposed rule. The NRC has stated that Part 53 spans nearly 1,000 pages of text, which is 114% the length of the equivalent Parts 50/52 framework.[1] Certainly, a single framework would help reduce this page count and facilitate both clarity and ease of implementation.

We recommend starting with Framework A in developing a single framework Part 53, since it is more technology-inclusive and performance-based than Framework B. Framework A also requires only two small changes in order to enable it to be used for all licensing approaches: 1) relocating the QHOs from the rule text back into the Policy Statement, and 2) relocating details on how the PRA must be used from the rule text into guidance. We do not recommend starting with Framework B to create a single framework Part 53, since Framework B essentially reproduces much of Parts 50 and 52, with only a few changes to make it more technology-inclusive or performance-based, and most of those changes are already included in Framework A. Other than the AERI approach, there is not much new in Framework B that needs to be considered for inclusion in Framework A.

In the July 21, 2022, Commission briefing, we heard the NRC staff objections to pursuing a single framework. Those objections, which the staff cited as the basis for continuing to pursue a Part 53 with dual frameworks, centered upon the purported need for QHOs in the rule text (addressed below) and for prescriptive details in the rule text.

There was a discussion on whether the rule language could be higher level, with detailed NRC expectations being included in guidance. The NRC staff said that the detail currently in the rule language is necessary to provide predictability for licensing reviews. The NRC staff also stated that guidance must be associated with a regulation or it could not be enforced. However, industry is not asking for requirements to be deleted, so there will remain a requirement with which guidance can be associated. Industry is asking only that the detail that has historically been provided in guidance, and which the NRC staff has moved up into rule language, be relocated back into guidance. This will not result in any less predictability

[1] In the July 28, 2022, NRC public meeting, the NRC stated that Framework A is 56% and Framework B is 58% of the length of the current Part 50 and 52 frameworks being replaced.

than already exists in Parts 50 and 52. Indeed, since it would enable a single framework, it would actually increase clarity and predictability. The NRC staff has stated that Framework A is unique in that it requires the PRA to be used in very specific ways, for example to establish the licensing basis events and for the safety categorization, in order to be able to use the technology-inclusive requirements for an applicant to establish their own safety functions, design features and functional design criteria. However, the NRC staff has not provided a basis for this assertion. In fact, there is nothing unique about the PRA, as compared to other tools for establishing the licensing basis events or safety categorization, that enables a technology-inclusive approach to establishing safety functions, design features and design criteria for the design. Furthermore, the NRC staff's requirements identifying the specific uses of the PRA essentially only allow the licensing approach documented in Regulatory Guide 1.233, called the "Licensing Modernization Project" or "LMP." While the NRC staff has said that Framework A does not require the use of LMP (which is true), the NRC staff has also said that they know of no other licensing approach that could be used to meet the details of the PRA requirements. It is these details that are found in guidance for the LMP licensing approach, and which we contend should remain in guidance and not elevated to rule language. Use of higher-level rule language with details in guidance will achieve the same level of predictability and increase flexibility, which is critical given the range of advanced reactor designs and applications.

2. **QHOs as Performance Criteria in the Rule Text**
In the July 12, 2022, NRC Commission briefing, a question was raised as to whether a performance-based rule should have performance criteria, and whether the QHOs should be the performance criteria. There was broad agreement that a performance-based rule should have performance criteria. However, the QHOs should not be the performance criteria. First, performance criteria already exist in the form of (1) dose criteria for normal operations and design basis events, and (2) the mitigation requirement for beyond design basis events. These performance criteria are already risk-informed since they are based on consequences and consider the likelihood of occurrence. Moreover, they are comprehensive in considering the standard of protecting the public health and safety.

Second, the NRC staff has not provided a sufficient technical or regulatory basis for including QHOs in the rule language. The NRC staff asserts that the QHOs should be the performance-criteria because they have served the agency well. NRC staff further contends that nobody has proposed alternative criteria. However, the relevant inquiry is whether new risk-based performance criteria (QHOs in this case) *must* be expressly incorporated into the rule language to meet the NRC's obligations under NEIMA and the AEA. It does not, as decades of NRC regulatory practice attest. Although the QHOs have served a useful function in Parts 50 and 52, they have done so as a Policy Statement and have been effectively implemented through guidance. Thus, elevating the QHOs and specific PRA uses into binding legal requirements (via their codification in Part 53) is unnecessary and, for the reasons explained below, is likely to have adverse consequences.

Third, including the QHO's in the rule language would establish risk-based performance criteria and utilize the QHOs in unprecedented ways. Risk-based performance criteria will introduce new and potentially unforeseen challenges for licensing advanced reactors. These challenges, including using the PRA as the basis for meeting the QHOs as a requirement, are explained in our detailed comments on Framework A (ML21309A578). The following is a list of the principal disadvantages of including QHOs in the rule, rather than continuing to apply them as a Policy Statement, consistent with Parts 50 and 52:

1) Increases regulatory uncertainty by establishing requirements without specifying the consequence limits (i.e., dose for immediate fatalities and latent cancers).
2) Reduces regulatory stability since changes to the consequence limits (i.e., dose for immediate fatalities and latent cancers) will now be regulatory limits instead of policy goals.
3) Is counter to Commission's intent that the QHOs serve as goals and not limits.
4) Not having consequence limits, and the complexity of demonstrating the QHOs are met, increases the potential for litigation and associated licensing risk.
5) Changes to non-radiological risks (fatalities and cancers due to other causes) can result in changes to the requirements that can force changes to the facility design or operational programs to ensure continued compliance with the new limits. (Note that QHOs would apply to the life of the facility).
6) Puts the burden of demonstrating compliance on the applicant (QHO as a Policy Statement puts burden on the NRC staff). Analyses and calculations related to demonstrating the QHOs are met would now be needed to demonstrate legal compliance with the new requirements.

Increased Regulatory Burden in Part 53 To Achieve a Similar Level of Safety

Four of the major concerns with the rule language involve the increase in regulatory burden, without a commensurate increase in safety. We have communicated these concerns to the NRC in detail for over 18 months. We also have provided specific and detailed recommendations on how the NRC can achieve its goals for the requirements without increasing regulatory burden. To be clear, when we talk about increased regulatory burden, we are not suggesting that Part 53 is imposing higher levels of safety. Rather, we view Part 53 as achieving a similar level of safety as Parts 50/52 but in a way that requires substantially more resources to demonstrate compliance. Details on these concerns are included in our letter dated November 5, 2021 (ML21309A578). The simple and straightforward resolution for most of these concerns is for the NRC to be consistent with Commission policies and the underlying bases for the requirements in Parts 50 and 52. The four critical concerns related to increased regulatory burden, as outlined in the main letter, are:

3. **ALARA as a Design Requirement**

   The NRC rule language, in both Framework A and Framework B, includes a performance requirement for the design to achieve doses As-Low-As-Reasonably-Achievable (ALARA). This is a new requirement, since in Parts 20 and 50/52 achieving doses ALARA is treated as an operational consideration to be accomplished through a Radiation Protection Program.

The NRC has said that Parts 20 and 50/52 require ALARA as a design requirement; however, the cited requirements relate to discrete aspects of the design. Specifically, 10 CFR 50.34(xv) states "Provide a capability for containment purging/venting designed to minimize the purging time consistent with ALARA principles for occupational exposure." Appendix I requires LWRs to meet design objectives (dose limits) as a means for achieving ALARA for effluents, and Part 20 states "The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to the members of the public that are ALARA." In contrast, the Part 53 requirements state "A combination of design features and programmatic controls must…achieve doses that are ALARA." The Part 53 requirement is much broader than the Parts 20 and 50/52 requirements because it subjects the entire reactor design to subjective ALARA limit. The Part 53 requirement for the design to achieve doses ALARA does not enhance safety and is not necessary, since Part 53 already establishes dose limits for the public and occupational exposures, and also provides ALARA through operational programs. The performance criterion of ALARA reduces predictability in that it is not an objective metric; rather, it is subjective and will depend upon the specifics of a given design and the preferences of individual NRC staff reviewers.

The NRC staff have stated that their intention is to apply ALARA in Part 53 the same way that it is applied in Parts 20 and 50/52. In response to observations that the rule language applies ALARA in new and greatly expanded ways, the NRC staff has stated that they plan to clarify, in the statements of consideration and guidance, that the rule language should not be applied as it is written. However, a more efficient approach clearly would be to change the rule language so that it matches Parts 20 and 50/52, thereby avoiding the need for SOCs and guidance to explain why the rule language is not correct or otherwise inconsistent with Parts 20 and 50/52.

4. **Designing to Protect Against and Withstand BDBEs**
Framework A and Framework B introduce new requirements that would result in the inclusion of beyond design basis events (BDBEs) into the design basis of the facility (the design would be required to protect against and withstand these events, in addition to mitigating the consequences of the events). This is inconsistent with how the BDBEs are addressed in Parts 50/52. In Parts 50/52, BDBEs are addressed through a mitigation requirement as an acceptable approach to protect the public health and safety, and the normal events and designs basis events are the only licensing basis events that the facility is required to be designed to withstand. In Part 53, the NRC requires the facility to be designed to protect against and withstand BDBEs, though the details in how the NRC requires this are slightly different between Framework A and B. Part 53 would likely require that the facility include structures, systems and components (SSCs) that would otherwise not be required by Parts 50/52 to withstand BDBEs, in addition to also requiring the traditional mitigation of the BDBEs. The fact that the SSCs required to withstand BDBEs are not required to be safety-related makes little difference, since Part 53 requires essentially the same level of administrative burden for non-safety SSCs as it requires for safety-related SSCs. The result is

that a facility licensed under Part 53 will likely need to include SSCs that are not necessary under Parts 50 and 52. Since the SSCs to withstand BDBEs are not required to be safety-related, it is not clear whether they would be able to survive a BDBE to perform the required function of withstanding the BDBE (as a comparison, the SSCs required to withstand a less severe DBE are required to be categorized as safety-related, which ensures their ability to survive a DBE). Furthermore, an approach to mitigate BDBEs already provides sufficient protection against BDBEs. Thus, Part 53 results in an increased regulatory burden and uncertainty without an increase in safety. The NRC staff have stated that their intention is to not include BDBEs in the design basis; however, the effect of the rule text is that the BDBEs are included in the design basis.

5. **Facility Safety Program**
The NRC preliminary rule language would increase regulatory burden by imposing a new and unnecessary Facility Safety Program (FSP) in Framework A. It is unclear what problem the NRC is trying to solve with these requirements. During a public meeting, the NRC staff suggested that this new requirement will allow the agency to more efficiently handle generic issues for a nuclear industry in which there are a large number of reactors deployed with varying technologies. However, the assumption of a reduction in the resources needed to perform NRC oversight through this requirement is questionable and has not been clearly explained or documented. The NRC has also suggested that the FSP would reduce regulatory burden on licensees. In the Spring of 2021, the industry asked the NRC to provide details on how the proposed approach to the FSP would reduce burden, and to provide examples of how past generic issues were addressed under the current Part 50 approach to generic issue resolution, and how those same issues would be addressed by the Facility Safety Program. To date, the NRC staff has not provided any information on how the proposed FSP could reduce (rather than increase) regulatory burden. Furthermore, the NRC has provided little additional information on how the FSP could be implemented. Our assessment of this requirement is that it would impose an enormous regulatory burden on licensees. First, it effectively duplicates most other programs required by the NRC. In addition, it requires a biennial safety review, which is inconsistent with Commission policy and has never been needed for existing reactors. Indeed, for decades, the NRC has rejected calls to mandate biennial safety reviews during its regular presentations before the Convention on Nuclear Safety. To reverse this longstanding policy decision by the Commission in the context of this proposed rule would be unprecedented. This would circumvent backfit protections and continually force unwarranted upgrades of the plant. The NRC should remove the FSP from Part 53, as this requirement imposes enormous regulatory burden without any apparent and justifiable increase in safety.

6. **New Programs and Terminology**
Part 53 reduces regulatory clarity when it uses concepts that are fundamental to the regulatory framework and which have long-established use but gives new names to these concepts. As an example, the safety standards in Part 53 do not align with the statutory requirements in the Atomic Energy Act (AEA). Specifically, the AEA establishes the following

safety standards that govern the requirements in Part 53: 1) from Section 182, "*reasonable assurance of adequate protection of public health and safety,*" and 2) from Section 161, "*to protect health or to minimize danger to life or property.*" The current version of preliminary rule language replaces these with different safety standards that are not clearly derived from the AEA and have no regulatory precedent. The new standards are included in 53.200 and are "*limit the possibility of an immediate threat to the public health and safety,"* and "*considering potential risks to public health and safety.*" The explanation provided by NRC staff during public meetings is that because the entirety of Part 53 satisfies the AEA, the AEA standards do not need to be referenced in Part 53, and the NRC thus should establish new standards to frame the Part 53 requirements. Such an approach is entirely inconsistent with the longstanding practice of the NRC and appears to reject decades of Commission precedent, with no indication that the Commissioners have approved such a dramatic change in policy. The approach proposed by the staff reduces regulatory clarity and efficiency because there is no clear connection between the Part 53 requirements and the AEA safety standards. Moreover, it creates new terminology that is inconsistent with terminology used in other Parts of NRC regulations for the same concepts. Another example is in the NRC's application of a new term, "functional design criteria" (FDC), to a fundamental concept that historically has been described by the term "principal design criteria" (PDC). While there may be necessary and appropriate modifications to how PDC are incorporated into the Part 53 framework (in contrast to how the PDC are incorporated into Parts 50 and 52), the fundamental concept, role and importance of PDC still exist. The NRC implicitly acknowledges this fact in that the definition for "functional design criteria" is nearly identical to the definition of PDC in Part 50 Appendix A.

Part 53 also contains numerous redundancies because it duplicates program requirements that already are being carried over from Parts 50/52. The net effect is to increase the number of areas where licensee programs require NRC approval from about 11 to roughly 24, while simultaneously requiring additional programmatic controls in over 20 other requirements. These additional 13 programs and 20 instances of programmatic controls have no equivalent in Parts 50 and 52.[2] Many of the new programs and programmatic controls proposed for inclusion in Part 53 – on top of the well-established programs from Parts 50 and 52 that are being imported into Part 53 – create redundant and overlapping programs. Although the NRC has stated that Part 53 allows multiple programs to be combined into a single program, this does not eliminate the increased burden and reduced predictability associated with numerous duplicative requirements. In short, the NRC can and should use consistent terminology between Part 53 and Parts 50/52, where fundamental regulatory framework elements in Part 53 are similar in concept in all of these Parts, and avoid duplicative program requirements.

[2] NEI and USNIC Letter dated November 5, 2021 (ML21309A578); Page 8 – Section D. Proliferation of Duplicative and Unnecessary Programs, Table 1.

Attachment B: Framework B Detailed Comments

	Affected Section	Comment/Basis	Recommendation
Industry maintains that a single framework, based on Framework A, that is technology inclusive, risk informed, and performance based, can and should be used for Part 53. However, if NRC staff desires Part 53 to include Framework B, specific comments follow below. All comments have been formulated based on Framework B preliminary proposed rule language that was made publicly available on or before August 01, 2022. For draft language that was released after August 01, 2022, there was insufficient time for the industry to review and develop formal comments as contained in this Attachment.			
1	General	There is a general concern that Framework B directly incorporates highly prescriptive, deterministic requirements from Parts 50 and 52, with minimal change to remove the LWR-centric nature of the requirements, incorporating technology-inclusive phrasing. Industry has previously expressed concern the Framework B language does not address the spirit nor letter of NEIMA nor the staff's proposal to develop Part 53 as described in SECY-20-0032. Drawing on language in SECY-20-0032 -- "NEIMA includes the following definition for …"technology-inclusive regulatory framework": (14) TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK—The term "technology-inclusive regulatory framework" means a regulatory framework developed using methods of evaluation that are *flexible and practicable* [emphasis added] for application to a variety of reactor technologies, *including, where appropriate, the use of risk-informed and performance-based techniques* [emphasis added] and other tools and methods."	Framework B should be revised to make more direct use of performance-based approaches as that term is defined in NRC's glossary. Specifically, a "regulatory approach that focuses on desired, measurable outcomes, rather than prescriptive processes, techniques, or procedures. Performance-based regulation leads to defined results without specific direction regarding how those results are to be obtained. At the NRC, performance-based regulatory actions focus on identifying performance measures that ensure an adequate safety margin and offer incentives for licensees to improve safety without formal regulatory intervention by the agency." While it is recognized that changing Framework B requirements to a "performance-based approach" and developing the implementing regulatory guidance would be a significant undertaking, it would result in a regulation that meets the expectations expressed in NEIMA and described in SECY-20-0032.

		From page 4 of SECY-20-0032: "The new alternative requirements and implementing guidance would adopt technology-inclusive approaches and include the appropriate use of risk-informed and performance-based techniques*, to provide the necessary flexibility for licensing and regulating* [emphasis added] a variety of advanced nuclear reactor technologies and designs. This new approach would: (1) continue to provide reasonable assurance of adequate protection of public health and safety and the common defense and security, (2) promote regulatory stability, predictability, and clarity*, (3) reduce requests for exemptions from the current requirements in 10 CFR Part 50 and 10 CFR Part 52*, [emphasis added] …" The Framework B approach of simply incorporating the prescriptive deterministic requirements from Parts 50 and 52 does not create a regulatory framework that is "flexible and practicable," it does not "provide the necessary flexibility for licensing and regulating" advanced nuclear plants, and it will not "reduce requests for exemptions from the current requirements." While it is recognized that the general approach in Framework B will necessarily be more conservative and prescriptive than the approach in Framework A, the wholesale incorporation of requirements from Parts 50 and 52 is not useful.	
2	General	Much of Framework B seems to focus on LWRs with some language included to address non-LWR technologies. This can be seen starting with definitions and the examples of	Review and revise Framework B to ensure a clear emphasis on non-LWR technologies.

		AOOs. While the scope of Framework B clearly is intended to address LWR and non-LWR technologies there appears to be an unfortunate LWR-emphasis carried over from Parts 50 and 52.	
3	General	Part 74 MC&A programs are required before the receipt of fresh fuel under the Construction and Manufacturing provisions. However, MC&A carries over into operation, but Part 74 is not referenced in the provisions for OL or COL.	Include Part 74 requirements in the provisions for Operating Licenses and Combined Licenses.
4	General	The on-going NRC rulemaking "Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing" is proposing a number of changes in Parts 50 and 52, and other related rules, that are pertinent to Framework B. However, the language in Framework B is consistent with or essentially identical to the existing language in Parts 50 and 52. Some of the changes being proposed would be particularly important to Framework B, such as the duration for design certifications, and a change/deviation process for Standard Design Approvals, just to mention two examples. Making the conforming changes in Framework B at this stage would be beneficial to the industry and to the NRC in eliminating confusion and wasted effort.	NRC should align the language in Framework B with the relevant language in the Part 50 and 52 lessons learned rule.
5	General	Aircraft Impact Assessments are required in 53.4730(a)(35) and are specifically required under 53.4969(a)(7)(xiii). The requirements in 53.4730(a)(35) closely mirror the requirements in 50.150 Aircraft Impact Assessment. However, in SECY-20-0093, "Policy and Licensing Considerations Related to Micro-Reactors," the staff identified aircraft impact assessment as one of the several topics that should be addressed for micro-reactors. In Enclosure 1 to SECY-20-0093, the staff specifically noted that aircraft impact assessments would be addressed "within	NRC should significantly revise the requirements in 53.4730(a)(35) to address aircraft impact assessment requirements appropriate to micro-reactors.

		the NEIMA-directed rulemaking for a technology-inclusive framework for advanced reactors." Continuing to address aircraft impact assessment relying on the approach in 50.150 is inconsistent with the commitment made in SECY-20-0093, and is inconsistent with expectations under NEIMA.	
SUBPART N – DEFINITIONS			
6	53.3010a	53.3010a Definitions – defines safety-related structures, systems, and components for non-light water reactors as those that are relied upon to remain functional during and following design basis accidents to assure: (1) the capability to perform safety functions determined in accordance with 53.4730(a)(5)(ii) and 53.4730(a)(36), including cooling to maintain the integrity of required systems and barriers such that these requirements and any other applicable requirements are met; or (2) the capability to shut down the reactor and maintain it in a safe shutdown condition; or (3) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in § 53.4730(a)(1)(vi).	Items 1 and 2 are prescriptive and in some ways duplicative. Item 1 should largely be subsumed by item 3. Barrier retention is primarily focused on release, which is captured through either traditional or functional containment, which corresponding guidance/policy that drives the treatment of such equipment. Item 2 assumes that a specific SSC is required both to achieve shutdown and maintain it in a shutdown condition, which is not entirely true for fast reactor technologies. Certain inherent characteristics may also be credited. It also leaves little flexibility by assuming a shutdown state is required to achieve a safe and stable state. Recommend removing items 1 and 2, using item 3 only for determination of SSCs that should be defined as safety-related.
SUBPART R – LICENSES CERTIFICATIONS, AND APPROVALS			
53.4730 General Technical Requirements – Provides the technical requirements applicable to the Safety Analysis Report in applications for a construction permit, an operating license, an early site permit, a combined license, a standard design approval, a standard design certification, or a manufacturing license. Comments and recommendations provided below on the various paragraphs in 53.4730 are applicable when the paragraphs are referenced in the provisions for the various application types but are not repeated.			

7	53.4730(a)(1)(vi)(C)	53.4730(a)(1)(vi)(C) – "The design demonstrates acceptable dose consequence criteria." • 53.4730(a)(1)(vi)(A) and (B) are the traditional 25 rem criteria. The (C) specific language does not appear in 50.34(a)(1), although language in 50.34(a)(1)(ii)(D) addresses "offsite radiological consequences." • 100.21(c)(2) states "Radiological dose consequences of postulated accidents shall meet the criteria set forth in § 50.34(a)(1) of this chapter for the type of facility proposed to be located at the site." That requirement points to the 25 rem criteria. • The concern is that 53.4730(a)(1)(vi)(C) is a way to incorporate the QHO considerations, without being specific about it.	53.4730(a)(1)(vi) should be revised to eliminate "C" or the language in "C" should be revised to be clear about what is meant by "acceptable dose consequence criteria." As written, this is open-ended and will lead to unnecessary iterations with the NRC.
8	53.4730(a)(3)	53.4730(a)(3) – "Kinds and quantities of radioactive materials" addresses meeting the requirements of Part 20. The last sentence states: "As required by Subpart B to 10 CFR part 20, a combination of design features and programmatic controls must, to the extent practical, be based upon sound radiation protection principles to achieve occupational doses that are as low as reasonably achievable." However, 10 CFR 20.1101(b) states "The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as reasonably achievable (ALARA)." 1. If the staff is going to cite other provisions in the NRC's regulations, it should be a correct quote. 2. There is no reason to paraphrase requirements from other regulations. It is sufficient to cite the specific	Revise 53.4730(a)(3) to, at a minimum, correctly quote 10 CFR 20.1101(b), or to simply cite that regulation with no need to repeat the language.

		Part 20 requirement, thereby ensuring clarity in the Framework B requirements.	
9	53.4730(a)(5)(vi)	53.4730(a)(5)(vi) Provides requirements for initiating events for chemical hazards. It is unclear what gap this is trying to include, and specifically requires initiating event identification that could result in events that do not have radiological consequences. Any internal events that could result in radiological consequences are accounted for in other sections. Requiring design features and criteria for events with non-radiological consequences is beyond the purview of the NRC, and handled through other organizations (e.g., OSHA).	53.4730(a)(5)(vi) should be revised to make clear that the requirement addresses radiological consequences stemming from an initiating event associated with a chemical hazard.
10	53.4730(a)(7)	53.4730(a)(7) Combustible gas control – This requires an "analysis and description of the equipment and systems for combustible gas control as required by 50.44." While 50.44 is principally relevant to water-cooled reactors, 50.44(d) pertains to "requirements for future non-water-cooled reactor applicants and licensees and certain water-cooled reactor applicants and licenses." 50.44(d)(1) requires information addressing whether accidents involving combustible gases are technically relevant for their design. 50.44(d)(2) requires "information (including a design-specific probabilistic risk assessment) demonstrating that the safety impacts of combustible gases during design-basis and significant beyond design-basis accidents have been addressed to ensure adequate protection of public health and safety and common defense and security." 50.44(d)(2) requires a design-specific PRA and makes no provision for alternative approaches, such as the AERI process, to be used.	53.4730(a)(7) should be revised to be a technology-inclusive requirement that includes a provision to use a risk-informed evaluation rather than requiring a design-specific PRA.

11	53.4730(a)(12)	53.4730(a)(12) Post-accident radiation monitoring and protection – Requires information to demonstrate compliance with (i) Perform radiation and shielding design of spaces around systems that may contain accident source term radioactive materials… and (ii) Provide a capability to promptly obtain and analyze samples…and (iii) Provide a capability for containment purging/venting designed to minimize the purging time consistent with ALARA principles.	Revise 53.4730(a)(12) to be less LWR-centric and more technology inclusive (e.g., eliminate references to "containment"). Revising 53.4730(a)(12) would present an opportunity to incorporate a performance-based requirement with performance targets that would be consistent with the underlying intent of the regulation.
12	53.4730(a)(34)	53.4730(a)(34) Description of risk evaluation – Requires a description of the risk evaluation and its results based on (i) a PRA or (ii) an alternative evaluation for risk insights (AERI), provided that the dose from a postulated bounding event to an individual located 100 meters (328 feet) away from the commercial nuclear plant does not exceed 1 rem total effective dose equivalent (TEDE) over the first four days following a release, an additional 2 rem TEDE in the first year, and 0.5 rem TEDE per year in the second and subsequent years. It is not clear why the cutoff distance is 100 meters and a basis for this distance could not be found. Given that the AERI approach is intended for facilities with maximum accidents of very low consequence, it would seem the consequences should be calculated using an actual distance of interest for the facility (since things like the source term and meteorology would be site-specific). The distance should be the boundary of the Owner Controlled Area, which is what power reactor sites use in their EP dose assessment/consequence models, if the distance to that boundary extends beyond 100 meters. Also, the "four days" term should be changed to be consistent with the SMR EP Rule version of the same criterion, i.e., "96 hours."	Revise the AERI entry criteria to remove the excessive conservatism so that they do not effectively constitute a barrier to making use of the alternative evaluation. A suggested rule text change for 10 CFR 53.4730(a)(34)(ii) is shown below. (ii) An alternative evaluation for risk insights (AERI), provided that the dose from a postulated bounding event to an individual located at the boundary of the Owner Controlled Area, but no less than 100 meters (328 feet) away from the commercial nuclear plant, does not exceed 1 rem total effective dose equivalent (TEDE) over ~~the first four days~~ 96 hours following a release, an additional 2 rem TEDE in the first year, and 0.5 rem TEDE per year in the second and subsequent years.

		While the addition of the AERI process is a positive change in Framework B, the specifics of the "entry criterion" are extremely conservative and, while characterized by the NRC as NOT being a safety criterion, they effectively become a very restrictive safety criterion for a designer that would seek to use the alternative evaluation.	
13	53.4731	53.4731 Risk-informed classification of structures, systems, and components 53.4731(a) provides definitions of RISC-1, RISC-2, RISC-3, and RISC-4 that are identical to the definitions in 50.69. 53.4731(b) Applicability and scope of risk-informed treatment of SSCs and submittal/approval process – Under (b)(1), "*Holders of a construction permit, or an operating, combined or manufacturing license*…that develop a PRA in accordance with the requirements of 53.4730(a)(34)(i) may voluntarily comply…" This is different from 50.69 which applies to a holder of an operating license or a renewed license; an *applicant for a construction permit or operating license; or an applicant for a design approval, a combined license, or a manufacturing license*. [Emphasis added.] It is not clear why the applicability of 53.4731 is more restrictive than the applicability of 50.69. ----------------------- The list of requirements in (b)(1) where compliance with 53.4731 provides a voluntary alternative to compliance with those requirements is effectively identical to the list in 50.69. However, 53.4731(b)(1)(iv) identifies 53.6355, which	1) 53.4731 should be revised so that applicability is consistent with 50.69. 2) The error citing 53.6355 in 53.4731(b)(1)(iv) should be corrected, presumably to 53.4105(b). 3) 53.4731(b)(1) should be revised to include the equivalent of 50.69(b)(1(xi) dealing with relief from certain testing requirements under Appendix A to part 100. 4) 53.4731 should be revised to permit use of the AERI process or other risk-informed processes rather than solely requiring a plant-specific PRA.

		does not exist. The requirement identified in 50.69 is 50.55(e) which is the counterpart to 53.4105(b). This error should be corrected. ------------------------- 53.4731(b)(1) does not include the equivalent of 50.69(b)(1(xi) dealing with relief from certain testing requirements under Appendix A to part 100. It is not clear why this relief is not included in 53.4731(b)(1). ------------------------- 53.4731(b)(2)(ii) requires a description of the measures taken to assure that the quality and level of detail of the systematic processes that evaluate the plant for internal and external events during normal operation, low power, and shutdown (*including the plant-specific probabilistic risk assessment (PRA), margins-type approaches, or other systematic evaluation techniques used to evaluate severe accident vulnerabilities)* [emphasis added] are adequate for the categorization of SSCs. Given this language, it is not clear why 53.4731 requires a plant-specific PRA versus permitting an adaptation of the AERI process or another risk-informed process.	
14	53.4909	53.4909 Contents of applications for construction permits; technical information. (a) *Preliminary safety analysis report.* Each application for a construction permit shall include a preliminary safety analysis report. The PSAR shall include the following information, *at a level of detail sufficient to enable the*	53.4909(a) should be revised to reflect a more realistic expectation for the level of detail required of a preliminary design necessary to support the Commission's findings as specified in 53.4933, "Issuance of construction permits."

		Commission to reach a conclusion on safety matters that must be resolved by the Commission before issuance of a construction permit: [Emphasis added] As a general matter, at the Construction Permit application stage, a plant design will not be sufficiently complete to satisfy the expectation in the 2nd sentence of 53.4909(a). More specifically, 53.4909(a)(7)(xi) requires the description of the risk evaluation required by 53.4730(a)(34). A construction permit by its very nature addresses a preliminary design. While risk evaluation tools are regularly used in the design of nuclear power plants, the level of maturity of the design at the construction permit stage does not support a robust risk evaluation. It is unrealistic to expect a risk evaluation (using a PRA or an alternative evaluation process) at a level of detail consistent with the second sentence of 53.4909(a) which would involve a detailed review by the NRC. Use of risk tools as part of the design process is a good practice but should not be included as required technical information for a construction permit.	53.4909(a)(7)(xi) should be removed or revised to require a description of the applicant's intended approach to qualifying the PRA or implementing the AERI process. This would be consistent with language in 53.4933(a).
15	53.4972 and 53.5019	53.4972, "Contents of applications for operating licenses; other application content," and 53.5019, "Contents of applications for combined licenses; other application content," each identify five items that must be included in the application but are in addition to the FSAR. The fifth item in both 53.4972 and 53.5019, or (a)(5) addressed "Mitigation of beyond-design-basis-events." The operative language in both 53.4972(a)(5) and 53.5019(a)(5) is identical, requiring that each application under Framework B that "does not meet the criteria in § 53.4730(a)(34)(ii) must include the applicant's plans for implementing the	53.4972(a)(5) and 53.5019(a)(5) should be eliminated because the event and mitigation strategies and equipment underlying 50.155 are not appropriate for the non-LWR technologies. Alternatively, 53.4972(a)(5) and 53.5019(a)(5) should be re-written as performance-based requirements with performance targets that can be addressed by each applicant on a technology-specific basis.

		requirements of § 50.155, including a schedule for achieving full compliance with these requirements and a description of the equipment upon which the strategies and guidelines required by § 50.155(b)(1) rely, including the planned locations of the equipment and how the equipment meets the requirements of § 50.155(c)." In other words, if an applicant can satisfy the AERI entry criteria, they do not need to address 50.155. However, all other applicants, regardless of technology employed in the design, must satisfy 50.155 which is based on LWR technology and the specific requirements in 50.155 cannot be reasonably adapted to non-LWR technologies. This would result in each non-LWR applicant that cannot satisfy, or does not choose to address, the 53.4730(a)(34)(ii) criteria being forced to submit an exemption request, resulting in unnecessary application preparation costs and increased review time and costs.	
16	53.4969(a)(7)(xiii)	53.4969(a)(7)(xiii) requires an aircraft impact assessment for all Operating License applications. (53.4969(a) requires a Final Safety Analysis Report for each operating license application and 53.4969(a)(7)(xiii) requires an aircraft impact assessment in accordance with 53.4730(a)(35).) However, 53.5016(a)(4)(xvii) only requires the aircraft impact assessment for Combined License applications that do not reference a standard design certification standard design approval, or manufacturing license. Since an Operating License application can reference a standard design certification or a standard design approval, there is an inconsistency in the requirements for an Operating License application and a Combined License application.	53.4969(a)(7)(xiii) should include language similar to 53.5016(a)(4)(xvii), deleting reference to a manufacturing license since a manufacturing license can only reference a Combined License.

17	53.5049 and 53.5052	53.5049, "Inspection During Construction," and 53.5052, "Operation Under a Combined License," specify timing for certain actions (for example, uncompleted ITAAC notification 225 days before the scheduled date for initial loading of fuel in 53.5049(c)(3) and notifying NRC of scheduled date for initial loading of fuel no later than 270 days before the scheduled date in 53.5052(a)). The timing of such actions is appropriate for large LWRs and their construction schedules. However, for physically smaller non-LWRs, with anticipated schedules much shorter than for the large LWRs, the timing for actions may be unrealistic, resulting in exemption requests and, potentially, unwarranted inspection or enforcement actions, stemming simply from the shorter timelines anticipated for non-LWR construction, moving fuel on site, etc.	NRC should engage the non-LWR vendor and potential license applicant community to discuss realistic timelines for construction and moving to operation and revise the expected timing for relevant actions, such as those in 53.5049(c)(3) and 535052(a), to be consistent with realistic timelines for non-LWRs.
SUBPART S – MAINTAINING AND REVISING LICENSING BASIS INFORMATION			
18	53.6030	53.6030, Revising design information within a manufacturing license 53.6030(b) states "The holder of an operating or combined license under Framework B of this part who references or uses a reactor manufactured under Framework B of this part…" However, 53.4120(e)(1) specifies that a manufactured reactor or major portions thereof may only be transported to the site of a licensee with a combined license. It would seem that 53.6030(b) erroneously includes the holder of an operating license. While this is not a substantive matter, it is one of several examples of errors and oversights in the Framework B text. If these errors are not corrected before publishing the rule,	NRC should conduct a thorough review of the Framework B language to identify and correct errors, no matter how big or small, to ensure that the final language is correct and unambiguous.

		they may lead to unnecessary confusing and protracted engagements between the NRC and the applicant/licensee.	
19	53.6052	53.6052, Maintenance of risk evaluations 53.6052(b) states that the risk evaluation must be maintained every 5 years. Maintenance is a continuous process. The more appropriate term would be to "update" the evaluation. 53.6052(b) states that "the licensee must upgrade the PRA to cover initiating events and modes of operation contained in consensus standards on PRA that are endorsed by the NRC." It is unclear how this would be applied for non-PRA approaches referenced in the rule, e.g., AERI.	The language in 53.6052(b) should be revised to reflect "updates" to the risk evaluation every 5 years. The language also should be revised to appropriately include non-PRA approaches.
20	53.6054	53.6054, Control of aircraft impact assessments 53.6054(a) states "For construction permits subject to §53.4730(a)(35)(i) of this section, if the permit holder changes the information required by §53.4909(a)(6)(xii) to be included in the preliminary safety analysis report…" However, 53.4909(a)(6)(xii) does not exist and it is not clear what is meant. 53.6054(b) addresses a similar requirement for operating licenses but that references 53.4969(a)(7)(xiv) which on functional containment. There is not a similar pointer to functional containment for a construction permit. Thus, the requirement in 53.6054(a) is incorrect.	As noted for 53.6030, it is important for NRC to conduct a thorough review of the Framework B language to identify and correct errors.
21	53.6055	53.6055, Control of licensing basis information in program descriptions, requires that program documents be included in licensing basis information. It appears to be redundant with the definition of licensing basis information in 53.6000 and is unnecessary. In over 300 pages of rule text,	NRC should review Framework B to identify any and all unnecessary or duplicative language and remove it.

		unnecessary or duplicative text creates the potential for confusion and inconsistent requirements.	
SUBPART U – QUALITY ASSURANCE			
22	Subpart U -- Quality Assurance	Subpart U is effectively word-for-word identical with 10 CFR 50, App. B. There are a few editorial differences and conforming changes, but these are not considered to be significant. Unfortunately, Subpart U does not include explicit provisions for an applicant or licensee to adopt other Quality Assurance standards, such as the ISO 9000 series of standards. An applicant or licensee could always seek an exemption to permit use of alternatives to Subpart U, but this imposes a burden on each applicant or licensee seeking to use an alternative, and a burden on the staff to review the exemption request. Addressing key alternatives as options in Subpart U would eliminate this burden and could support export of US technology or import of foreign technologies.	Subpart U should be revised to include options for developing applicant or licensee quality assurance plans.

Attachment C: Specific Comments on DG-1413 (Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Power Plants)

Section and Page Number	Comment	Potential Resolution
General	*The guidance provided in the DG is overly prescriptive. In cases where NRC has previously endorsed requirements described elsewhere (e.g., requirements specified in the ASME/ANS PRA Standards and guidance provided in NEI 18-04), the DG should simply indicate that an acceptable approach to meet regulatory requirements is for the applicant to demonstrate the provisions of the approved referenced approach were achieved.*	
General	*Several of the approaches specified in the DG (e.g., incorporation of BDBEs into the design basis, specifying QA requirements on the plant PRA in addition to those specified in the approved ASME/ANS standard) could be interpreted to represent additional requirements than those that are currently specified in Parts 50 or 52 (such guidance is referred to in the specific comments below as "implied requirements"). Inclusion of these implied requirements for Part 50 or Part 52 applications could be interpreted to constitute a backfit if these parts were to be modified to include them; inclusion of these requirements within Part 53 will serve as a substantial disincentive to license plants under this regulatory regime.*	
General	*While important, initiating event identification and ensuring a comprehensive set of initiators is developed is not the only way to ensure a design is safe. Providing engineering margin is also an acceptable and proven mechanism. The DG should be revised to permit use of alternative methods by the applicant to demonstrate that adequate levels of safety are achieved.*	
1) Purpose, Page 1	The purpose section (and throughout) introduces the term "licensing event" which is not a definition anywhere in Title 10 of the Code of Federal Regulations. It is unclear why this new term is being introduced.	Revise the DG to use terminology that is consistent with existing regulatory requirements or provide additional clarification for the term "licensing event" and provide justification for why the new classification is needed.

Section and Page Number	Comment	Potential Resolution
2) Applicable Regulations, Page 6	The incorporation of 53.4730(a)(5)(iv)(A) and 53.4730(a)(5)(v)(A) adds requirements to address Beyond Design Basis Events (BDBEs) within the design basis. This addition does bring US licensing requirements into closer conformance to international standards and requirements; however, it is inconsistent with (going beyond) current licensing requirements for LWRs and, if adopted, would result in substantial differences between the regulatory requirements between current generation LWRs and advanced reactor designs. Because these represent additional requirements on advanced reactors, which are considered inherently safer than existing LWRs, it raises the question of whether they should be applied retroactively to the existing fleet. Because imposition of such requirements would not meet the criteria established by the backfit rule, they should not be specified for licensing of advanced reactor designs.	Reconsider Framework B requirements. Inclusion of these requirements for Part 50 or Part 52 applications could be considered to constitute a backfit and require evaluation of the costs / benefits as per the backfit rule if they were to be adopted.
3) Table 1, Page 9	10 CFR 50.2 definition of safety-related SSCs is not the same as design basis events. Additionally, 50.49 is specific to environmental qualification of electrical equipment; it is unclear why those references are being used. It's not clear what the difference between external events and natural phenomena are in the list provided under design-basis events.	Provide clarification of the intent and necessity of including these in the regulatory guidance.

Section and Page Number	Comment	Potential Resolution
4) Table 1, Page 10	In Table 1 there are inconsistencies in the designated licensing event categories among the different frameworks. Framework A introduces "Unlikely Event Sequences" and "Very Unlikely Event Sequences" in lieu of "Design Basis Events" and "Beyond Design Basis Events" that are used in NEI 18-04 and Framework B. Because the decision on which framework to apply for a particular plant license is dependent on the plant owner / operator (licensee), it is imperative that the categorizations among the different frameworks be standard to the greatest extent practicable, and that the same terminology be applied across all frameworks	Recommend that Framework A be rewritten to use nomenclature and definitions consistent with those in NEI 18-04 and Framework B.
5) Table 2, Page 10	Table 2 provides options available for licensing event identification but seems to imply that DG-1413 must be used for traditional approaches and RG 1.233 must be used for enhanced approaches. Is the intent that DG-1413 should always be used and that RG 1.233 can be used to supplement the approach when enhanced use of risk insights is desired? However, because NRC has endorsed use of the ANS/ASME advanced reactor PRA standard for trial use in RG 1.233, the applicant should only need to demonstrate that the requirements of the standard are met if a PRA is used.	Provide clarification of when DG-1413 is expected to be used and/or when the use of RG 1.233 and following the PRA standard is acceptable. Additionally, for instances where the guidance provided in the DGs goes beyond the requirements of the ANS/ASME advanced reactor PRA standard endorsed for trial uses in RG 1.233, a basis should be provided as to why the additional activities are considered to be needed. (Also refer to comment 10 below on Page 15 of the Guidance.)

Section and Page Number	Comment	Potential Resolution
6) Table 2, Page 10	Table 2 makes it seem like non-LWR applicants that use PRA for risk insights would have to seek exemptions - what is the basis for that? If that isn't the intent, then this language is unclear.	Provide the basis for the need for exemptions, or additional clarification.
7) Section B, Licensing Frameworks, Page 11	It appears that the intent of Part 53 is to bring in additional requirements that are specified in international guidance or regulatory requirements. This seems to add extra burden that may not be necessary.	A framework that doesn't require additional burden, but that also doesn't conflict with international standards is more desirable than imposing more requirements. Any requirements that are added to Part 53 for the purpose of providing alignment with international standards should be reviewed for consistency with requirements with Parts 50 and 52 and determine whether the proposed requirements add additional burden to the license applicant compared to the requirements in Parts 50 or 52. If additional requirements beyond those specified in Parts 50 or 52 are included, then justification should be provided for why they are being imposed.
8) Section B, Licensing Frameworks, Page 11 (3rd paragraph)	"Designers and applicants who voluntarily seek ***enhanced use of risk insights*** to inform the licensing basis may use the guidance in RG 1.233 to identify licensing events" (emphasis added). "Enhanced use of risk insights" is not defined.	Provide additional clarification of what is meant by "enhanced use of risk insights."
9) Section B, Licensing Frameworks, Page 11 (3rd paragraph)	Guidance implies that one must either use LMP or use DG-1413; however alternative methods may be suitable.	Clarify the relationship between when DG-1413 should be used and when RG 1.233 should be used, or when other approaches are acceptable.

Section and Page Number	Comment	Potential Resolution
10) Section C, Staff Regulatory Guidance, Page 15	The last paragraph on Page 15 states that the guidance in this section is to be used when applicants decide to use AERI or traditional uses of PRA, and that RG 1.233 should be used for the identification of licensing events when applicants voluntarily seek enhanced uses of PRA. The link to NEI 18-04 in step 21 of Figure 1 is confusing when compared to the guidance provided in Table 1 and in the last paragraph of Page 15 which indicates that either DG-1413 or RG 1.233 should be used (and not both).	Remove link back to NEI 18-04 in Figure 1 and clarify the relationship between when DG-1413 should be used and when RG 1.233 should be used.
11) Section C, Figure 1	A substantial portion of the guidance can be characterized as specification of a process that the applicant should follow rather than providing specific objectives and criteria of what would be considered acceptable in a regulatory application. This is different from guidance provided for licensing of LWRs (in particular the SRP – RG 1.800) which specifies "what" must be considered and provided for review and leaves up to the applicant "how" to achieve the objectives and meet the requirements. Although the process displayed in Figure 1 is logical, it is overly prescriptive when compared to the approach specified in NEI 18-04.	The approach is logical and appears to be complete; however, current regulatory guidance does not state specific processes that licensees / applications must follow. Current regulatory guidance generally leaves it to the applicant to identify and apply the specific approach taken to develop the necessary information for the license application. The regulator's role is to review the application to ensure it provides sufficient information (with supporting technical analyses) to provide reasonable assurance (via meeting specified acceptance criteria) that plant design and operation do not result in adverse impacts to public health and safety and the environment. The DG should be revised to reflect this approach and if the flowchart is retained, it should be made explicitly clear that the process only provides an

Section and Page Number	Comment	Potential Resolution
		example of an approach that an applicant / license could use.
12) Section C, Figure 1 (Box 2 and Page 19, C.1.2)	NRC details review team expectations. The NRC has yet to justify the need for its review team composition expectations beyond those outlined under 10 CFR Part 50, Appendix B and an implementing QAPD.	Provide clarification of NRC review team expectations and justification for any additional implied requirements imposed beyond those specified in current regulations.
13) Section C, Figure 1 (Box 5 and Page 20, C.2.3)	Separately listing a search for chemical hazards is unnecessary and goes beyond the mission of the NRC. Potential hazards should be comprehensively identified as they pertain to radiological impacts and release; but otherwise do not need to be separately evaluated.	Provide clarification of NRC expectations and justification for additional activities imposed beyond those specified in current regulations. In particular, the linkages between activities to evaluate chemical hazards on the impacts (frequency and severity) of radiological releases should be provided in the DG.
14) Section C, Figure 1 (Box 22 and Page 25/26, C.6.3)	Grouping by frequency is too prescriptive, especially for smaller, simpler systems and does not have a corresponding regulatory basis.	Provide clarification of NRC expectations and justification for additional implied requirements imposed beyond those specified in current regulations. In particular, although grouping by frequency is logical (and has been the standard approach for LWRs), the DG should be revised to indicate that alternative approaches also can be used by applicants / licensees.
15) Section C, Page 20, C.2.4	Flexibility for a graded approach to providing for risk insights should be afforded in the guidance. The language appears to indicate that either a full scope PRA or use of the AERI framework is needed. However, there are a variety of applications of risk insights that should be afforded.	Provide clarification of NRC expectations and justification for additional implied requirements imposed beyond those specified in current regulations.

Section and Page Number	Comment	Potential Resolution
16) Section C.2.5, Page 21	Many advanced reactor designs are fundamentally different from LWRs (where the design, operational and accident characteristics, and licensing requirements are well established); it is not clear in the DG who is responsible for providing the definitions for severe accident conditions and risk assessment end states (i.e., the applicant or the regulator) for the different reactor designs. Additionally, since the risk analysis will be part of the plant licensing basis, is it the responsibility of the applicant to provide the definition of what constitutes a safe stable state or does NRC expect to develop definitions that will be used by all advanced reactor vendors seeking licenses / design certifications?	The endorsed guidance provided in NEI 18-04 requires plant damage states to be defined; hence the RG should also indicate that the applicant is expected to provide those definitions in their submittal.
17) Section C.2.5, Page 21	What process is envisioned to develop and validate computational codes for safety system analyses? An assumption is that the EMDAP approach defined in RG 1.203 would be acceptable. Does NRC expect to approve codes for use (as for current LWRs?). Since PRAs (or AERI) risk assessments are an integral part of the licensing of advanced reactors, are there additional expectations related to the acceptability of methods and codes used for these analyses beyond those specified in the applicable ANS/ASME PRA standard (as endorsed in its respective RG)?	Provide additional clarification to address these issues.

Section and Page Number	Comment	Potential Resolution
18) Section C.3, Page 22	For analyses using the qualitative (e.g., FMEAs, HAZOPs, etc.) and quantitative (e.g., ETs/FTs) methods described in Section C.3, does NRC intend that these analyses will become part of the licensing basis; and if so, what does that mean for future changes that could be made by the applicant / licensee (e.g., would a change in plant operation or maintenance procedures that results in changes in a FMEA or FT require a license amendment)?	Provide additional clarification to address these issues. Since changes to these analyses do not constitute a need for a license amendment for LWRs, it is not anticipated that they should be required for advanced reactors.
19) Section C.3.2, Page 22	This section conflates the grouping and bounding of events. Initiating event identification may occur in tandem with grouping; prescribing that grouping occur only after identifying all initiating events is overly prescriptive.	Provide clarification of NRC expectations and revise DG to permit applicant / licensee to determine the most appropriate process to be used to develop the necessary analyses and bases / justifications for the regulatory submittals.
20) Section C.4.4, Page 24	The endorsement of RG 1.200 (for LWRs) and RG 1.247 (for non-LWRs) is useful for meeting the independent review requirements. Reference to these RGs could also satisfy many other facets of the licensing event identification process.	The overall guidance in DG-1413 could substantially be shortened and simplified by stating this as an overall principle.
21) Section C.4.4, Page 24	It is unclear what is driving the extension of QA within the guidance itself beyond what is accounted for within the 10 CFR Part 50 Appendix B and an implementing QAPD.	Provide clarification on the gap the NRC is seeking to address through these items in C.4.4. and provide justification for additional implied requirements imposed beyond those specified in current regulations.

Section and Page Number	Comment	Potential Resolution
22) Section C.5.3, Page 25	Would these requirements bring the PRA IE evaluations under the plant QA program, or just those AOOs, DBAs, BDBEs that are specifically included in the site licensing analysis. If so, would the rest of the PRA program be pulled in as well?	PRAs are not included in the plant licensing basis for Part 50 and are not subject to QA requirements (i.e., Appendix B) other than those specified in the endorsed ASME/ANS PRA Standards. The NRC should provide additional clarification on their expectations on these issues.
23) Section C.6.3, Page 25 (also throughout)	The DG discusses categorization of events by frequency, which is largely an element of the LMP and for which there is not a clear regulatory basis. It is later discussed that grouping strategies may employ other grouping characteristics.	Provide additional clarification, given that sufficient flexibility should be afforded with respect to grouping strategies. Also see comment #19 above.
24) Section C.7, Page 25	The initial statement defines those designers/applicants subject to documentation requirements, but it is unclear who would not fall into the categories of designers or applicants in this section. It also suggests that all documentation ever created that supports initiating event identification must be preserved for the life of the plant.	This appears to be broader scoping than that of prior precedent. Provide clarification of NRC expectations and justification for additional implied requirements imposed beyond those specified in current regulations.
25) Appendix A, Page A-1	Generally, this appendix constitutes specifics on "how to" guidance rather than what is required.	Remove prescriptive guidance that describes how an applicant / licensee should meet a particular requirement; replace with review acceptance criteria as applicable.
26) Appendix A, Page A-1	EPRI 1022997 has been updated and should be replaced with EPRI 3002005287.	Update Reference A-6.

Section and Page Number	Comment	Potential Resolution
27) Appendix A, Page A-2	It is not clear what the intent or value of providing the list of references serves. It could be interpreted that approaches described in the references constitute expectations of NRC staff that licensees must use.	If NRC intends specific methods to be applied or approaches employed, they need to be explicitly indicated.
28) Appendix A, Page A-3	It is not clear what the purpose of providing the list of possible inductive analysis approaches is.	Provide clarification as to whether or not the NRC expectation is that an applicant needs to select one or more of these approaches and justify its use.
29) Appendix A, Page A-6	Similar to comment #28, it is not clear what the purpose of providing the list of possible deductive analysis approaches is.	Provide clarification as to whether or not the NRC expectation is that an applicant needs to select one or more of these approaches and justify its use.

Attachment D: Specific Comments on DG-1414 (Alternate Evaluation for Risk Insights (AERI) Framework)

Section and Page Number	Comment	Potential Resolution
General	*As described in the DG, the effort required to implement the AERI framework is not substantively less than would be required to perform a PRA, thus making the AERI option not beneficial from the perspective of most applicants / licensees.*	
1) Related Guidance, Page 4	Reference to (SRM)-SECY-93-092 is circular and not useful.	For clarity, the DG should be revised to indicate the specific items in the SECY that are relevant to the DG and regulatory review, rather than require the applicant / licensee to retrieve the SECY, review it, and attempt to determine what NRC staff considers to be the critical issues.
2) Related Guidance, Page 5	Reference to (SRM)-SECY-03-0047 is circular and not useful.	For clarity, the DG should be revised to indicate the specific items in the SECY that are relevant to the DG and regulatory review, rather than require the applicant / licensee to retrieve the SECY, review it, and attempt to determine what NRC staff considers to be the critical issues.
3) Background, Page 7	The AERI process explicitly requires comparisons to the QHOs (e.g., latent cancer risks). There will be very large uncertainties associated with these estimates and the DG does not provide any discussion of NRC expectations related to evaluation of uncertainties in the outcomes from the AERI method related to evaluation of these uncertainties. Additionally, the intent of the AERI process steps C4 through C6 is clear; however, once the provisions of C3 are demonstrated (i.e., evaluation of bounding events demonstrate the QHOs are met with high	Discuss NRC expectations on how uncertainties should be addressed. Reconsider the need to perform detailed assessments of Steps C4 through C6 if Step C3 is demonstrated to have been met.

Section and Page Number	Comment	Potential Resolution
	confidence), this would effectively make these tasks unnecessary.	
4) Background, Page 9	It is stated that a dose estimate using a bounding event should be used to confirm that the entry condition is met.	It should be noted that the ability to demonstrate these criteria are met will likely require plant design to be essentially complete with a good understanding of accident progression. (This may make the choice to use the AERI process difficult and potentially limit it from being a practical alternative.)
5) Background, Page 9	It is stated that a demonstrably conservative risk estimate for the bounding event can be used to support a comparison with the QHOs.	The key is to have clear guidance and criteria as to what constitutes a demonstrably conservative bounding analysis. The DG should be expanded to provide specific guidance on the evaluation criteria that will be applied in regulatory review.
6) Background, Page 10	Five examples are provided at the bottom of the page for possible severe accident vulnerabilities. However, the use of a single failure criterion in the plant design should eliminate items (b) – (e) from resulting in a severe accident; hence leaving only example (a) = common cause (and at that the most prevalent causes being very rare external events if basic principles of defense in depth and diversity are implemented).	Add discussion that provides this clarification.
7) Section C.1.2, Page 14	The constraints listed in Section C.1.2 may have sufficient economic impact (e.g., limit power production capability) so as to reduce the benefits of the AERI approach for most advanced reactor designs.	Because the discussion indicates there is a great amount of regulatory uncertainty associated with use of AERI, this uncertainty will be seen as a strong impediment to its use. For those issues which could result in regulatory uncertainty, NRC staff should reconsider the approach

Section and Page Number	Comment	Potential Resolution
		and develop guidance to eliminate or substantially reduce the uncertainty.
8) Section C.3.8, Page 17	An issue that is not addressed in the DG are NRC expectations related to analytical model fidelity and implementing software quality assurance and verification / validation. Is the expectation that the models and software codes meet requirements similar to safety analysis developed for LWRs as specified in RG 1.203? This is a potentially significant issue for advanced reactors given that there currently do not exist models and software for the various non-LWR reactor designs that have been subject to NRC review and approval.	Provide additional guidance regarding NRC expectations regarding software quality assurance and verification / validation requirements.
9) Section C.8.2, Page 22	Given that there exists minimal operational experience for non-LWR advanced reactor designs, what are NRC expectations related to use of expert opinion in developing and evaluating the risk assessments (for both AERI and PRA approaches)?	Provide additional guidance related to the use of expert opinions.
10) Section C, General Comment	The critical criteria related to the decision to apply AERI are (1) design is such that a "severe accident" cannot occur, (2) bounding estimates of dose that would be experienced are inconsequential (for both acute and long-term exposure without implementation of protective actions), and (3) there would be limited benefits conferred by performance of a PRA with respect to licensing decisions. – Key regulatory guidance is provided in C.2.2. that dose estimates for the bounding events	Given the constraints and implied requirements specified for the AERI approach, it appears that it would be much more straightforward to develop a PRA to support licensing decisions. Additionally, use of a PRA would eliminate any sources of regulatory uncertainty that exist if the AERI approach were to be applied. Simplify the AERI process such that it is a more attractive option for the industry that can meet the entry requirements.

Section and Page Number	Comment	Potential Resolution
	in AERI assume that an individual at the EAB does not take any protective actions in either the early phase (i.e., evacuation) or intermediate phase (i.e., relocation) of the event. – Key regulatory position is provided in C.3.2. that applicants should follow guidance in ASME/ANS RA-S-1.4-2021 as endorsed in Trial RG 1.247 and in C.3.3 that the results can be compared to the QHOs for prompt and latent cancer fatalities. – Requirements specified in the DG would basically require the applicant to perform most of the assessments necessary for a PRA with the exception of (1) the need to put into an ET/FT model and (2) quantify the results.	

Attachment E: Comprehensive List of Industry Comment Submissions and Presentations

Many hundreds of pages of comments, produced through thousands of hours of effort, have been formally submitted to the NRC beginning in August 2020. While the below lists are limited to NEI and USNIC submissions, an equivalent amount of submissions were made by members of the industry and several non-governmental organizations. Submissions below start with the most recent.

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 letter, 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. "USNIC Comments on NRC's Rulemaking on Risk-Informed, Technology Inclusive Regulatory Framework for Advanced Reactors," July 15, 2021 (ML21196A499)
6. "Unified Industry Position on the NRC's Rulemaking on TIRIPB Regulatory Framework for Advanced Reactors," NEI and 18 other signatories, July 14, 2021 (ML21196A498)
7. "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)
8. "USNIC suggested update to Part 53 NRC Preliminary Language-Subpart B," February 3, 2021 (ML21035A003)
9. "NEI Input on the NRC Rulemaking on Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," December 23, 2020 (ML20363A227)
10. "NEI Input on the NRC Rulemaking Plan on, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," October 21, 2020 (ML20296A398)

Presentations at NRC Public Meetings

1. "Industry Perspectives on Part 53," Commissioner Briefing, July 21, 2022
2. "Part 53 Rulemaking: Framework B," (NEI) and "General Part 53 Comments, High level Insights on Framework A, and Going Forward," (USNIC) Advanced Reactor Stakeholder Meeting, June 30, 2022
3. "Results of Nuclear Energy Institute and U.S. Nuclear Industry Council 2022 Part 53 Industry Survey," NRC Advanced Reactor Stakeholder Meeting, May 11, 2022
4. "Part 53 Rulemaking: Selected Topics," (NEI, ML22088A034) and "Part 53 Rulemaking: General Approach, QHOs, BDBE, ALARA, Facility Safety Program, and Other Topics," (USNIC), NRC Part 53 Public Meeting, March 29, 2022
5. "Part 53: Perspective on PRA, Process, Concerns, and Going Forward," (USNIC) NRC Advanced Reactor Stakeholder Meeting, March 16, 2022

6. "Industry Perspectives on Part 53," December 17, 2021, ACRS – Joint presentation NEI/USNIC. Topics include: QHOs, PRA, ALARA, BDBE, etc.
7. "Part 53 – NEI Perspectives," December 9, 2021, Commission Briefing. Topics: Key Issues, Path Forward, Stakeholder Engagement
8. "Part 53 Programs," and "Change Control – 53.1322," NRC Part 53 Public Meeting, September 15, 2021
9. "Role of the PRA," NRC Advanced Reactor Stakeholder Meeting, August 26, 2021
10. "Manufacturing Licenses," June 10, 2021, at NRC Part 53 Meeting (starting slide 62)
11. "Part 53 Graded Approach to PRA," NRC Advanced Reactor Stakeholder Meeting, May 27, 2021
12. "Part 53," April 8, 2021. Part 53 Meeting. Topics: Subpart C (slide 75), Subpart E: Construction and Manufacturing
13. "Part 53 Rulemaking – NRC ACRS Meeting," March 17, 2021. Topics include: 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.
14. "Construction Permit Guidance," (NEI slides 18-31, Stakeholders meeting), February 25, 2021
15. "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)
16. "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)
17. "Part 53 Rulemaking," November 18, 2020. Topics include: Safety Criteria, Objectives and AEA Standards, ALARA, Safety Paradigm. (ML20318A007, slides 37-45)
18. "Part 53 Rulemaking," August 20, 2020. Topics: Objectives, QA, Role of PRA (ML20232D114, slides 121-127)

Attachment F: Comments on Operational Requirements

	Affected Section	Comment/Basis	Recommendation
FRAMEWORK A, SUBPART F – REQUIREMENTS FOR OPERATIONS [NOTE: SOME COMMENTS ALSO REFER TO SPECIFIC PROVISIONS IN FRAMEWORK B, SUBPART P, AS NOTED]			
1	SUBPART F 53.725(a) and 53.800(a)	Part 53.725(a) & 53.800 discuss the General Licensed Reactor Operator (GLRO) licensing process. 1. From 53.725(a): "…a general license is effective without the filing of an application with the Commission or the issuance of licensing documents to a particular person." 2. From the discussion section of 53.810: "Individuals licensed under this provision as GLROs are licensed by the Commission…". Further clarification is needed on how and to whom a GLRO license is issued. Is it issued to the facility then the facility tracks the individuals that meet the requirements, or is the license issued to the individual?	Recommend that the NRC staff provide clarification of how the GLRO license is issued and ensure that it is consistent throughout the rule. Is the GLRO license issued to the facility or to the individual? If it is issued to the facility, does the NRC approve of the GLRO training program, then the facility tracks those individuals that meet the requirements?
2	SUBPART F 53.730(b)(7)(i)	53.730(b) Human system interface design requirements – Some sections in this area, (b)(4) & (b)(5), provide examples to clarify how the requirements can be met. Section 53.730(b)(7)(i) does not provide additional examples of how this requirement is to be met. The requirements may be understood if the operators are in the control room, but if an evacuation of the control room is needed it is unclear how this requirement would be met. Is receiving plant operating data in a remote location acceptable?	Recommend the NRC provide examples in 53.730(b)(7)(i) on what are acceptable ways to receive data, such as at a remote location, centralized facility, or remote shutdown panel.
3	SUBART F 53.730(f)(1) through (5)	Parts 53.730(f) and 53.4226(f) discuss the requirements of the staffing plan. The requirements in these sections are more prescriptive than current regulations and should be commensurate with the	Recommend that Parts 53.730(f) and 53.4225(f) be revised to reflect the new "walk-away safe" technology. More detail could be provided in guidance to ensure the proper staffing is provided based on the technology of

	Affected Section	Comment/Basis	Recommendation
	SUBPART P 53.4226(f)(1) through (3)	technology, as many of the advanced reactors are “walk-away safe,” including actions performed by the human, when performed incorrectly, do not result in plant degradation or release of radiation to the public and environment.	the application. Section 5 of the Technical Specifications (TS) should be used to provide the details around the staff needed.
4	SUBPART F 53.730(g) SUBPART P 53.4226(g)	Part 53.730(g) Training and Examination Programs – This section removes the ambiguous reference to INPO in the current regulation, which is appreciated. However, to ensure complete understanding, is the intention that if this section is met then the sections of 10 CFR 55 that are currently required to be met for Operator training programs are not needed to be met under Part 53?	Recommend that the NRC staff provide validation that sections 40, 41, 43 & 45 of 10 CFR 55 do not need to be met if the requirements in 10 CFR 53.730(g) are met.
5	SUBPART F 53.730(f) 53.740(b) SUBPART P 53.4226(f) 53.4230(g)	For advanced reactors that want to deploy multiple modules, it will be difficult to prove how much staff is needed as the project scales. This will be specifically true of the maintenance & chemistry staffing. The staffing required to safely operate the plant should be covered under Chapter 5 of the TSs, the remainder of plant staffing should be left to the facility licensee, and a separate staffing plan should not be required.	Recommend that the staff determine which positions are required to operate the plant (Operators, Chemistry & Radiation Protection) and have requirements for those positions to be specified in Section 5 of the Technical Specifications. A complete staffing plan should not be required for non-operational positions. If further information was needed for the non-operational positions, this could be done within guidance.
6	SUBPART F 53.730(f)	Item 53.730(f) (2) and (3) describes how the staffing plans provide sufficient qualified operators across all modes of operation to provide assurance that plant safe safety functions will be assured. Item (2) for specific license operators calls out “all modes of operation,” and specifically requires that the	Recommend that the NRC staff provide clarification as to when a HFE analysis and assessment is required. Is it required only for those plants that do not have GLRO’s, or do plants that have GLRO’s need to do an HEF analysis and assessment?

	Affected Section	Comment/Basis	Recommendation
		description is supported by a Human Factors Engineering (HFE) analysis and assessment. Item (3) for generally licensed operators uses different language for "monitor(ing) fueled reactors" and "facility operation at all times during operating phase," and does not require an HFE analysis – even though item (4) in this section appears to require an HFE evaluation for both plant types. Why are these different and is an HFE analysis and assessment needed for either type of plant?	
7	SUBPART F 53.730(g) SUBPART P 53.4226(g)	Items 53.730(g) Training and Examination Programs This section requires that the Operator Training programs are approved as part of the operating license or combined license for the plant. How does the staff foresee that periodic and routine training program updates done as part of typical SAT based training programs would be addressed, and inspected, within this methodology? Parts 53.730(g) and 53.4226(g) discuss similar topics but have different requirements. Is this as planned, or will they be the same in the future?	Recommend that the NRC staff provide further information as to how revisions to the Operator Training programs will be handled by the NRC. Will programs have to be re-approved if they are revised, following initial approval? Also recommend that the NRC staff provide clarification of the differences between Parts 53.730(g) and 53.4226(g).
8	SUBPART F 53.740(g)	Items 53.740(g) and 53.4230(g) lay out the requirements for a senior licensed operator to directly supervise core alterations, however this requirement	Recommend that the NRC staff provide additional clarification in this area, specifically around alterations of the core while the plant is operating.

	Affected Section	Comment/Basis	Recommendation
	SUBPART P 53.4230(g)	does not apply when altering the core while the plant is operating. No additional reasoning on why this requirement is not needed while the plant is operating and how the core would be altered while the plant is operating.	
9	SUBPART F 53.785(b) SUBPART P 53.4250(b)	Items 53.785(b) and 53.4250(b) Operator licensing initial examination program There is not much information in this section, especially as compared to NUREG-1021 used by the current LWR fleet. Does the staff anticipate that a guidance document would be employed to provide more clarity as to what is expected here?	Recommend that the NRC staff provide further guidance to provide more clarity to the expectations in these sections.
10	SUBPART F 53.800(a)(3)	Item 53.800(a)(3) has requirements associated with defense in depth, as described under Part 53.250, that can be met without reliance on human actions for event mitigation. Having no reliance on human actions to assure defense in depth functions seems counter-intuitive given that 53.250 states that no single design feature, human action, or programmatic control, no matter how robust, should be exclusively relied upon. Is there a threshold to PRA risk analysis below which defense in depth actions do not have to be automatic?	Recommend that the NRC staff determine a threshold to PRA risk analysis below which defense in depth actions do not have to be automatic.

	Affected Section	Comment/Basis	Recommendation
11	SUBPART F 53.815(f)	Part 53.815(f) seems to contradict the requirements of 53.815(b) – why require an exam when a facility licensee can then waive the exam requirement?	NRC staff should provide guidance as to when the requirements for an exam could be waived.
12	SUBPART F 53.830	Part 53.830 discusses that a General License expires when the GLRO is no longer employed in a position that may involve the manipulation of the control of the commercial nuclear plant. Is there a timeframe as to when this would be required? If a GLRO is on a temporary administrative assignment, would the license need to be expired, then brought back once the GLRO is complete with their assignment?	Recommend that the NRC staff provide further guidance in this area regarding expected timeframes for when a General License would have to expire.
13	SUBPART F 53.835 SUBPART P 53.4240	Parts 53.835 & 53.4240 discuss Operator Licensing Applicability. These sections appear to be redundant and add no value at this time. These sections could be deleted and sections 53.840 and 53.4242 updated accordingly. There is a section (b) in each of the parts that has been reserved, but no information is available at this time.	Recommend that the NRC staff remove Parts 53.835 & 53.4240 or provide further details within them to differentiate them from Parts 53.840 & 53.4242.
14	SUBPART F 53.840 SUBPART P 53.4282	Parts 53.840 and 53.4282 discuss the training & qualification requirements for the facility. Multiple training programs are identified, but engineering is not one of them. In Parts 53.730(f)(1) and 53.4226(f)(1) it states, "the staffing plan must include a description of how engineering expertise will be available to the on-shift operating personnel during all plant conditions." This appears to be in contradiction to Parts 53.840 and	Recommend that the NRC staff remove the requirement for engineering expertise in Parts 53.730(f) and 53.4226(f). If it is determined that the engineering expertise is providing benefit to the health and safety of the public, based on the new technology of Advanced Reactors, then it should be determined if a training & qualification program is also needed for this engineering expertise positions.

	Affected Section	Comment/Basis	Recommendation
		53.4282, which are commensurate with the design of the Advanced Reactor plants. If an engineering training & qualification program is not needed, why is engineering expertise required? The need for engineering expertise is left over from TMI and an understandable requirement for the current LWR fleet. However, based on the technology behind the new Advanced Reactors, the requirement for engineering expertise no longer provides the additional benefit to the health and safety of the public.	
FRAMEWORK B, SUBPART P – REQUIREMENTS FOR OPERATIONS			
16	General	Some of the programs required in Subpart P (i.e., the “Process Control Program” in 53.4310(c), the “program” required in 53.4390(a) and details in 53.4390(b), and the “Integrity Assessment Program” required in 53.4400) are overlays to specific requirements in Subpart P but do not contribute further to plant safety. They will, however, contribute to increased burden and general complexity of the operational requirements by adding the overlay program requirements.	NRC should review the language in Framework B and delete requirements, such as the cited overlay programs, that do not contribute to the safe operation of the plant.
17	53.4200	53.4200, Operational objectives – Lays out the broad objectives for operations. Stipulates that: • Each holder of an operating license or combined license under Framework B must define, implement, and maintain controls for plant SSCs, responsibilities of plant personnel,	53.4200 should be deleted.

	Affected Section	Comment/Basis	Recommendation
		and plant programs during the operating life of each commercial nuclear plant. • Each such licensee must maintain the capabilities and reliabilities of facility structures, systems, and components to ensure that these structures, systems, and components can perform their specified safety functions if called upon during design-basis events. • Each such licensee must ensure that plant personnel have adequate knowledge and skills to perform their assigned duties. • Each such licensee must implement plant programs during operations to ensure that plant safety is maintained during normal operations and design-basis events. Each of these "objectives" mirrors specific requirements provided in Subpart P. This type of introductory information offers the potential for inconsistencies and confusion as the rule would be implemented. 53.4200 does not provide information or requirements that would directly contribute to the safe operation of a plant but does offer the potential for confusion.	
18	53.4213	53.4213, Technical specifications. 53.4213 provides the specific requirements for technical specifications that must be included with the OL or COL. The TS must include items in the following categories: (1) Safety limits, limiting safety system settings, and limiting	Recommend deleting "or acts as a precursor to identify an issue that would affect the integrity of a fission product barrier" in Criterion 3.

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		control settings; (2) Limiting conditions for operation; (3) surveillance requirements; (4) design features; (5) administrative controls; (6) decommissioning; (7) initial notification; and (8) written reports. 53.4213 flows directly from 50.36 with conforming changes to delete reference to fuel cycle facilities and non-power reactors. One notable difference is in Criterion 3 for limiting conditions for operation. Criterion 3 in 53.4213(b)(2)(ii) states "A structure, system, or component that is part of the primary success path and which functions or actuates to mitigate a design basis accident or transient that either assumes the failure of, presents a challenge to, *or acts as a precursor to identify an issue that would affect* the integrity of a fission product barrier." [Emphasis added.] It is not clear why this is added to Criterion 3 but may complicate the definitions of LCOs under Criterion 3.	
19	53.4310	53.4310 Radiation Protection. 53.4310(a) requires a Radiation Protection Program for operations sufficient to ensure compliance with Part 20. 53.4310(b) must have a program for the control of radioactive effluents and for keeping the doses to members of the public as low as reasonably achievable.	Recommend deleting 53.4310(c).

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		It also requires the program be contained in the Offsite Dose Calculation Manual. 53.4310(b)(2) requires the Annual Radiological Environmental Operating and Radioactive Effluent Release reports. 53.4310(c) requires a "Process Control Program" to identify the administrative and operational controls for solid radioactive waste processing, process parameters, and surveillance requirements to ensure compliance with Parts 20, 61, and 71. 53.4310 essentially consolidates requirements to comply with applicable requirements of Part 20 as specified in 50.34(b) and 52.79, requirements stemming from 50.36a (the ODCM stems from the requirements in 50.36a and Appendix I to Part 50). The requirement for a "Process Control Program" appears to be a new required program but consolidates administrative and operational controls on radioactive waste processing stemming from Parts 20, 61, and 71, into a single program. It is not clear that consolidating these requirements into a "program" is a necessary requirement. While it will ensure licensees under Part 53 will be aware of the various requirements, it is likely to impose additional burden associated with "developing, implementing, and maintaining" the	

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		Process Control Program, without contributing to the safe operation of the plant.	
20	53.4350	53.4350 Fire Protection flows directly from 50.48 and Appendix R to Part 50. It is extremely prescriptive and doesn't incorporate lessons learned from the operating fleet. It is noted that 50.48(c) allows for use of NFPA-805 (risk-informed, performance-based fire protection). However, the approach is being applied to existing plants that have separation issues related to three areas: 1) un-approved local manual actions, 2) separation issues related to fire-induced multiple spurious operations (MSOs) and 3) fire wrap or other barriers that were found to not match the original fire rating, such as HEMYC. Current advanced reactors do not have any of these issues, so NFPA-805 (50.48(c)) is not useful. The issue here is that for an advanced reactor with very low fire risk, 53.4350 is extremely complicated but provides no burden reduction for the base fire protection requirements such as fire brigade, regulatory required suppression/detection, etc. Regarding opportunities to introduce performance-based language into 53.4350, it is noted that NFPA is transitioning to a more performance-based approach where brigade size not specified, water supply determined by analysis, etc. Unfortunately, this has not	53.4350 should be significantly revised to make use of a truly performance-based approach, incorporating experience from the operating fleet and performance-based approaches being addressed by NFPA, as appropriate.

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		been incorporated into the NRC requirements, but introducing these concepts into 53.4350 would be an improvement.	
21	53.4360	53.4360 Inservice inspection/Inservice testing: 53.4360(a) requires that BWRs and PWRs licensed under Framework B to meet the requirements of the ASME B&PV code for ISI and the ASME OM code for IST, as specified in 50.55a. 53.4360(b) requires non-light water reactors to develop, implement, and maintain programs for ISI and IST that meet the requirements in 53.880. From the version of 53.880 released on 2/28/2022, 53.880(a) requires risk insights be used to supplement the ISI and IST programs. 53.880(b) requires pre-service baseline inspections and tests using the same techniques as will be used in future testing. 53.4360(b) requiring 53.880 creates a challenge for non-LWRs that meet the AERI entry criteria since they may not have a PRA that presumably would be required to provide "risk insights" under Framework A. This raises a question about potential application of AERI to provide risk-insights.	53.4360(b) should be revised to address ISI/IST for plants that can and are making use of AERI.

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22	53.4380	53.4380 Environmental qualification of electric equipment important to safety for nuclear power plants. 53.4380 is essentially identical to 50.49, with some deletions of old and inapplicable text. 53.4380 retains the detailed, prescriptive, and deterministic requirements on qualification from 50.49. There are no options based on risk-insights, using either a PRA or AERI.	53.4380 should be revised to be performance-based and to provide options to include risk-insights, using either a PRA or AERI, as a basis for alternative EQ requirements.
23	53.4390	53.4390 Procedures and guidelines, requires: (a) Each holder of an operating license or combined license under Framework B of this part must have a program for developing, implementing, and maintaining an integrated set of procedures, guidelines, and related supporting activities to support normal operations and respond to possible unplanned events. (b) The program required by paragraph (a) of this section must include but is not limited to development, implementation, maintenance, and supporting activities of procedures and guidelines for the following: 1) Plant operations 2) Maintenance activities under § 53.4205 3) Program requirements under this subpart 4) Emergency operating procedures if human intervention is needed to respond to design basis	53.4390(a) should be revised to simply include the phrasing from 50.34(b)(6)(iv) and 52.79(a)(29)(i). 53.4390(b) should be deleted in its entirety.

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		accidents identified in accordance with the requirements of § 53.4730(a)(5)(i) 5) Procedures that describe how the licensee will address the following areas if the licensee is notified of a potential aircraft threat: i. Verification of the authenticity of threat notifications; ii. Maintenance of continuous communication with threat notification sources; iii. Contacting all onsite personnel and applicable offsite response organizations; iv. Onsite actions necessary to enhance the capability of the facility to mitigate the consequences of an aircraft impact; v. Measures to reduce visual discrimination of the site relative to its surroundings or individual buildings within the protected area; vi. Dispersal of equipment and personnel, as well as rapid entry into site protected areas for essential onsite personnel and offsite responders who are necessary to mitigate the event; and vii. Recall of site personnel. 53.4390(a) is similar to 50.34(b)(6)(iv) which simply requires "plans for conduct of normal operations, including maintenance, surveillance, and periodic	

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		testing of structures, systems, and components." This same language is included in 52.79(a)(29)(i). The language is 53.4390(a) is more expansive for no apparent reason. 53.4390(b) is extremely specific and is essentially an overlay to the requirements for programs and procedures required under Subpart P. It specifies what must be included in the overarching program required under 53.4390(a). 53.4390(b) is an overlay to other programs and plans required under Subpart P and it is not clear exactly what purpose it is to serve. It adds burden with no obvious safety benefit.	
24	53.4400	53.4400 Integrity assessment program requires: Each holder of an operating license or combined license licensee under Framework B of this part must develop, implement, and maintain an integrity assessment program to monitor, evaluate, and manage: a. The effects of plant aging on SSCs identified in § 53.4400(d). The program may refer to surveillances, tests, and inspections conducted for specific SSCs in accordance with other requirements in Framework B of this part or conducted in accordance with applicable accepted consensus codes and standards;	53.4400 should be deleted.

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		b. Cyclic or transient load limits to ensure that SSCs are maintained within the applicable design limits; and c. Degradation mechanisms related to chemical interactions, operating temperatures, effects of irradiation, and other environmental factors to ensure that the capabilities and reliabilities of SSCs satisfy the principal design criteria for the commercial nuclear plant. d. Plant structures, systems, and components within the scope of this section are-- 1) Safety-related structures, systems, and components; and 2) Non-safety-related structures, systems, and components: i. That are relied upon to mitigate accidents or transients or are used in plant emergency operating procedures; or ii. Whose failure could prevent safety-related structures, systems, and components from fulfilling their safety-related function; or iii. Whose failure could cause a reactor scram or actuation of a safety-related system. The issues addressed in 53.4400 are important issues relative to plant safety. However, they are addressed through other requirements such as plant maintenance in 53.4210, technical specifications in 53.4213, ISI/IST	

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		in 53.4360, the facility description and design requirements detailed in 53.4730(a)(2), and the overall quality assurance requirements specified in Subpart U. 53.4400 is an overlay to these other programs required under Subpart P and it is not clear exactly what purpose it is to serve. It adds burden with no obvious safety benefit.	