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; RulemakingComments Resource; TRUE, Doug; NICHOL, Marcus; jeff.merrifield@pillsburylaw.com; cyril.draffin@usnic.org
Subject:	[External_Sender] Comprehensive Industry Comments on the NRC's Rulemaking on Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)
Date:	Friday, November 05, 2021 2:52:42 PM
Attachments:	11-05-21_NEI-USNIC Comprehensive Comments NRC Part 53 - Cover Letter.pdf

THE ATTACHMENT CONTAINS THE COMPLETE CONTENTS OF THE LETTER

November 5, 2021

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, *Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)*

Dear Mr. Dorman:

The Nuclear Energy Institute (NEI)[1] and the U.S. Nuclear Industry Council (USNIC)[2], and our members appreciate the Nuclear Regulatory Commission's (NRC) efforts to develop a technology-inclusive, risk-informed, and performance-based regulatory framework for advanced reactors, commonly referred to as the Part 53 rulemaking. As Secretary of Energy Jennifer Granholm has observed: "Carbon-free nuclear power is an absolutely critical part of our decarbonization equation."[3] We firmly believe that an efficient, effective Part 53 can provide a gateway for safe, reliable nuclear power to play a significant role in the global fight to reduce carbon emissions.

The purpose of this letter is to provide timely and detailed input on the NRC's Part 53 preliminary rule language released through October 18, 2021, which constitutes the staff's comprehensive plans for the Part 53 regulatory framework. Our comments highlight the beneficial features the staff has incorporated into Part 53 that we think should be retained, as well as areas where we believe changes are needed, to achieve a Part 53 rule that meets the statutory requirements in the Nuclear Energy Innovation and Modernization Act (NEIMA) and conforms to the Commission direction in SRM-SECY-20-0032. These changes also will achieve the goal that the final rule is used and useful, as described in the "Unified Industry Position" letter dated July 14, 2021 (ML21196A498), by being 1) available for use by all technologies and risk-informed licensing approaches, 2) less burdensome over the lifecycle of activities (e.g., licensing, construction, operations, oversight), than regulating under the existing Parts 50 and 52, and 3) built upon performance-based requirements that define clear and objective acceptance criteria. We believe these changes would also address most of the ACRS recommendations for improvements.

We believe the NRC's current preliminary Part 53 rule language requires substantive change. For over a year, we have actively participated in NRC public meetings, promptly identified our concerns, and provided robust recommendations to the staff to try to make Part 53 workable. However, to date, changes to the preliminary rule language have been minimal and productive dialog on key issues raised by stakeholders has been limited.

With that said, we believe that the relatively modest and straightforward set of changes outlined in our attached comments can be incorporated without impact on the Commission's schedule for Part 53. All of these comments have been previously discussed with the NRC, and are accompanied by proposed language changes that address the comment. Our proposed changes also obviate the need to pursue the development of Part 5X as a parallel regulatory framework, by making the current Part 53 language more flexible and inclusive, and avoiding the need for excessive resources and time that developing parallel frameworks would entail. Finally, we stand ready to assist the staff in the development of additional guidance that may be needed to enable these changes.

Attachment A provides comments by specific topical areas and addresses both what we view as beneficial features of the preliminary Part 53 rule language that should be retained in the draft rule, and significant challenges that must be resolved in developing the rule language. Broadly summarized, these comments reflect our concerns that the current Part 53 rule language 1) increases regulatory burden beyond that imposed on the current reactor fleet without achieving a commensurate increase in safety, 2) unnecessarily excludes certain licensing approaches and technologies, 3) reduces regulatory clarity and flexibility, and 4) lacks a coherent and integrated approach to both the rule's key regulatory functions and its safety paradigm. Attachment A explains the bases for our concerns, and contains references to additional details in Attachment B.

Attachment B provides detailed comments on nearly all of the preliminary Part 53 rule language released by the NRC to date. Our comments are provided on a regulation-by-regulation basis. Importantly, the Attachment B comments also contain proposed resolutions to our concerns in the form of specific proposed revisions to the NRC's preliminary Part 53 rule language. We believe that incorporating these changes would serve to address our topical concerns discussed in Attachment A. Attachment B also contains comments on matters that are not discussed in the topical areas of Attachment A and which, while still important, have less of a bearing on ensuring that Part 53 is used and useful

Attachment C provides a listing of the prior submissions made by our organizations since 2019. This includes countless presentations at NRC meetings, numerous letters with formal comments and proposed resolutions, and several white papers with detailed content that can serve as the starting point for developing guidance.

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[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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objective acceptance criteria. We believe these changes would also address most of the ACRS recommendations for improvements.

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Attachment A provides comments by specific topical areas and addresses both what we view as beneficial features of the preliminary Part 53 rule language that should be retained in the draft rule, and significant challenges that must be resolved in developing the rule language. Broadly summarized, these comments reflect our concerns that the current Part 53 rule language 1) increases regulatory burden beyond that imposed on the current reactor fleet without achieving a commensurate increase in safety, 2) unnecessarily excludes certain licensing approaches and technologies, 3) reduces regulatory clarity and flexibility, and 4) lacks a coherent and integrated approach to both the rule's key regulatory functions and its safety paradigm. Attachment A explains the bases for our concerns, and contains references to additional details in Attachment B.

Attachment B provides detailed comments on nearly all of the preliminary Part 53 rule language released by the NRC to date. Our comments are provided on a regulation-by-regulation basis. Importantly, the Attachment B comments also contain proposed resolutions to our concerns in the form of specific proposed revisions to the NRC's preliminary Part 53 rule language. We believe that incorporating these changes would serve to address our topical concerns discussed in Attachment A. Attachment B also contains comments on matters that are not discussed in the topical areas of Attachment A and which, while still important, have less of a bearing on ensuring that Part 53 is used and useful

Attachment C provides a listing of the prior submissions made by our organizations since 2019. This includes countless presentations at NRC meetings, numerous letters with formal comments and proposed resolutions, and several white papers with detailed content that can serve as the starting point for developing guidance.

The NRC staff have invested significant time and resources in the development of the preliminary rule language and we applaud the transparency with which they have undertaken this effort. We, too, are vested in achieving a successful Part 53 and, therefore, have invested significant resources in participating in the numerous public meetings the NRC has held, and in reviewing and commenting on the draft rule language. Now that the NRC staff has pushed through the initial writing of all the planned subparts (excluding decommissioning), we hope the NRC is in a position to address the comprehensive and detailed stakeholder input that has been provided to date and to make substantive changes in the next iteration of Part 53 preliminary language.

We look forward to working with the staff to answer any questions or provide additional context on the comments that we have provided in order to establish a Part 53 that will enable the efficient and effective licensing of advanced reactors. If you have questions concerning our input, please contact Marc Nichol at NEI at mrn@nei.org, and 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

Attachment A - Topical Comments on NRC's Comprehensive Preliminary Part 53 Rule Language
Attachment B - Detailed Comments on NRC's Comprehensive Preliminary Part 53 Rule Language
Attachment C – NEI and USNIC Prior Submissions to NRC Regarding Part 53

Cc: Ms. Marian Zobler, General Counsel, NRC
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Attachment A
Topical Comments on NRC's Comprehensive Preliminary Part 53 Rule Language

Contents

Attachment A
Topical Comments on NRC's Comprehensive Preliminary Part 53 Rule Language

Introduction

These comments were prepared by the Nuclear Energy Institute and the U.S. Nuclear Industry Council.

The primary goal of the Nuclear Regulatory Commission's (NRC's) Part 53 rulemaking must be to achieve a regulatory framework that meets the statutory requirements in the Nuclear Energy Innovation and Modernization Act (NEIMA), the Atomic Energy Act (AEA), and the Administrative Procedures Act (APA). We believe an equally important goal is that the final rule is used and useful. As described in the "Unified Industry Position" letter dated July 14, 2021 (ML21196A498), a used and useful rule is one that ensures safety while also being 1) available for use by all technologies and risk-informed licensing approaches, 2) less burdensome over the lifecycle of activities (e.g., licensing, construction, operations, oversight), than regulating under the existing Parts 50 and 52, and 3) built upon performance-based requirements that define clear and objective acceptance criteria. The comments within this attachment, as supplemented by more detailed comments in Attachment B, recommend the essential changes to the NRC's preliminary rule language that are needed in order to establish a Part 53 rule that achieves these important goals and conforms to the Commission direction in SRM-SECY-20-0032. Attachment C provides references to prior comment submissions that previously provided perspectives on these topics, some as far back as 2019.

Of primary importance is to create a Part 53 that ensures safety more efficiently than Parts 50 and 52. As Part 53 is an optional rule, applicants have a choice under which Part they license and operate their nuclear facility. As discussed in more detail in the comments of this Attachment and in Attachment B, the NRC has created in the current version of the Part 53 preliminary rule language technology-inclusive equivalents to the LWR-specific safety requirements in Parts 50 and 52. However, the NRC's proposed rule language, if enacted, would substantially increase regulatory burden by expanding NRC control over the nuclear facility far beyond what exists for current reactors. Further, the NRC's proposed rule language would exclude certain technologies and licensing approaches from using Part 53 that could otherwise meet the safety requirements. If Part 53 is not more efficient than Parts 50 or 52, then the choice of the applicant will be as follows: 1) choose to use Part 53, which would minimize the need for exemptions but impose more regulatory burden overall; or 2) choose to use Parts 50 or 52, which would require exemptions from LWR-specific requirements but involve less overall regulatory burden and uncertainty. Thus, if Part 53 is not more efficient than Parts 50 and 52, then applicants will not use it, and the Congressional intent to craft a more efficient and flexible licensing mechanism for advanced reactors as required by NEIMA will be lost.

In a number of areas, the NRC preliminary rule language establishes requirements that are not consistent with the considerations in 50.109 (The Backfit Rule), in that they are not needed for adequate protection and are not justified by the consideration of the costs and benefits. In most cases, they are also not consistent with established NRC Policy or Commission decisions on the same topics addressed in prior rulemakings, such as the Policy Statement on the Regulation of Advanced Reactors, Policy Statement on the Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities, Policy on As-Low as Reasonable Assurance (ALARA), Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants, and the Rulemaking on the Mitigation of Beyond Design Basis Events.

Attachment A
Topical Comments on NRC's Comprehensive Preliminary Part 53 Rule Language

Some stakeholders have stated that predictability and flexibility are mutually-exclusive attributes of rule language. While this is certainly true for prescriptive rule language, it is also certainly not the case for performance-based rule language. Performance-based rule language focuses on desired measurable outcomes, rather than prescriptive design features, processes, techniques, or procedures. Thus, the benefit of performance-based rule language is that it can be both predictable <u>and</u> flexible. The NRC describes these benefits in NUREG/BR-0303 as follows: "*Performance-based approaches focus primarily on results. They can <u>improve the objectivity and transparency</u> of NRC decision making, <u>promote flexibility</u> that can <u>reduce licensee burden</u>, and <u>promote safety</u> by focusing on safety-successful outcomes.*" (emphasis added). While the NRC Part 53 preliminary rule language does introduce some performance-based requirements, there are key areas that are prescriptive and need more work to incorporate performance-based principles.

This attachment provides comments on the NRC's comprehensive preliminary Part 53 rule language (as of October 18, 2021) in topical areas where and why we believe major changes are needed to produce a clear, predictable, efficient and flexible Part 53 that ensures safety in a technology-inclusive, risk-informed and performance-based manner. Specific feedback and recommendations for changes to the NRC's Part 53 preliminary rule language are included in the detailed comments in Attachment B. References connecting the comments in this attachment to detailed comments in Attachment B are provided to the extent possible. Attachment B also includes comments on matters that are not discussed in the topical areas of this attachment and which, while still important, have less of a bearing on ensuring that Part 53 is used and useful. Like the NRC staff, we seek success in the adoption of a workable Part 53 framework and have attempted to outline our concerns and recommendations in a coherent and constructive manner that is intended to achieve that shared goal.

I. Beneficial Features of Part 53

The NRC has incorporated several beneficial features into the Part 53 framework. Those features should not go overlooked and should be preserved in the final rule. In these specific areas, the preliminary rule language achieves a more modern technology-inclusive, risk-informed, and performance-based regulatory framework. These areas are summarized below.

1) Technology-Inclusive Technical Requirements

The NRC has done a very good job creating technology-inclusive equivalents to LWR-specific requirements found in Parts 50 and 52. The requirements for the safety criteria, safety functions, design features and functional (principal) design criteria are among the most noteworthy examples. No longer do these safety requirements prescribe specific structures, systems and components (SSCs) that must be met, but rather, the Part 53 equivalents define the outcomes of the safety design. Thus, the technology-inclusive approach to the safety requirements in Part 53 increases flexibility and minimizes the need for exemptions.

The NRC has also formulated a modern and more intuitive safety paradigm for the design, comprised by the safety criteria, safety functions, design features and functional design criteria. The primary concept used by the NRC is that for the regulations to ultimately satisfy the Atomic Energy Act requirements for protecting the public health and safety, they must establish stable and predictable dose-based criteria.

This is complemented by an equally important concept used by the NRC, i.e., that a hierarchical approach to the safety paradigm for design can ensure that every requirement serves a purpose in providing assurance that the safety criteria are met. This results in increased clarity and predictability for the safety design of the facility. As discussed in comment II.4.B of this Attachment, the safety paradigm for the design is only a portion of the Part 53 regulatory framework, and other areas require significant work to establish a coherent and integrated safety paradigm that includes elements other than the design for Part 53.

2) Organization and Structure of the Rule

The NRC's organization of Part 53 into subparts that align with various stages of the plant lifecycle adds clarity to the rule. The NRC has established subparts around the safety objectives, design and analysis, construction and manufacturing, maintenance and operation, among others. This approach is modern, clear and intuitive.

The NRC has also separated technical requirements from documentation requirements. Technical requirements are primarily in Subparts B through F, and documentation requirements are primarily in Subparts H through J. This separation adds clarity and also is modern and intuitive.

3) Increased use of Performance-Based Approaches

There are a few areas, specifically Safety Criteria, Emergency Preparedness (EP) and Security, where the NRC is pursuing the creation of requirements that are more performance-based than equivalents in Parts 50 and 52. The safety criteria are performance-based in that they focus on the radiological impacts to the public, based on dose consequences. The performance-based EP requirements are primarily being established in a parallel rulemaking for small modular reactors (SMRs) and other new technologies and are expected to be published in a Final Rule soon. The NRC is still early in the development of the Security requirements for Part 53, and more work is be needed to develop the details. We support the NRC's performance-based EP and Security rulemaking efforts. We believe that a one-size-fits-all approach, while perhaps appropriate for the existing fleet of large light water reactors, is not appropriate for the new generation of advanced reactors, many of which will have source terms that approximate that of a research reactor or irradiator. For these reasons, the applicable approaches for EP and Security should be more closely tailored to the actual risks presented by these new technologies. As discussed in comment II.3.C of this Attachment, the NRC's Part 53 preliminary rule language for many other requirements is prescriptive and thus lacks the benefits of the performance-based approach.

II. Challenges with the Current Part 53 Rule Language

1) Increasing Regulatory Burden without a Commensurate Increase in Safety

The NRC's Part 53 preliminary rule language proposes many requirements that would expand the NRC's control of the nuclear facility far beyond what it is today for existing reactors. Most, if not all, of these requirements likely could not be established in Parts 50 and 52 because they would not meet the backfitting requirements, since they are neither needed for adequate protection nor justified through consideration of the costs and benefits. The effect is to increase regulatory burden without a commensurate increase in safety. These requirements result in increased regulatory compliance burden, for example, by requiring submittal of more detailed information to the NRC to receive approvals, increasing NRC control over activities that are currently controlled by the licensee, or increasing regulatory treatment of SSCs. This is contrary to our expectations of the regulatory framework required by NEIMA, whereby we believed that the rule would be less burdensome given the reduced risks posed by this new generation of nuclear technologies.

In discussions with the NRC during public meetings, the staff has stated that the increased burden in some areas is more than outweighed by the decreased burden in other areas. Unfortunately, in our careful reading of the proposed language provided by the staff, the only decreased regulatory burden in Part 53 that we can discern is a reduced need for exemptions to LWR-specific requirements. That benefit, however, does not outweigh the significantly increased burden discussed in our comments. Any other reduced burden would be attributable to the reduced risks of advanced reactors, independent of using Part 53 or Parts 50 and 52.

A. Expanding ALARA Beyond an Operating Principle to be an Absolute

The NRC preliminary rule language would increase regulatory burden by establishing a design requirement for as low as reasonably achievable (ALARA). Part 20 does not contain a design requirement for ALARA, and ALARA has always been an operational consideration. The issue here is how the NRC is proposing that ALARA would apply to design features and the degree to which design features are required for ALARA purposes. As the Commission has noted, "the ALARA concept is intended to be an operating principle rather than an absolute." Standards for Protection Against Radiation; Final Rule, 56 Fed. Reg. 23359, 23366 (May 21, 1991). The NRC preliminary rule language, however, appears to treat ALARA as the latter. In reviewing the Atomic Energy Act, we found no explicit nexus between ALARA and statutory requirements for the NRC's regulation of the design of nuclear power reactors.

ALARA can be achieved solely through the implementation of the licensee's radiation protection program. See 56 Fed. Reg. at 23367 ("The final rule establishes a requirement for all licensees to have a radiation protection program that includes provisions for keeping radiation doses ALARA.").In fact, this has been the case for existing reactors and will be the case for new reactors licensed under Parts 50 and 52. Moreover, when the Commission established the ALARA program requirement, it "expressly intended that the level of this program and efforts to document it are commensurate with the size of the licensed facility and the potential hazards from radiation exposure and the intake of radioactive materials." 56 Fed. Reg. at 23367.

Therefore, the imposition of a design requirement for ALARA will drive costs for regulatory compliance without a commensurate safety benefit and is inconsistent with the development of more risk-informed, performance-based and efficient regulatory framework for advanced reactors. The preliminary Part 53 language changes the means by which ALARA is implemented from one of a good operating practice to one of purported central importance for design criteria, and consequently risks unreasonably broadening the scope of safety in the regulations. As constructed, the language of the rule has no practical endpoint for additional measures, and it is left to negotiation between the NRC and the designer as to how much is good enough. The preliminary rule language is an example of where the rule is not efficient and does not improve safety because the safety objective for normal plant worker safety is already set by a different regulatory section within the rule. Since ALARA requirements are included in

10 CFR Part 20 requirements for radiation protection (an approach that has worked well for decades), Part 53 need not duplicate or add to those requirements.

The NRC should remove the design requirement for ALARA and rely on the proven effectiveness of the radiation protection program to achieve ALARA, in Part 53. Additional details are provided in Attachment B comments/proposed resolutions B-8 and B-9.

B. Increased Regulatory Burden and Reduced Clarity on Non-Safety SSCs

The NRC preliminary rule language would increase regulatory burden by applying requirements intended to apply only to safety-related SSCs to non-safety-related but safety-significant (NSRSS) SSCs. This effect, while likely unintentional, appears to be a remnant of the two-tier safety structure proposed in the NRC's original preliminary rule language. While the two-tier nomenclature was removed, the functional requirements remain largely the same. The issue is how the requirements downstream of the safety criteria are applied. In particular, the applicability of design-related requirements and some of the operational requirements, appear to be nearly identically to both safety-related and NSRSS SSCs. This is further complicated by the NRC's application of special treatment and programmatic controls rule language nearly identically to both categories of SSCs.

The NRC's introduction of new requirements for *"special treatment"* reduces regulatory predictability and is not needed. The related requirements state that special treatment must be established and applied to the safety-related and NSRSS SSCs. However, these requirements are vague and subjective, as they do not establish the purpose or the desired outcome for the special treatment requirement. The definition of special treatment effectively says that it is "requirements that apply to certain SSCs." If this is the case, then a more straightforward approach would be to state, in each requirement that applies to safety-related and/or NSRSS SSCs, how the requirement applies to those categories of SSCs, describing differences where appropriate. In fact, the Part 53 requirements that apply to these SSCs already achieve this outcome, and this is similar to the approach taken in Parts 50 and 52. Thus, to say that these SSCs must apply special treatment is effectively duplicating the requirements that already say they apply to those SSCs. The concept of special treatment therefore should not be included in Part 53, as the duplicative nature of the requirement reduces clarity and predictability.

The concerns with the use of the concept of programmatic controls is discussed in detail in comment II.1.D of this Attachment.

It appears that the intent is that safety-related SSCs are those that flow back to the safety criteria for DBAs, while NSRSS SSCs are mostly those that flow back to the safety criteria for licensing basis events (LBEs) other than DBAs. However, the rule language is not clear in this regard, which reduces regulatory clarity and predictability.

The NRC should delete the confusing and unnecessary concept of "special treatment", and instead revise relevant design and operational requirements to clarify the applicability to SR and NSRSS SSCs and clarify the differences between the classifications of SSCs in Part 53. Additional details are included in Attachment B comments/proposed resolutions, including: A-15, B-3, B-4, B-5 and B-6.

C. Inclusion of Beyond Design Basis Events in the Design Basis

The NRC's application of downstream design requirements to 53.220, which includes a focus on BDBEs, effectively includes BDBEs in the design basis. Parts 50 and 52 include BDBEs in the licensing basis, but do not include them in the design basis. If BDBEs are included in the design basis, then they are no longer "beyond" the design basis but are the design basis. This is a dramatic increase in the NRC's regulatory control and is inconsistent with an approach that would align regulatory burden with the risk posed by the technology – which in the case of advanced reactors is even smaller than the risk posed by the current large LWR fleet. While it is true that the design features and SSCs needed to mitigate BDBEs are part of the licensing basis, they should not be treated in the same manner as design basis events, since doing so would increase regulatory burden without increasing safety. Furthermore, we note that inclusion of the Quantitative Health Objectives (QHOs) in the proposed rule language is the root cause of the treatment of BDBEs as part of the design basis. While BDBEs must be part of the licensing basis, they should not be part of the design basis.

The NRC's proposed rule language for Part 5X demonstrates even more clearly that BDBE is being included in the design basis.

Including BDBE in the design basis is not consistent with the current regulatory treatment of BDBE through mitigation measures. In fact, the Commission directed the staff to remove design requirements for BDBE for new reactors and requirements for severe accidents in the Proposed Rulemaking for Mitigation of Beyond Design Basis Events in SRM-SECY-15-0065 (ML15239A767). In making this decision, the Commission recognized that the NRC still has the ability to provide oversight for mitigation of BDBE and the implementation of voluntary severe accident mitigation guidelines (SAMGs).

In relation to BDBEs, the Commission specifically noted that requirements should not establish a separate standard for new reactors. In Commissioner Burn's vote record (ML15239B241), he noted that "I agree with Commissioner Ostendorff that a more flexible approach for new reactor applicants [mitigation] is preferred over the additional design requirements proposed by the staff. The Advanced Reactor Policy Statement itself provides sufficient encouragement for new reactor designers to see ways to reduce reliance on operator actions and provide longer time constants for decision making during accidents, while retaining the flexibility in implementation options sought be the Commission."

The Advanced Reactor Policy Statement has in fact incentivized current advanced reactor designers to incorporate into their designs safety features that reduce reliance on human actions and result in longer time constants for decision making. Further to this point, the NRC recognized in the 2019 Final Rule Statements of Consideration SRM-M190124A (ML19023A040) that "the more performance-based approach taken with this rule allows an applicant for a new reactor license or design certification to provide innovative solutions to address the need to effectively prioritize event mitigation and recovery actions between the source term contained in the reactor vessel and that contained within the SFP." In further describing this flexibility, the NRC stated that "new reactors may use installed plant equipment for both the initial and long-term response to a loss of all ac power with less reliance on portable equipment and offsite resources than currently operating nuclear power plants."

In relation to severe accidents, the decision noted that the Commission considered that addressing events with extremely low likelihood were not required for adequate protection and thus considered the costs and benefits in relation to requirements. This is reflected specifically in Commissioner Burn's vote sheet discussion on SAMGs (ML15239B241), in which he quoted the ACRS as stating: "Given the extremely low likelihood that an event will lead to the use of SAMGs, regulatory requirements should not impose unnecessary burden or divert attention from more important safety objectives." His conclusion in that case was that the benefits could not justify the costs because "… the additional defense-in-depth that would be gained from making the SAMGs a regulatory requirement rather than a voluntary initiative does not provide a sufficient basis to support this provision of the proposed rule."

The NRC should remove the QHOs from the rule language and continue to rely on the Safety Goal Policy Statement and establish requirements that include BDBEs in the licensing basis by requiring mitigation and not by requiring that they be part of the design basis. Additional detail is provided in Attachment B comments/proposed resolutions B-4 and 5X-7.

D. Proliferation of Duplicative and Unnecessary Programs

The NRC preliminary rule language would increase regulatory burden by increasing the NRC's regulatory approval over licensee controls. The net effect would be 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. Most, if not all, of these requirements likely could not be established in Parts 50 and 52 because they would not meet the NRC's backfitting requirements. Many of the new programs and programmatic controls proposed for inclusion in Part 53, that are in addition to the scope of the well-established programs from Parts 50 and 52 that are also being included in Part 53, create redundant and overlapping programs in Part 53. For the QA program specifically, the splitting up of the QA requirements and redistribution of those requirements across numerous Part 53 subparts, as well as significant deviations from Part 50 Appendix B QA requirements, reduces clarity and predictability and unnecessarily increases regulatory burden. Table 1 provides some examples of unnecessary programs proposed by the NRC.

Table 1 Redundant and Unnecessary Programs in Part 53

Unnecessary Part 53 Program	**Reason it is Not Necessary**
53.480 Design Control Quality Assurance	Redundant with QA Program Requirements
53.490 Design and Analyses Interfaces	Redundant with QA Program Requirements
53.610(a)(1&7) and 53.620(a)(1&6) Construction and Manufacturing Quality Assurance	Redundant with QA Program Requirements
53.620(b)(1)(IV)(vii) – Manufacturing, Manufacturing Activities	Redundant with QA Program Requirements
53.740 Design Control	Redundant with QA Program Requirements

Attachment A
Topical Comments on NRC's Comprehensive Preliminary Part 53 Rule Language

Unnecessary Part 53 Program	Reason it is Not Necessary
53.460(c) Human Action Performance Program	Redundant with the training and other operational programs related to performance of human actions
53.700 Operational Objectives	Redundant with most other operational programs
53.710 Transition from construction/manufacturing to operation	Redundant with activities covered by the issuance of an OL or Authorization to load fuel for a COL
53.800 Operational Programs	Redundant with most other operational programs
53.850 Integrity Assessment Programs	Redundant with Maintenance, ISI/IST, Technical Specifications, and aging management (which is not needed until license renewal)
53.880 Criticality Safety Program	Not necessary to require a program for compliance with 70.24. 50.68 is a better model for criticality control.
53.890, 53.892, and 53.894 Facility Safety Program, Criteria and Plan	Redundant with nearly all other programs, codifies periodic safety review, and circumvents backfit protection
53.900 Procedures and Guidelines	Not required for existing reactors, and not addressing any problem

The NRC has introduced over 20 requirements (e.g., 53.210, 53.220, 53.230, 53.240, 53.250, 53.260, 53.270, 53.400, 53.410, 53.420, 53.425, 53.430, 53.440, 53.460, 53.470, 53.490, 53.500, 53.510, 53.540, 53.610, 53.122) for new *"programmatic controls"*. This is in addition to the programs already required in the preliminary rule language. This is highly problematic since the concept of programmatic controls is effectively redundant with the concept of "*programs"*, which is a term with a long history of use by the NRC and its licensees. This duplication creates substantial additional regulatory burden. Although the NRC defines the term programmatic controls, it does not define the underlying concept. Thus, it is not clear why programmatic controls are even necessary as a general matter, much less needed in particular situations. Furthermore, the NRC's requirements for programmatic controls are vague and subjective. The requirements all say, "Programmatic controls must be provided…", but provide no clarity regarding the purpose that such controls serve, or the desired outcome they are intended to achieve.

All of these requirements for duplicative or otherwise unnecessary programs would significantly expand the NRC's regulatory footprint to encompass activities and documents (e.g., procedures and calculations), and result in much more information being included on the docket. The operating experience of existing reactors demonstrates that the NRC does not need to require and control a program for this type of information. This also contradicts the NRC efforts in the Advanced Reactor Content of Applications (ARCAP) and other areas to right-size the level of detail in applications.

Another source of increased regulatory burden is proposed section 53.1185, which would require that a substantial portion of the PRA be included in the licensing basis and hence on the docket. Under current Parts 50 and 52, new reactor applicants need to provide only a summary of the PRA and its results for inclusion on the docket. It is unclear why the Agency seeks to impose this new requirement; perhaps because the NRC wishes to have more control over the PRA of the plant, or because requirements for 53.450 and 53.220 are a more risk-based approach to the safety case. We do not believe either of these rationales provides a valid basis for this new PRA-related requirement (comment II.2.A of this Attachment addresses our concerns about creating requirements that exclude many risk-informed approaches). If the NRC believes, based upon the way in which more risk-based approaches rely on the PRA in the safety case, that those approaches should include more of the PRA in the licensing basis, then this should be addressed in guidance, since it is dependent upon the specific licensing approach used. If the NRC believes additional clarity must be incorporated in the rule, then the requirement should be conditionally based on those particular uses of the PRA (e.g., only applicable if the PRA is used as the foundation of the safety case, and not applicable if the PRA is used as a complement, as directed in the PRA Policy Statement for selecting LBEs and categorizing SSCs).

The NRC should remove the requirements for "programmatic controls" and other unnecessary programs from Part 53, and consolidate the QA requirements into one requirement that is compatible with Part 50 Appendix B. Additional details are provided in Attachment B in numerous comments/proposed resolutions, including A-17, B-10, C-6, C-8, C-9, E-1, F-1, F-2, F-5, F-6, F-10, F-11, F-14, F-15, F-16, H-5 and H-7.

E. Facility Safety Program

The NRC preliminary rule language would increase regulatory burden by imposing a new and unnecessary Facility Safety Program (FSP), and 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.

Our assessment of this requirement is that it would impose an enormous amount of regulatory burden on licensees. First, it effectively duplicates most other programs required by the NRC. In addition, it requires a periodic safety review, which is inconsistent with Commission policy and has never been needed for the existing reactors. Indeed, for decades, the NRC has rejected calls for the imposition of periodic 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 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 this point, the NRC staff provided little additional perspective on how this proposed approach could reduce (rather than increase) regulatory burden. Furthermore, the NRC has provided little additional information on how the FSP could be implemented.

The NRC should remove the FSP from Part 53, as this requirement imposes enormous regulatory burden without any increase in safety. See also comment/proposed resolution F-15 in Attachment B.

2) Unnecessarily Excluding Licensing Approaches and Technologies

A. Excluding Risk-Informed Licensing Approaches

As discussed in the Unified Industry Position letter, it is imperative that Part 53 not exclude any risk-informed approach that can demonstrate that the design meets the safety criteria. Parts 50 and 52 provide flexibility for applicants to use a wide range of risk-informed approaches, including the approach mandated in Part 53, and so Part 53 should also afford this same flexibility. To be clear, we are not against a requirement that the applicant incorporate risk insights from a PRA into the design, and in fact we propose a requirement for PRAs that is more extensive than the requirement Parts 50 and 52. However, we do believe the NRC's preliminary requirement for PRA goes beyond what is reasonable and results in the exclusion of all but one risk-informed approach. The Nuclear Energy Institute's (NEI's) September 28, 2021 letter on risk-informed approaches (ML pending) discussed some of the detailed concerns about how the NRC's preliminary rule language would only accommodate one known risk-informed approach (even though it has never been approved by the NRC - or any other nuclear regulator worldwide - in a license application). While simultaneously, the NRC approach to establish a parallel Part 5X that cannot utilize the beneficial features of Part 53 would make it more difficult to use all other known risk-informed licensing approaches, most of which have been previously approved by the NRC in a license application. With this letter, NEI provided a September 2021 white paper, titled "Technology-inclusive, Risk-informed, Performance-based Approaches for Development of Licensing Bases Under Part 53", that outlined a variety of risk-informed approaches that industry would like to use to license advanced reactors under Part 53. The NEI letter on risk-informed approaches also stated that "with relatively straight forward changes to the NRC staff's Part 53 preliminary rule language, primarily by removal of unnecessarily prescriptive details usually found in guidance, the NRC can establish a Part 53 rule that allows the variety of risk-informed licensing approaches that industry plans to use for advanced reactors, and this can be accomplished on the Commission directed schedule." The U.S. Nuclear Industry Council (USNIC) also highlighted similar concerns regarding the treatment of PRAs in their July 15, 2021 letter to the NRC (ML21196A499).

The NRC Part 53 preliminary rule language appears to be developed specifically around the details in NEI 18-04, as complemented by the ongoing NEI's Technology Inclusive Content of Applications (TICAP) guidance and NRC's Advanced Reactor Content of Applications Project (ARCAP). However, the NEI guidance was never envisioned to serve as the only allowable licensing pathway for a Part 53 rule. Rather, they are intended to create a new option for a more risk-based licensing approach to be available for those applicants that wish to make PRA the foundation of the safety case. It is noted that while some potential applicants are interested in using the more risk-based approach, not all are interested in it. The USNIC 2021 Advanced Nuclear Survey found a variety of ways advanced nuclear developers plan to use PRAs. Of 17 developers, six plan on using significant PRA input (similar to LMP), four plan on using medium PRA input (similar to existing regulatory framework), five plan on using minor PRA input (similar to maximum credible accident approach), and two plan on taking another licensing methodology approach; and some developers using LMP may use PRA consistent with existing regulatory framework (ML21237A463, slide 32). Therefore, the LMP, TICAP and ARCAP guidance documents should not be used as an entry condition to be able to use Part 53, because it establishes requirements for the PRA that are far in excess of the expectations established by the Commission in the PRA Policy Statement.

There are two main elements of the Part 53 preliminary rule language that lead to the outcome of excluding all but one risk-informed licensing approach. These are the 53.450 Analysis Requirements and 53.220 Safety Criteria for LBEs other than DBAs. Changes to these requirements to remove detail that is historically found in guidance, or the NRC Policy Statements, would enable Part 53 to be used by all risk-informed licensing approaches. For 53.450, this would be to remove the mandate that PRA must be used as the primary basis for (rather than allow the use of risk insights from a PRA, as directed in the PRA Policy Statement) specific activities and would allow the PRA to serve a more balanced role in establishing the safety case. For 53.220, this would be to remove the QHOs from the rule language and to continue to apply it through the Safety Goal Policy Statement. Guidance can also be used to the extent that alternative integral risk criteria to the QHOs are needed for a specific type of technology. We are supportive of requiring the performance of a systematic identification of initiating events and the incorporation of risk insights from a PRA. However, additional details that prescribe the exact manner in which this should be accomplished should be included in guidance, so that the rule itself does not exclude all other risk-informed approaches.

A prescriptive approach to the PRA requirement is not necessary or appropriate, since all of the risk-informed approaches in NEI's September 2021 white paper would be able to meet the other Part 53 requirements. The NRC staff affirmed this position in the October 28, 2021 public meeting when they said that the PRA is a tool and that meeting Part 53 requirements is not dependent upon a specific use of the PRA tool. Thus, the prescription of details for the PRA in rule language would increase the amount of PRA that must be used for all advanced reactors, irrespective of their need to rely on the PRA for the safety case. Such detail is typically found in guidance rather than rule language, and in fact the requirements for PRA in 53.450 are far more detailed than the equivalent requirements in Parts 50 and 52, which are consistent with the NRC's PRA Policy Statement. The NRC codifies the expectation for broader use of PRA in the licensing basis in the requirements of 53.1185. As discussed in comment II.1.D of this Attachment on increased regulatory burden, there should not be a goal in Part 53 to require a more expansive inclusion of the PRA in the licensing basis.

The NRC staff also said in the October 28, 2021 meeting that the details in 53.450 for requirements of PRAs that allow only one type of risk-informed approach was necessary because the QHOs are in the rule. However, it is unclear why the NRC believes the QHOs must be in the rule at all, rather than relying on the long-standing implementation of QHOs through the NRC's Safety Goal Policy. As documented in Attachment 2 of NEI's February 11, 2021 letter (ML21042B889), "*It is recognized that regardless of whether the QHOs are in the Safety Goal Policy or Rule Language, the design, analysis, and licensing approach that would be taken by an applicant, and the NRC scope of review would be the same. Likewise, the risk-informed approach in NEI 18-04 would be implemented the same under both approaches. The difference is in the legal compliance with the requirements that exists for the license and the potential to eliminate other requirements, if the QHOs are in the rule language*." Thus, there is no increase in safety achieved by including the QHOs in the rule, and no need to do so in order to accommodate a particular licensing approach. However, including the QHO in the rule text could introduce unforeseen licensing complications, particularly since the NRC's proposed requirement for the QHOs does not include the dose limits associated with early fatalities or latent cancer fatalities. If the QHOs are in the rule, they must be met for legal compliance, and since the PRA is the basis for meeting the QHOs, more, if not all, of the PRA will need to be submitted on the docket and would be subject to contention. A more appropriate approach to address the safety criteria for LBEs other than DBAs would be to provide mitigation for beyond design basis events (BDBEs), which is already required (although the use of the Part 50 requirement is LWR-specific and should be replaced with a technology-inclusive version) and is the outcome produced by the QHOs for BDBEs anyway; and if necessary, supplement with a dose criteria for anticipated operational occurrences (AOOs). As discussed in USNIC's February 3, 2021 comments (ML21035A003) on Subpart B, section (b)(2), the "Quantitative Health Objectives from 53.23 should be removed, because no parallel QHO requirement in 10 CFR 20, 50, or 52; QHO calculations would be required in addition to quantitative limits at site boundaries in 53.23, and QHO method was attempted in 1986 but was deemed impractical and replaced by core damage frequency (CDF) and large early release frequency (LERF) in 1990." While our recommendation is to not include QHOs in the rule and continue to implement them through the Safety Goal Policy, we acknowledge that this is not the unanimous view of all members. There is at least one member of industry that believes QHOs must be in the rule to provide regulatory predictability by avoiding the need to develop surrogate metrics for the QHOs. Therefore, more discussion on the benefits and disadvantages of the options of how to address QHOs in a way that achieves both predictability and flexibility would be beneficial.

Removing the details from these requirements may require some conforming changes, but they would not change the nature in which downstream requirements apply, in particular the design and operational requirements. Operational requirements such as 53.720, Maintaining capabilities and availability of structures, systems, and components, and 53.730, Maintenance, repair, and inspection programs, can still be met in the same way with the changes proposed to 53.450 and 53.220.

NEI 18-04, NEI's TICAP and the NRC's related ARCAP are ultimately based upon the Part 50 and 52 framework, and thus do not contain the guidance related to the differences between Part 53 and Parts 50 and 52. Consequently, these documents do not address the full scope of the Part 53 safety paradigm (as discussed in comment II.4.A of this Attachment on need for a regulatory philosophy for Part 53). Furthermore, they also only provide guidance for one approach to licensing under Part 53, which we urge the NRC not to use as a reason to limit Part 53 only to this one approach, as we address in our comment II.2.A of this Attachment. NEI offered in the September 28, 2021 letter to develop guidance on the implementation of the Part 53 safety paradigm that would inform the applicability of NEI 18-04 and other risk-informed approaches, as described in NEI's September 2021 white paper, for Part 53.

Attachment A
Topical Comments on NRC's Comprehensive Preliminary Part 53 Rule Language

The NRC has stated publicly that Part 53 does not include a single failure criterion (SFC) requirement and has indicated that licensing approaches that do not use PRA in the manner mandated in the preliminary rule language for 53.450 and 53.220 would still need to meet the SFC requirement. However, the NRC definition of Defense in Depth (DID) contains a more performance-based method for achieving the underlying purpose of the SFC. Specifically, the NRC has included in defense in depth the requirement that "*no single layer of defense, no matter how robust, is exclusively relied upon* [for safety]" (see also 53.250). It is further noted that this performance-based requirement for DID is not dependent upon a specific use of PRA and could be applied for a variety of risk-informed licensing approaches that apply PRA in a variety of ways. Thus, it would not be accurate to claim that SFC requirements would need to be applied to licensing approaches that do not use PRA in a "leading" role, so long as those approaches demonstrate that "*no single layer of defense, no matter how robust, is exclusively relied upon* [for safety]." Additionally, the NRC should include the in Part 53 the Commission direction on SFC found in SRM-SECY-19-0036, "*In any licensing review or other regulatory decision, the staff should apply risk-informed principles when strict, prescriptive application of deterministic criteria such as the single failure criterion is unnecessary to provide for reasonable assurance of adequate protection of public health and safety*." Defense in Depth is important in supporting an adequate safety case for both LMP and non-LMP applications— by conducting analyses to evaluate uncertainties and potentially increase margins. On February 3, 2021, USNIC (ML21035A003) recommended the following language for Subpart B; "The facility must provide, as necessary, defense-in-depth that is appropriate given the SSCs to perform the required facility function(s) and the significance of the impact if the SSCs fail to perform the required facility function."

The NRC has issued a parallel Part 5X "Technology-inclusive alternative requirements for commercial nuclear plants" framework to address concerns that Part 53 excludes most risk-informed approaches. The parallel framework is risk-informed, and not deterministic, because it requires the use of the PRA. It appears that the NRC approach to separate Part 53 and Part 5X is based on a view that either PRA or deterministic methods are used for certain design and analysis elements (e.g., Part 53 requiring a maximal use of PRA and Part 5X requiring a maximal use of deterministic analyses). However, this does not reflect actual practice, in which both PRA and deterministic methods are used together to perform those design and analysis methods, and various approaches utilize PRA and deterministic tools in a range of combinations. It is not necessary to create two parallel technology-inclusive, risk-informed, performance-based frameworks since our comments demonstrate that relatively few straightforward changes to Part 53 would enable it to work for all risk-informed approaches. Therefore, our detailed comments on Part 5X in Attachment B focus on whether any of the language should be considered for inclusion in Part 53. Our conclusion is that while the majority of Part 5X should not be used, there are a few areas that could be considered for incorporation into Part 53. Finally, we note that the NRC staff has not described why they believe that the prescriptive approach to PRA in 53.450 is the only approach that can utilize the more modern safety paradigm of the current Part 53 preliminary rule language (see comment II.4.B of this attachment).

The NRC should revise the requirements on QHOs and PRA uses to enable Part 53 to accommodate all risk-informed approaches, with conforming changes to other requirements as appropriate, and not pursue two parallel regulatory frameworks with binary approaches to PRA. Additional details are in Attachment B comments/proposed resolutions B-4, C-5, F-3, F-4, H-5, I-4, I-6, and 5X-1 through 5X-10.

B. Excluding Technologies

The NRC preliminary rule language proposes a rule scope that is similar to the scope in Parts 50 and 52. However, the NRC is restricting the applicability of Part 53 only to commercial advanced nuclear plants licensed under AEA Section 103. Part 53 does not need to be so limited in scope, and the rule could easily be applicable to all production and utilization facilities licensed under AEA Section 103 or 104. In the October 26, 2021 NRC public meeting on Part 53, the NRC stated that they intend to revise rule language so that Part 53 is not restricted to only being used by "advanced reactors." The following comments are consistent with achieving the goal that the NRC.

The exclusion of any nuclear plant that is not considered "advanced" might unnecessarily exclude technologies that could meet the Part 53 safety requirements. While NEIMA did define "advanced nuclear reactor" when it provided statutory requirements for the NRC to develop a Technology-Inclusive Regulatory Framework, it did not limit such framework only to "advanced" reactors, but rather stated that it should be "*flexible and practicable for application to a variety of reactor technologies*." NEIMA, Section 3(14); see also S.Rept. 115–86 (May 25, 2017) (noting that Congress intended for the NRC to "develop regulations to enable the efficient licensing of advanced nuclear reactors" by using "risk-informed, performance-based approaches [that] allow the NRC to develop processes that are more flexible and applicable to the unique aspects of diverse technologies").

The NRC should not limit the use of Part 53 to facilities according to f the features defined as an advanced nuclear reactor in the NEIMA (B thru H), such as "*lower levelized cost of electricity*," "*increased thermal efficiency*" and "*ability to integrate into electric and nonelectric applications*," since these fall outside the NRC's authority of regulating nuclear safety.

The NRC could limit the use of Part 53 to reactors that have "*additional inherent safety features,*" since that is consistent with the NRC's authority for regulating nuclear safety. However, we believe that limiting the use of Part 53 to reactors with "*additional inherent safety features*" is unnecessary and reduces clarity, since the nature of the Part 53 requirements themselves are to ensure the safety of nuclear facilities. There is no real benefit for the NRC to create an artificial screening criterion to compare a Part 53 applicant's use of inherent safety features in the design to "significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of this Act." As long as a proposed design can meet the Part 53 requirements for safety, that should be sufficient justification for utilizing Part 53. Creating a screening criterion to use Part 53 based on the increased use of inherent safety features is unnecessary, and in fact is contrary to the NRC's Advanced Reactor Policy Statement, which encourages but does not require enhanced safety of advanced reactors.
The NRC should remove language in Part 53 that would restrict its use by technologies that do not meet the definition of "advanced reactor." Additional details are in Attachment B comments A-1 and A-2.

3) Use of Rule Language that Reduce Regulatory Clarity and Flexibility

Reduction of regulatory clarity and flexibility will lead to a less predictable and less efficient rule. The following discusses areas where the preliminary rule language results in a significant reduction in regulatory clarity and flexibility.

Attachment A
Topical Comments on NRC's Comprehensive Preliminary Part 53 Rule Language

A. AEA 182 and 161

The preliminary rule language reduces regulatory clarity and flexibility by not clearly connecting the proposed Part 53 requirements back to the safety standards in 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 do not clearly relate back to 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. We are very concerned because the Part 53 preliminary rule language establishes new requirements in Part 53 that have no equivalent in Parts 50 and 52 and would greatly expand the NRC's regulatory control well beyond what is in place for existing reactors without an increase to safety (as discussed in comments in section II.1 of this Attachment). This appears to be a clear case of regulatory overreach that contravenes the longstanding safety policy embraced by the Commission for decades consistent with the safety standards established by the Atomic Energy Act. Furthermore, there is no explanation on what the new safety standards mean, how they can be met, or how they even relate to all of the requirements in Part 53. The NRC would need to invest significant resources in defining these standards, to ensure consistency with the AEA. Thus, additional clarity in Part 53 would be achieved by providing insight into the application of the AEA standards, rather than creating entirely new standards.

The original preliminary rule language (ML20311A004) for 53.20 (later to be renumbered 53.200) established the AEA statutory standards identified above as the basis for Part 53. This earlier version also attempted to clarify how the requirements within Part 53 relate back to these safety standards through the use of two-tiers of safety criteria in 53.22 and 53.23. While other comments discuss concerns with the two-tier structure and the specific details of the second-tier criteria, the underlying goal of adding clarity by explaining how requirements in Part 53 relate back to the AEA safety standards, and the differences in the application of the two AEA standards, is commendable. In fact, NEI built upon this concept in proposed alternatives to the safety criteria in the February 11, 2021 letter. Additionally, USNIC in the February 4, 2021 Part 53 meeting supported the use of adequate protection standard; and in the April 8, 2021 Part 53 meeting raised a concern regarding the change from the initial preliminary language of Part 53 that referred to the need for "reasonable assurance of adequate protection," to the 2nd iteration of Subpart B that dropped need for reasonable assurance of adequate protection.

A lack of clarity on how requirements in Parts 50 and 52 relate back to the AEA safety standards has caused regulatory uncertainty associated with those parts. Ultimately, the NRC, industry and other stakeholders have spent extensive resources in understanding the applicability of requirements because the relationship of the requirements to the AEA safety standards has never been clarified. Even after decades of implementing the standard of "reasonable assurance of adequate protection" the NRC has had to issue multiple recent memos to staff to avoid misapplication of this standard in application reviews (ML19015A290, ML18240A410, and ML19260E683). Such challenges will be exacerbated in Part 53 if it does not provide clarity on how the requirements relate back to the AEA safety standards.

The NRC should utilize the safety standards from the AEA (Sec. 182 and Sec. 161) rather than creating new standards and should clarify how requirements in Part 53 relate back to the AEA safety standards, and the differences in the application of the two AEA standards. Additional details are included in Attachment B comment/proposed resolution B-1, B-3 and B-4.

B. Need for consistency in use of regulatory terminology

The Part 53 preliminary rule also reduces regulatory clarity when it uses concepts that are fundamental to the regulatory framework and which have long regulatory precedent but gives new names to these concepts. One such example is in the NRC's application of a new term "functional design criteria" (FDC) to a fundamental concept that has regulatory precedence through the existing 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. The following shows the similarities (emphasis added):

- Part 50 PDC: "The principal design criteria establish the necessary design, fabrication, construction, testing, and <u>performance requirements for structures, systems, and components</u> important to safety; that is, structures, systems, and components that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public."
- Part 53 FDC: "Functional design criteria means <u>requirements for the performance of SSCs</u>. For safety-related SSCs, these criteria define requirements necessary to demonstrate compliance with first tier safety criteria in § 53.210(b). For non-safety-related but safety-significant SSCs, these criteria define requirements necessary to meet the second tier safety criteria in § 53.220(b)."

The use of the term functional design criteria instead of PDC reduces clarity because several stakeholders have mistakenly believed that Part 53 does not include the fundamental concept of PDC and have thus viewed this as a concern. Other stakeholders may have trouble understanding how to apply functional design criteria within the Part 53 framework, solely because it is not clear that they serve the same purpose as PDC, for which the purpose and application are well established through regulatory precedent. While only one example is discussed here, there are other examples, such as the use of the term "non-safety-related but safety significant", and this is related to concerns for creating unnecessary concepts/terms, such as special treatment and programmatic controls addressed in our other comment II.1.D of this Attachment.

The NRC should use consistent terminology between Part 53 and Parts 50 and 52, where fundamental regulatory framework elements in Part 53 are similar in concept in all of these Parts. Additional details are provided in Attachment B comments/proposed resolutions A-15, A-21 and C-2.

C. Prescriptive, rather than performance-based requirements

As discussed earlier, performance-based rule language results in a rule that is both predictable <u>and</u> flexible. Performance-based rules are also more efficient and effective than prescriptive rules, as they allow for more innovation. While the NRC's preliminary rule language improves upon the use of performance-based principles in some areas, there are many other requirements that contain very prescriptive rule language. Prescriptive rule language focuses on mandating the processes, techniques, or procedures, rather than defining the desired, measurable outcomes. Details in 53.450 related to the mandated uses of PRA, as discussed in comment II.2.A of this Attachment, is one example where including detail in the regulations that is more appropriately included in guidance leads to prescriptive requirements. Many other requirements use prescriptive, yet open-ended language that reduces rather than improves clarity of the requirement. One such example is the multiple uses of the phrase "*Design features and programmatic controls must be provided…*", which prescribes the features rather than defining the desired outcome. Where it is used, the rest of the requirement can provide a performance-based criteria for the underlying purpose. For example, in 53.210, the rest of the requirement defines the acceptable dose limit for design basis accidents. Since other requirements, specifically 53.400 for design features, and numerous requirements related to program. already specify that these elements are needed for Part 53 applicants and licensees, the frequent use of this phrase is not necessary. The phrase does reduce regulatory predictability since it will lead NRC reviewers and applicants to focus on the process rather than the outcome.

High-level rule language that is performance-based does not reduce clarity and predictability, but rather improves clarity and predictability by defining the desired measurable outcomes. While this may be counter-intuitive, it is explained by the fact that the regulations are necessarily focused on the outcome, protection of public health and safety. Prescriptive requirements that state a licensee must do things such as "provide SSCs" or "use the PRA to categorize SSCs" does little in regards to focusing on the outcome. Rather, because prescriptive requirements focus on the process, they must then add detail to the requirements explaining all the elements of the process, techniques or procedures. At the end, there is still no clarity or predictability for the applicant/licensee or the NRC reviewer to objectively measure whether meeting the prescribed process has resulted in the desired outcome of protecting the public health and safety. The result is a rule that is subjective and lacking in clarity and predictability. In-contrast, performance-based rule language that defines the measurable outcome and explains the purpose of the requirement is objective, leading to a clearer and more predictable rule. While there will certainly be much discussion of the process and method used to demonstrate the outcome in the application and NRC review, these discussions benefit from being able to focus on how they demonstrate the clear regulatory outcome is achieved.

Prescriptive rule language also reduces flexibility in that it mandates a specific process, and areas of overly prescriptive preliminary rule language is part of the cause for our concerns related to comment II.3.C of this Attachment on the exclusion of many risk-informed approaches and the increase in regulatory burden without an increase in safety. Performance-based rule language, on the other hand, increases flexibility in that it allows a variety of processes to demonstrate that measurable objectives are met. Where there are approaches expected to be used by many applicants, guidance will aid in streamlining the development and review of the application. However, to the rule should not limit the approaches allowed under Part 53 in pursuit of more efficient development and review of applications, because applicants will still choose to use other approaches and will thus increase the need for exemptions in Part 53. Indeed, we recognize that more flexible rule language could result in more applications that do not rely on established guidance. However, what we are proposing could also make it easier for the NRC staff to conduct the review of these applications, because a focus on the acceptance criteria makes it easier for the NRC to determine whether the design meets the requirements. This is in contrast to a prescriptive, one-size-fits-all requirement, which makes it clear that something must be provided, but leads to subjectivity in the decision on what is good enough. Therefore, performance-based requirements meet the intent of NEIMA, to enable the deployment of these innovative technologies by reducing regulatory burden, not increasing it.

The NRC should improve the language of requirements throughout Part 53 to be more performance-based. Additional details are included in Attachment B comments/proposed resolutions A-11, A-15, A-16, B-1, B-3, B-4, B-7, B-10, C-3, C-4, C-5, D-1, and E-1.

4) Lack of a Clear Vision and Regulatory Philosophy to Establish Part 53 Framework

We urge the NRC to establish a clear vision and specific goals for the final rule, and to utilize a systematic approach to developing the rule. We have proposed details in this area, and NEI's letter from October 21, 2020 - ML20296A398, is one of the first that provided input on these topics – see Attachment C for others. The vision, goals and systematic approach are important to ensure that the final rule will be successful.

A. Lack of Clarity on the Safety Paradigm

As discussed in comment I.1 of this Attachment, the NRC has done a good job of defining the safety paradigm for the design. However, the safety paradigm for the <u>design</u> is only a portion of the Part 53 safety paradigm for the entire regulatory framework, and other areas need more clarity. In particular, the roles of all the technical features of the plant, i.e., design features (safety paradigm of the design), human actions and programs, and the relationship among them are not clear, and may be contributing to the increase in regulatory burden, without an increase in safety, discussed in comment II.4.B of this Attachment.

The consideration of the sources for radioactive material is a first-order consideration in the safety of a nuclear facility. Without a source of radionuclides, there is no radiological hazard to the public or workers. Likewise, larger sources of radionuclides tend to have larger risks of radiological hazards, all other things considered equal. Although Part 53 requirements clearly acknowledge the role of the radioactive material in the safety paradigm, the NRC has not included a requirement to characterize the radionuclide sources. Since a clear understanding of the radionuclide sources drives the application of nearly all other requirements, the NRC should establish such requirements.

There are some elements of the safety paradigm for the design that could be made clearer and could benefit by structural changes. For example, the preliminary rule language has a hierarchy of requirements that flow down from the safety criteria to the design features to the functional design criteria. It is noted that the design features only address the physical features of the facility, i.e., SSCs, and not other elements such as human actions and programs. However, the functional design criteria, which as discussed in comment II.3.B of this Attachment are the equivalent to PDC in Parts 50 and 52, cover all of the technical features of the plant, SSCs, human actions and programs. For this and other reasons, we believe the design features should be downstream of the functional design criteria, not upstream as they are in the current rule language.

The NRC should develop a more coherent and integrated safety paradigm that clarifies the purpose and relationship of design features, human actions and programs, and includes a more full consideration of the source term. Additional details are provided in Attachment B comments/proposed resolutions A-17, A-20 and B-2, and on other requirements relating to this topic.

B. Integrating safety, security, emergency planning and siting

While the NRC's effort to address safety, security, emergency planning (EP) and siting all in Part 53 is an improvement toward a more integrated regulatory framework, we believe there are more opportunities to integrate these aspects of the nuclear facility in a holistic manner. While the schedule for the final rule may preclude much progress in creating a truly integrated and holistic approach to safety, security, EP and siting, it is noted that improving the integration of siting should be feasible under the current rulemaking schedule.

In regards to siting, while we agree with the NRC approach to include siting requirements in Part 53, rather than cross-reference Part 100, the NRC preliminary rule language is identical to the current Part 100 requirements. Thus, the NRC does little more than relocate the siting requirements from one part to another and does not endeavor to establish a more modern technology-inclusive, risk-informed and performance-based approach to siting that is more appropriate for Part 53. By doing so, the NRC is injecting further ambiguity in its regulations by having the same requirement in two separate locations. If the NRC is to integrate these standards in Part 53, they should be tailored to reflect the reduced risk of the advanced reactor designs. Otherwise, if no changes to Part 100 are anticipated, then a cross reference would appear to be sufficient.

We believe an incremental approach to siting in Part 53 is a missed opportunity to achieve transformational changes that result in a more efficient regulatory framework to protect the public health and safety.

The NRC should endeavor to better integrate safety, security, EP and siting, and in particular should reevaluate the approach to siting by recognizing that it is largely the same as it was originally conceived in 1960s/1970s, and that Part 53 is being built upon more a more modern and flexible regulatory framework. Additional comments regarding the need to better integrate siting and safety in Part 53 are provided in Attachment B comments/proposed resolutions in D-1, D-2 and D-3.

C. Lack of an Understanding of Purpose and Application of Requirements

By design, performance-based regulations that are succinct, clear, and predictable in their application will rely on guidance to establish additional details to clarify how to fully implement those regulations in specific situations.

The ACRS has proposed that the NRC add clarity to the rule by including more description of the purpose and underlying intent of the requirements. We would agree that this is a worthwhile pursuit and done well would increase regulatory clarity and predictability. However, we also recognize that poor execution of such an effort could actually reduce clarity and predictability. Examples of where the NRC has attempted to include clarity on the purpose of requirements, but actually reduced clarity by creating duplicative, vague and confusing requirements, are found in 53.200 Safety Objectives, 53.500 Siting Requirements, 53.600 Construction and Manufacturing Scope and Purpose, 53.700 Operational Objectives, and 53.800 Programs. Details on how these provisions could be modified to achieve the ACRS goal of adding clarity to the purpose of requirements are provided in Attachment B comments/proposed resolutions B-1, C-1, D-2, E-2, F-1 and F-6.

Experience in the regulation of nuclear facilities under Parts 50 and 52, as discussed in comments II.2.A and II.3.C of this Attachment on the role of guidance in Part 53, demonstrates the need for guidance to accompany the proposed rule, especially in areas where Part 53 is significantly different than the Parts 50 and 52 framework. One primary difference between the Part 53 framework and the Parts 50 and 52 framework is in the safety paradigm, for which guidance is critically important, and for which a lack of a details is likely contributing to the lack of clarity in the safety paradigm discussed in comment II.4.B of this Attachment. As discussed in comment II.2.A of this Attachment on risk-informed, industry is willing to develop guidance around the safety paradigm.

There are also requirements in Part 53 that deviate significantly from Part 50 and 52 concepts and thus necessitate development of implementation guidance. An example is the NRC's proposed change control process in 53.1322, which is based on PRA results rather than safety analyses. It is noted that the outcome of this proposed change control criteria appears to be identical to the outcome of continuing to use a 50.59-like process. The details in guidance for the 50.59 change control process is critical to the applicability and usefulness of the change control process. Thus, the benefits and risks of the NRC's proposed PRA-based change control criteria cannot be evaluated until guidance is proposed. We recommend not proposing requirements for which the implementation is a "black box" due to lack of guidance, and even if PRA-based change control criteria are included, Part 53 should also include an option to use 50.59-like criteria.

The NRC should identify the guidance that needs to accompany the Part 53 to provide clarity and should issue draft guidance with the proposed rule so that stakeholders can fully understand the NRC's proposed Part 53 regulatory framework. It is noted that the NRC staff stated in the October 28, 2021 public meeting that they would update the list of needed guidance to accompany Part 53. Additional details are provided in Attachment B comments/proposed resolutions I-4 and I-6.

D. Lack of goals for regulatory efficiency

While the NRC has understandably focused on the ability of Part 53 to provide appropriate levels of safety, the NRC does not appear to be focused on the regulatory efficiency of Part 53. Parts 50 and 52 have created substantial amounts of regulatory inefficiency, particularly in licensing review and oversight activities. Establishing goals for regulatory efficiency is the first, and a fundamental, step in achieving regulatory efficiency. The NRC should establish requirements that establish desired measurable outcomes for regulatory efficiency, and then utilize these goals to both ensure the Part 53 framework is aligned to achieve them, and that NRC licensing review and oversight activities are performed in a manner than can efficiently provide reasonable assurance that nuclear facilities are safe. An example of how application review duration goals can be incorporated into Part 53 is included in proposed 53.39(d) of NEI's discussion draft from February 11, 2021. Similar approaches should be developed around the cost of licensing reviews, and the costs of NRC oversight. NEI's October 21, 2021 letter proposed that "*Part 53 should enable the NRC to achieve more reasonable licensing schedule and cost goals (e.g., less than 2 years and $10M), and regulatory oversight goals (e.g., less than 0.5% of the operations and maintenance costs of the plant) that are compatible with the needs of industry to make pragmatic, informed business decisions about licensing new technologies."*

Attachment B
Detailed Comments on NRC's Comprehensive Preliminary Part 53 Rule Language

This attachment provides detailed comments on the NRC's comprehensive preliminary Part 53 rule language and were prepared by the Nuclear Energy Institute and the U.S. Nuclear Industry Council. Detailed comments are provided regulation by regulation with proposed resolutions. Many of these comments are related to the Topical Comments in Attachment A and references connecting the comments are provided in Attachment A. While these detailed comments are intended to be comprehensive, additional comments may result from further evaluation of the preliminary rule language, additional discussion with the NRC, or NRC revisions/additions to the preliminary rule language. References are provided to the versions of the rule language that were used as the basis for these comments, and where possible, they are the latest known versions of the NRC's preliminary rule language as of October 18, 2021.

Detailed Comments on Subpart A – General Provisions

Comments are based on NRC's released version on April 26, 2021 (ML21112A195).

Comment Number	NRC Preliminary Requirement	Industry Comment	Proposed Resolution
A-1	53.010 Scope	The NRC requirement is similar to the scope requirements in 50.1 and 52.0. However, the NRC is restricting the applicability of Part 53 only to commercial advanced nuclear plants licensed under AEA Section 103. Part 53 should not be so limited in scope and the rule could easily be applicable to other types of licenses. Furthermore, the creation of a new term, "commercial advanced nuclear plants", as the sole applicability of the rule, instead of using the terms of "production and utilization facilities" that define the applicability of Parts 50 and 52 lead to confusion on how Part 53 is an optional alternative to Parts 50 and 52.	Expand applicability to all production and utilization facilities licensed under AEA Section 103 or 104, for clarity and consistency with the scope of 50.1 and 52.0. Please modify 53.010 as follows: *"This part provides ~~an optional framework~~ for the issuance, amendment, and termination of licenses, permits, certifications, and approvals for <u>production and utilization facilities</u> ~~commercial advanced nuclear plants~~ licensed under Section 103 <u>and 104</u> of the Atomic Energy Act of 1954, as amended (68 Stat. 919), and Title II of the Energy Reorganization Act of 1974 (88 Stat. 1242). <u>A plant may be licensed and regulated under Part 53, instead of Part 50 or Part 52 at the election of the applicant or licensee of a production or utilization facility</u>." (Conforming changes throughout Part 53 may be necessary)*

A-2	53.020 Definitions - Advanced nuclear plant (or facility)	The NRC should not define or restrict Part 53 to a concept of "advanced" nuclear plants. While NEIMA did define "advanced nuclear reactor" when it provided statutory requirements for the NRC to develop a Technology-Inclusive Regulatory Framework, it did not limit such framework only to "advanced" reactors, but rather stated that it should be "*flexible and practicable for application to a variety of reactor technologies*." The NRC should not limit the use of Part 53 to facilities with all but one of the features (B thru H) defined as an advanced nuclear reactor in the NEIMA, such as "*lower levelized cost of electricity*," "*increased thermal efficiency*" and "*ability to integrate into electric and nonelectric applications*," since these fall outside the NRC's authority of regulating nuclear safety. The NRC could limit the use of Part 53 to reactors that have "*additional inherent safety features,*" since that is consistent with the NRC's authority for regulating nuclear safety. However, we believe that limiting the use of Part 53 to reactors with "*additional inherent safety features*" is unnecessary and reduces clarity, since the Part 53 requirements themselves are intended to ensure the safety of nuclear facilities. As long as a proposed design can meet the Part 53 requirements for safety, that should be a sufficient justification for utilizing Part 53. Creating a screening criterion to use Part 53 based on the increased use of inherent safety features is unnecessary, and in fact is contrary to the NRC's Advanced Reactor Policy Statement, which encourages but does not require enhanced safety of advanced reactors.	Delete the term "*Advanced nuclear plant [or facility]*" throughout Part 53 and replace with the terms "*production facility"* and *"utilization facility*" as defined in 50.2.

A-3	53.020 Definitions – Construction	As noted in the NRC's preliminary rule language, this definition should be updated to the Part 53 terminology.	For items (1) i through iv, these should be replaced with the definitions of Safety Related and Non-Safety-Related but Safety Significant in 53.020. Items (1) v through vii should reference the equivalent requirements in Part 53.
A-4	53.020 Definitions – Anticipated Operational Occurrences, Licensing Basis Events, Unlikely Events, Very Unlikely Events and Design Basis Accidents	There is some confusion with these terms: • Deviation from long-standing terms "DBE" and "BDBE"; • Reference to guidance to establish an example of quantitative criteria; • Inconsistent use of terminology among the definitions; • Lack of flexibility provided for the use of the PRA in forming the basis of the safety case.	We recommend that the NRC replace the terms and definitions with the following" *"Licensing basis events* (LBEs) are unplanned events and include AOOs, DBAs, and BDBEs that are considered in the licensing of a production or utilization facility. LBEs may include one or more reactor modules." *"Anticipated operational occurrences (AOOs)* are a grouping of similar event sequences that are unplanned, but may occur one or more times during the life of a nuclear facility. AOOs established through quantitative methods are event sequences with a mean frequency of 1×10-2/plant-year and greater. AOOs take into account the expected responses of all SSCs within the plant, regardless of safety classification." (if needed) *"Design basis accidents (DBAs)* are derived from the DBEs and are used to establish the design of safety-related SSCs. DBAs take into account the expected responses of only those safety-related SSCs relied upon to mitigate or prevent event sequences."

			"Design Basis Events (DBEs) are a grouping of similar event sequences that are not expected to occur during the life of a nuclear facility. DBEs established through quantitative methods are event sequences with mean frequencies between 1x10-2 and 5x10-4 per plant year. DBEs take into account the expected response of all SSCs within the plant regardless of safety classification." *"Beyond Design Basis Events (BDBE)* are a grouping of similar event sequences that are very unlikely to occur during the life of a nuclear facility. While BDBE are part of the licensing basis, they are not part of the design basis. BDBEs established through quantitative methods are event sequences with mean frequencies between 1x10-4 and 5x10-7 per plant year. BDBEs take into account the expected response of all SSCs within the plant regardless of safety classification."
A-5	53.020 Definitions – Defense in Depth	The definition of defense in depth is not needed, since a specific requirement is not needed to achieve defense in depth. If the term and definition is retained, then the current NRC preliminary language should be revised to avoid creating unintended consequences through the prescriptive nature of the definition.	Delete the term and definition. If the term is not deleted, then the definition should be revised as follows: *"Defense in depth <u>is a design philosophy that provides reasonable assurance that the design meets the safety criteria in 53.210 over the life of plant by addressing uncertainties in the performance of safety functions through measures such as increased safety margin and</u>*

			multiple layers of protection ~~means inclusion of multiple independent and redundant layers of defense in the design of a facility and its operating procedures to compensate for potential human and mechanical failures so that no single layer of defense, no matter how robust, is exclusively relied upon. Defense-in-depth includes, but is not limited to, the use of access controls, physical barriers, redundant and diverse key safety functions, and emergency response measures~~."
A-6	53.020 Definitions – Design Control	There is no need for a definition of "*Design Control*" in Part 53, and inclusion of a definition could cause unintended consequences. "Design Control" is a QA requirement in Part 50 Appendix B, Criterion II (which should serve as the basis for QA requirements in Part 53). However, the definition in Part 53 conflicts with the use of the term in Appendix B in that Part 53 applies Appendix B QA requirements to all SSCs, rather than to only safety-related SSCs (as is done by Appendix B). This would lead to every LBE (including AOOs and BDBEs), and their related SSC categories (NSRSS and NSR) now being considered subject to QA controls that have historically only applied to safety-related SSCs.	Delete the definition of "*Design Control*" and rely on the QA requirements in Part 53 (based on Part 50 Appendix B) to describe the scope and intent of Design Control.
A-7	53.020 Definitions – Design Features	It is important to define the purpose for the types of technical features (design features, human actions and programs) that are needed for nuclear facilities. Changes to the NRC definition for "*design features*" are needed to improve clarity and predictability.	Change the definition to: "Design features ~~means~~ are the characteristics of active and passive structures, systems and components ~~and inherent characteristics of those SSCs~~ that contribute to limiting the total effective dose equivalent to the individual members of the public during normal

			operations and prevent or mitigate consequences of unplanned events."
A-8	53.020 Definitions – Deterministic and Probabilistic Risk Assessment	The NRC definitions for "*deterministic*" and "*probabilistic risk assessment (PRA)"* are not entirely consistent with the historic uses of these terms, or with how these terms are defined on the NRC's website. Changes to these definitions are needed to improve clarity and predictability. This is particularly important because there are different interpretations of how PRA are used, as discussed in NRC meetings on Part 53.	Change the definitions to align with current NRC definitions of these terms as follows (from NRC's website): "*Deterministic* is consistent with the principles of "determinism," which hold that specific causes completely and certainly determine effects of all sorts. As applied in nuclear technology, it generally deals with evaluating the safety of a nuclear power plant in terms of the consequences of a predetermined bounding subset of accident sequences." "*Probabilistic risk assessment (PRA)* is a systematic method for assessing three questions that the NRC uses to define "risk." These questions consider (1) what can go wrong, (2) how likely it is, and (3) what its consequences might be. These questions allow the NRC to understand likely outcomes, sensitivities, areas of importance, system interactions, and areas of uncertainty, which the staff can use to identify risk-significant scenarios. The NRC uses PRA to determine a numeric estimate of risk to provide insights into the strengths and weaknesses of the design and operation of a nuclear power plant."
A-9	53.020 Definitions – End State	The NRC definitions for "*end state*" is not entirely consistent with other NRC uses of this term. Changes to	Change the definition to:

		these definitions are needed to improve clarity and predictability.	"*End state* means the set of conditions at the end of an event sequence in which the facility has achieved and is anticipated to maintain a safe and stable configuration."
A-10	53.020 Definitions – Inherent characteristic	The definition of "*inherent characteristic*" is confusing and it is unclear how it is used in Part 53. The only place this term is used is in the definition of "*design features.*" In our comment on that term, we recommend deleting the use of "inherent characteristic" since it is not necessary. Furthermore, since the Part 53 requirements do not distinguish between inherent and other characteristics, there is no need to create and define a term that is unused by Part 53.	Delete the term and definition "*inherent characteristic*".
A-11	53.020 Definitions – Initiating Event	The definition of "*initiating event*" is confusing and unnecessary. The only place this term is used is in the definition of "*Event Sequence*" and there is no need to define "initiating event" in the rule, since the term is not used anywhere else in Part 53. Since there is no benefit to clarity and predictability from defining the term in the rule language, the NRC should allow flexibility for its use by allowing guidance to define the term, which could be used differently for different licensing approaches.	Delete the term and definition "*initiating event*". If the NRC retains the term, replace the definition with something that is more clear and performance-based, such as: "*Initiating Event* means an unintentional change in the plant configuration that leads to the progression of an event sequence that is not part of normal plant operations."
A-12	53.020 Definitions – Manufacturing	The NRC has defined the term "*manufacturing*" to mean activities conducted under a manufacturing license. However, manufacturing activities occur for any type of license in order to produce equipment and components. It is unclear why this term needs to be defined, and whether it is the NRC's intention that all manufacturing activities	Delete the term and definition "manufacturing".

		must seek a manufacturing license, even if those activities are performed pursuant to a CP or COL. Or whether it is the NRC's intent to say that the NRC only has regulatory jurisdiction over manufacturing performed under an ML, and thus the NRC does not have jurisdiction for manufacturing under a CP or COL. We urge the NRC not to pursue either of these objectives, since they are not needed and are inconsistent with practices under Parts 50 and 52. Thus, defining the term leads to a lack of clarity.	
A-13	53.020 Definitions – Mechanistic Source Term and Fission Product Release	The NRC introduces two terms and definitions related to the release of radionuclides to the public that were not defined in Parts 50 and 52. While we agree that defining these terms leads to greater regulatory clarity and predictability, it is not clear that both terms are needed. Further, the term "*fission product release*" implies that these are radionuclides produced by fission, although the definition would not be so restrictive. Finally, the term "*mechanistic source term*" only appears once in the Part 53 requirements and it is included as a parenthetical "e.g.," list of example analytical methods. Thus, it is not clear whether the NRC is requiring the use of mechanistic source term analyses or not.	Define only one term for radionuclide releases and align Part 53 requirements to utilize this terminology. We would recommend the following term and definition: *"Radionuclide release* means the amount and composition of radioactive material released to the environment, after accounting for any retention of radionuclides provided by reactor design features. The radionuclide release may be determined by a mechanistic source term analysis, which calculates radionuclide release by using models and supporting scientific data that simulate the physical and chemical processes that describe the radionuclide inventories and the time-dependent radionuclide transport mechanisms that are necessary and sufficient to predict the radionuclide release."
A-14	53.020 Definitions – Light-Water Reactor, Non-	The definition for *"light-water reactor", "non-light water reactor", "small modular reactor"* and "*microreactor*" are confusing and it is unclear how they are used in Part 53. In	Delete the terms and definitions for *"light-water reactor", "non-light water reactor" "small modular reactor"* and "*microreactor*".

	light-water reactor, Small modular reactor, and Microreactor	fact, these terms are not found anywhere in Part 53, except in their definitions. The distinction between these technologies is therefore not necessary, especially since Part 53 is intended to be a technology-inclusive rule. Further, the definition for *"microreactor"* is incorrect in that microreactors may include both LWR and non-LWR technologies.	
A-15	53.020 Definitions – Safety-related, Non-safety-related but safety significant (NSRSS), Special Treatment, and Non-safety-significant	The NRC's definition of "*safety-related*" has benefits over the Part 50 definition in that basing safety-related on the 25 rem dose limit is more technology-inclusive and performance-based than the LWR-specific criteria in Part 50. However, the NRC's definition also introduces new concepts that are not warranted and can lead to unintended consequences, specifically in applying safety-related to human actions and that the new term of special treatment to safety-related SSCs warrant. The issue with creating safety-related human actions is that they do not share the same nature as SSCs, and thus the requirements that apply to safety-related SSCs are likely not be applicable to humans, and vice-versa. This is also a problem with the NRC's definition of NSRSS, which creates non-safety-related safety significant human actions. The NRC appears to address this challenge by applying *"special treatment"* to safety-related SSCs. However, the NRC is also applying special treatment to certain non-safety-related SSCs, and does not define the differences in the special treatments between these types of SSCs. Thus, it is possible, or even likely, that NSRSS SSCs will receive an	Delete the term and definition for "special treatment", and delete or replace the term in other uses throughout Part 53. Revise the definitions for categories of SSCs as follows: *"Safety-related (SR) SSCs* means those SSCs ~~and human actions~~ that ~~warrant special treatment and~~ are relied upon for DBAs to demonstrate compliance with the safety criteria in § 53.210~~(b)~~. "~~*Non-Safety-Related but*~~ *Safety Significant (~~N~~SRSS) SSCs* means those non-safety-related SSCs ~~and human actions that warrant special treatment and are not safety-related but are relied on to achieve~~ whose degradation or loss could result in a significant adverse effect on defense-in depth, safety margin or ~~perform~~ risk~~-significant functions~~." (Note that in comments on other requirements we used the NRC term for clarity of the comments; however, the revised term should be implemented throughout Part 53.)

		equivalent regulatory burden as SR SSCs. The application of the term "special treatment" to SR and NSRSS SSCs reduces regulatory predictability and in fact is not necessary. While the NRC appears to be applying the term "special treatment" to describe how Part 53 requirements apply to SR and NSRSS SSCs, such an approach was not necessary in Parts 50 and 52. The NRC's Part 53 definition of "special treatment" effectively says that it is "requirements that apply to certain SSCs," and thus provides no clarity or regulatory stability. The approach in Parts 50 and 52 is to state within specific requirements whether they apply to safety-related or risk-significant SSCs. The same can be done in Part 53, where the requirements define to which category of SSCs they apply, and in fact most Part 53 requirements already do this. Thus, the use of the term "special treatment" creates confusion and provides no regulatory benefit. The definition of "NSRSS" uses the term "risk significant function", which itself is not defined. It is unclear what this term means and it is not used anywhere else in Part 53 (except for in definitions addressed in this comment and for QA requirements that should be replaced with requirements based upon Part 50 Appendix B.) The definition of NSRSS is also not consistent with the common definition of safety significant in use today.	*"Non-Safety-Significant (NSS)* SSCs means those SSCs ~~not warranting special treatment,~~ that are not safety-related or safety-significant and are therefore not subject to requirements in Part 53 ~~are not relied on to achieve adequate defense-in-depth or to perform risk-significant functions~~."
A-16	53.020 Definitions – Performance-based	The NRC definition of *"performance-based"* in Part 53 differs from the historical NRC definition, which will create confusion and reduce regulatory clarity and predictability. It is noted that the NRC only uses the term *"performance-*	Revise the definition of "*performance-based"* to align with the NRC's established definition as follows (from the NRC website):

		based" in two locations, in 53.860, where the phrase "performance-based or deterministic" is not needed and should be deleted, and in 53.890 relating to the Facility Safety Program, which should not be included in Part 53.	*"Performance-based* means a~~n~~ regulatory approach ~~to decision-making~~ that focuses on ~~the~~ desired ~~objective of calculable or~~ measurable~~, observable~~ outcomes, rather than prescriptive design features, processes, techniques, or procedures. Performance-based ~~decisions~~ regulation leads to defined results without ~~limited~~ 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."
A-17	53.020 Definitions – Programmatic controls	It is important to define the purpose for the types of technical features (design features, human actions and programs) that are needed for nuclear facilities. The NRC has introduced a new term *"programmatic controls,"* however, the definition and the application of the term in the Part 53 requirements is vague and subjective. Thus, there is no clarity or predictability in what would constitute acceptable programmatic controls. This is concerning since there are over 20 Part 53 regulations that have open ended requirements for programmatic controls. Furthermore, the concept of programmatic controls effectively duplicates the concept of "*programs"* which is not defined in NRC regulations but is reasonably well understood by virtue of its long history of use by the NRC and licensees. However, the NRC does not define this term	The term and definition for "programmatic controls" should be deleted and the use of the term in other instances in Part 53 should be deleted. The term "program" should be defined so that the purpose of programs can be understood, as follows: "*Programs* are the administrative measures and controls that are relied upon by the NRC to provide reasonable assurance that plant design, construction, maintenance and operation meet the safety criteria in 53.210 and 53.220 for the lifetime of the plant. Programs may apply to design features and/or credited human actions. Programs that require

		in Part 53, although it is used for over 24 required programs. The concept and term of "*programmatic controls*" is not needed, and is duplicative of the term "*program*".	NRC approval are specified in the regulations for various technical areas (e.g., QA)."
A-18	53.020 Definitions – Safety criteria	The NRC's definition of *"safety criteria"* establishes equal footing for the criteria of 25 rem for DBAs in 53.210 with the criteria for AOOs and BDBEs in 53.220. This can lead to all SSCs relied upon for all LBEs being treated the same, such that NSRSS SSCs relied upon for AOOs are treated equivalently to SR SSCs relied upon for DBAs.	Add clarity by revising the definition as follows: "*Safety criteria* means metrics that establish ~~a level of safety based on requirements in~~ the performance-based criteria that are safety-related, in § 53.210 and, non-safety-related but safety-significant, in § 53.220."
A-19	53.020 Definitions – Site characteristics	The use of the term *"radioactive material escaping"* in the definition of *"site characteristics"* is confusing as it does not relate to another defined term. We propose in other comments to use the term *"radionuclide release"*.	Revise the definition as follows: *"Site characteristics* means the meteorological, geological, seismological, topographical, hydrological, and other characteristics of the site and surrounding area that may have a bearing on the consequences of a radionuclide ~~active~~ release ~~material escaping~~ from the nuclear plant as well as demographic features of a site. ~~(§ 53.500).~~"
A-20	53.020 Definitions – Human actions	It is important to define the purpose for the types of technical features (design features, human actions and programs) that are needed for nuclear facilities. The NRC uses the term *"human actions"* throughout Part 53 but has not defined the term. Lack of a definition reduces regulatory clarity and predictability.	Include a definition of *"human actions"* as follows: "*Human actions* are actions taken by a licensed operator or senior operator to manipulate plant design features to maintain or return the facility to compliance with the license and regulations."

A21	53.020 Definitions – Functional Design Criteria	"Functional design criteria" in Part 53 serve the same underlying purpose as "principal design criteria" in Parts 50 and 52. Since PDC concept has a long regulatory precedent and is well understood in the design and licensing of nuclear facilities, changing the term to "functional" rather than "principal" design criteria reduces regulatory clarity and predictability. Similarly, changes to the definition of these design criteria, that are not necessary to align with other changed terms or concepts in Part 53, reduces regulatory clarity and predictability. Establishing two levels of identical functional design criteria (one for DBAs and one for all other LBEs) is confusing and appears to be an artifact of the original NRC approach to a two-tier Part 53 regulatory framework, which was abandoned in the third iteration of subparts B&C. Finally, while the definition of PDC in Part 50 is focused on being met solely by SSCs, the actual PDC are formed around the concept that they may be met by SSCs, human actions, or programs, or a combination thereof.	Change the term and definition as follows: "~~*Functional*~~ *Principal design criteria* (PDC) means ~~requirements for the performance of SSCs. For safety-related SSCs, these criteria define requirements~~ the necessary and sufficient design, fabrication, construction, testing and performance requirements that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public. PDC may be fulfilled by SR and NSRSS SSCs, human actions, or programs, or a combination thereof. ~~to demonstrate compliance with first tier safety criteria in § 53.210(b). For non-safety-related but safety-significant SSCs, these criteria define requirements necessary to meet the second tier safety criteria in § 53.220(b).~~" Change the use of the term throughout Part 53.

Attachment B
Detailed Comments on NRC’s Comprehensive Preliminary Part 53 Rule Language

Detailed Comments on Subpart B – Technology Inclusive Safety Requirements

Comments are based on NRC’s released version on August 10, 2021 (ML21202A162).

Comment Number	NRC Preliminary Requirement	Industry Comment	Proposed Resolution
B-1	53.200 Safety Objectives	The requirement establishes new safety standards that do not have a basis in the Atomic Energy Act (AEA), and replaces the safety standards that the NRC has relied upon for decades and which do originate from the AEA. Replacing the safety standards of “*reasonable assurance of adequate protection of public health and safety*” from AEA 182 and “*to protect health or to minimize danger to life or property*” from AEA 161, which have a long history of regulatory and judicial precedent with new standards of “*limit the possibility of an immediate threat to the public health and safety*”, and “*considering potential risks to public health and safety*”, which have no such precedent, reduces regulatory clarity and predictability. Such an approach is entirely inconsistent with the longstanding position 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 NRC would need to invest significant resources in defining these standards to ensure consistency with the AEA. Thus, additional clarity in Part 53 would be achieved by providing insight into the application of the AEA standards, rather than creating new standards. It is also unclear what the NRC is attempting to accomplish with this requirement, since the requirement essentially encompasses the entire objective of Part 53, since it states *“Each commercial nuclear plant must be designed, constructed, operated, and decommissioned to…”* If the	The NRC should modify the requirement to use the well-established safety standards from the AEA, clarify their application in Part 53, and state that the requirement is intending to clarify the purpose of the Part 53 requirements, as follows: “The purpose of Subpart B is to define the standards of safety for ~~each commercial nuclear plant must be~~ the design~~ed~~, construction~~ed~~, operation ~~ed~~, and decommissioning ~~ed~~ of production and utilization facilities licensed under Part 53. The AEA Section 182 standard of “*reasonable assurance of adequate protection of public health and safety”* is achieved by 53.210 and related requirements. The AEA Section 161 standard of “*protect health or to minimize danger to life or property”* is achieved by 53.220, 53.260, 53.270, and related requirements. ~~to limit the possibility of an immediate threat to the public health and safety. In addition, each commercial nuclear plant must take such additional measures as may be appropriate when considering potential risks to public health and safety. These safety objectives shall be carried out by~~

		NRC's intent is to establish the purpose of Part 53, then the requirement should be written to state that this is a purpose statement, which clarifies the collective nature of Part 53 requirements and the outcome achieved by meeting the collective requirements, and is not a requirement that an applicant and licensee must explicitly meet. This requirement reduces regulatory predictability and flexibility because it uses language that is prescriptive, yet open-ended, rather than using performance-based language that is clear and measurable. Specifically, the phrase "must take additional measures" prescribes the feature rather than defining the desired outcome.	~~meeting the safety criteria identified in this subpart.~~" The NRC should also rename this requirement, as follows: "Safety <u>Standards</u> ~~Objectives~~"
B-2	53.205 Radionuclide Sources	The consideration of the sources for radioactive material is a first order consideration in the safety of a nuclear facility. Without a source of radionuclides, there is no radiological hazard. Likewise, larger sources of radionuclides tend to have larger risks of radiological hazards, all other things considered equal. However, the NRC has not included at the beginning of the Part 53 safety framework a consideration of the radionuclide sources, which influences how a given nuclear facility must meet the Part 53 requirements. While the NRC did include consideration of fuel and waste, this is not until the design requirements in 53.440. Even there, the NRC did not consider other sources of radionuclides.	Include a new requirement as follows: <u>*"53.205 Radionuclide Sources.*</u> <u>*The radiological hazard of the facility, which could potentially be released to the environment, must be characterized, including the maximum power level, nature and inventory of radioactive materials, and the expected chemical and physical form during all phases of operation. All sources of radionuclides that could be released to the environment should be considered, such as fuel in the reactor, fuel outside the reactor and radioactive wastes."*</u>

B-3	53.210 Safety Criteria for Design Basis Accidents	This requirement uses language that is prescriptive, yet open-ended, rather than using performance-based language that is clear and measurable, thereby resulting in reduced regulatory predictability and flexibility. Specifically, the phrase "*Design features and programmatic controls must be provided*" prescribes the features rather than defining the desired outcome. This phrase does not add clarity because other requirements, specifically 53.400 for design features, and numerous requirements related to programs already specify that these elements are needed for Part 53 applicants and licensees. Thus, duplication of this phrase here and in many other locations in Part 53 will add regulatory burden, in terms of demonstrating compliance, without any benefit to safety.	Revise the requirement to be more performance-based, by deleting the phrase "*~~Design features and programmatic controls must be provided…~~*"
B-4	53.220 Safety Criteria for Licensing Basis Events Other than Design Basis Accidents	The intent of 53.220 appears to be define the safety criteria for AOOs and BDBEs, which the NRC preliminary rule language attempts to achieve by incorporating the Quantitative Health Objectives (QHOs) into rule language. While defining safety criteria for other LBEs is important, the NRC's preliminary requirement results in numerous complications throughout the rule and does not adequately achieve the objective. 53.220(b) is unnecessary as it codifies the QHOs from the NRC's Safety Goal Policy Statement, which are applicable to Part 53 applicants and licensees regardless of whether they are included in the rule language or remain solely in the policy statement. Inclusion of the QHOs in the rule language will create unintended consequences, as it will require that the PRA be used to demonstrate regulatory compliance, and thus likely need to be included in the	Achieve the intent of establishing safety criteria for LBEs other than DBAs with performance-based criteria that are more appropriate to those types of events, resulting in requirements that are more clear, predictable and flexible, by replacing 53.220 with the following four changes. 1) Rename 53.220 to "*Mitigation of Beyond Design Basis Events*" with the following rule language: *"For BDBEs, each applicant or licensee shall develop, implement, and maintain mitigation strategies and guidance that are capable of being implemented site-wide and must include the following:* *(a) The capability to maintain or restore the safety functions necessary to meet the safety criteria in 53.210.*

		licensing basis. This will add regulatory burden, in terms of demonstrating compliance, without any benefit to safety. As documented in Attachment 2 of NEI's February 11, 2021 letter, "*It is recognized that regardless of whether the QHOs are in the Safety Goal Policy or Rule Language, the design, analysis and licensing approach that would be taken by an applicant, and the NRC scope of review would be the same. Likewise, the risk-informed approach in NEI 18-04 would be implemented the same under both approaches. The difference is in the legal compliance with the requirements that exists for the license and the potential to eliminate other requirements, if the QHOs are in the rule language*." Thus, no increase in safety results from including the QHOs in the rule, and there is no need to do so to accommodate a particular licensing approach. However, including the QHO in the rule text could introduce unforeseen licensing complications, particularly since the NRC proposed requirement for the QHOs does not include the dose limits associated with early fatalities or latent cancer fatalities. If the QHOs are in the rule, they must be met for purposes of strict legal compliance with the rule's terms (not for actual safety reasons). Furthermore, since the PRA is the basis for meeting the QHOs, more, if not all, of the PRA will need to be submitted on the docket and potentially subject to contention. The use of 53.220 throughout Part 53 also introduces unintended consequences insofar as these other requirements rarely distinguish between the safety significance of 53.210 and 53.220. Thus, other LBEs are elevated to similar importance as DBAs, and NSRSS and	<u>*(b) The acquisition and use of offsite assistance and resources to support the functions required by paragraph (a) of this section indefinitely, or until sufficient site functional capabilities can be maintained without the need for the mitigation strategies*</u> <u>*(c) Strategies and guidance to provide the capabilities in (a) under the circumstances associated with loss of large areas of the plant impacted by the event, due to explosions or fire, to minimize radiological releases*</u>*."* 2) If the NRC believes it is necessary, create a new requirement 53.225 called "*Safety Criteria for AOOs*" and replace rule language with: *"Each nuclear facility shall demonstrate the following for AOOs,* *(a) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release would not receive a radiation dose in excess of 1 rem (10 mSv) total effective dose equivalent; and* *(a) An individual located at any point on the outer boundary of the low population zone who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 1 rem (10 mSv) total effective dose equivalent."*

		NSS SSCs are elevated to similar importance to SR SSCs. While some requirements specify differences among these in order to mitigate this unintended consequence, it is not consistently applied and results in an unnecessarily cumbersome regulatory framework. The outcome is increased regulatory burden for NSRSS and NSS SSCs and decreased regulatory predictability. Such an outcome is not worth including the QHOs in rule language when the QHOs are equally applicable and effective when applied through the Policy Statement. The NRC's application of downstream design requirements to 53.220, which includes a focus on BDBEs, effectively includes BDBEs in the design basis. While BDBEs must be part of the licensing basis, they should not be part of the design basis. If BDBEs are included in the design basis, then they are no longer "beyond" the design basis, but are the design basis. This is a dramatic and unnecessary increase in the NRC's regulatory control. While it is true that the design features and SSCs needed to mitigate BDBEs are part of the licensing basis, they should not be treated in the same manner as design basis events, since doing so would increase regulatory burden without increasing safety. While the NRC could revise all downstream requirements to avoid expanding the design basis to included BDBEs, and still establish a safety criteria for BDBEs, the more efficient approach would be to correct the source of the problem, which is how the NRC has established safety criteria for BDBE. The solution is to require mitigation of BDBEs, as is done for existing reactors, rather than establish dose-based criteria for the BDBEs. The NRC already has a BDBE mitigation requirement in 53.450 but the Part 50 requirement	3) Continue to apply the NRC's Safety Goal Policy Statement to the licensing of nuclear facilities under Part 53, consistent with the Commission's original intent for application of this policy. 4) Any clarity provided by 53.220(a) can be incorporated into requirements that it is attempting to clarify (e.g., 53.240, 53.250 or 53.400).

		incorporated in 53.450 is LWR-specific and should be replaced with a technology-inclusive version and relocated here. While our recommendation is to not include QHOs in the rule and continue to implement them through the Safety Goal Policy, we acknowledge that this is not the unanimous view of all members. There is at least one member of industry that believes QHOs must be in the rule to provide regulatory predictability by avoiding the need to develop surrogate metrics for the QHOs. Therefore, more discussion on the benefits and disadvantages of the options of how to address QHOs in a way that achieves both predictability and flexibility would be beneficial. 53.220(a) is unnecessary because it states that "*SSCs, personnel and programs be provided*", essentially duplicating the requirements in 53.240 and 53.250, as well as 53.400 (although it is not referenced). Thus, the only apparent purpose of this requirement is to ensure these other requirements are met; it does not itself establish a safety criterion. Such duplication of requirements leads to increased regulatory burden, from a compliance perspective, with no attendant increase in safety.	
B-5	53.230 Safety Functions	It is unclear what purpose is served by defining primary and alternative safety functions, other than to justify including the QHOs in the rule language in 53.220. Does the NRC intend that some safety functions (primary) are only needed to meet the standard of "*reasonable assurance of adequate protection of public health and safety*" and other safety functions (additional) are needed to meet the standard "*to protect health or to minimize*	Revise the requirement for greater clarity, as follows: "(a) The ~~primary safety function is limiting the release of radioactive materials from the facility and must be maintained during routine operation and for licensing basis events over the life of the plant.~~

		danger to life or property"? While such distinction could make Part 53 more efficient, it is not clear that this is the NRC's intent since these standards were replaced in 53.210. Safety functions should relate to the DBAs, safety-related SSCs, and back to 53.200. Any other functions the plant needs to provide may be safety significant, but would not be safety-related. The statement that the safety functions must be maintained for all licensing basis events implies that there is an equivalence in the design standards for SR SSCs needed for the DBAs to meet 53.210, and the NSRSS and NS SSCs that are relied upon for AOOs and BDBEs. This could result in unintended consequences in that the NSRSS and NS SSCs are elevated to need similar confidence in performance as SR SSCs. Such an outcome would increase regulatory burden without an increase in safety.	~~(b) Additional~~ safety functions <u>necessary to meet 53.210</u> ~~supporting the retention of radioactive materials during licensing basis events~~—such as <u>limiting radionuclide release, criticality control,</u> controlling heat generation <u>and</u> heat removal, and chemical interactions--must be defined. (~~c~~ <u>b</u>) The ~~primary and additional~~ <u>SR SSCs must be capable of performing their intended</u> safety functions during DBAs. <u>NSRSS SSCs may be relied upon to accomplish the safety functions for other LBEs</u>. ~~are required to meet the safety criteria defined in §§ 53.210 and 53.220 and are fulfilled by the design features and programmatic controls specified throughout this part~~."
B-6	53.240 Licensing Basis Events	This requirement provides valuable clarity in terms of the types of events that must be considered in the design and licensing of a nuclear facility. The requirement also provides clarity in referencing other requirements that interface with the selection of licensing basis events. However, the requirement does include language that duplicates requirements in other parts of the rule, and such duplication should be avoided as it could lead to unintended consequences and increased regulatory burden, without an increase in safety.	Revise the requirement as follows: *"Licensing basis events must be identified for each commercial nuclear plant <u>that</u>* *<u>(a)</u> ~~and analyzed in accordance with § 53.450 to support assessments of the safety requirements in this subpart. The licensing basis events must~~ address combinations of <u>relevant</u> malfunctions of plant SSCs, human errors, and the effects of external hazards.* *<u>(b)</u> ~~ranging from~~ <u>include</u> anticipated operational occurrences<u>, design basis accidents and beyond design basis events.</u> ~~to very unlikely event sequences with estimated frequencies well below the frequency of events~~*

			~~expected to occur in the life of the commercial nuclear plan~~t. *(c) are analyzed in accordance with § 53.450 to support assessments of the safety requirements in this subpart.* *~~The analysis of licensing basis events must include analysis of one or more design basis accidents in accordance with § 53.450(f). The analysis of licensing basis events must be used to confirm the adequacy of design features and programmatic controls needed to satisfy safety criteria defined in §§ 53.210 and 53.220 and to establish related functional requirements for plant SSCs, personnel, and programs~~."*
B-7	53.250 Defense in Depth	A specific requirement in Part 53 for defense in depth (DID) is not necessary in order to achieve defense in depth. As an example, Parts 50 and 52 do not contain a requirement for defense in depth, but do achieve the desired outcome by applying a DID philosophy. The NRC's proposed DID requirement is prescriptive and is not performance-based or risk-informed. For example, the NRC prescribes that "*no single feature no matter how robust should be exclusively relied upon.*" However, what if the consequences of a particular design that did not protect against a single failure were less than 1 rem? In this case the single failure protection is not needed to meet the safety criteria in Part 53. Furthermore, the requirement is written in a way that it is applicable to NSRSS and NS SSCs, because it applies to 53.220. However, is not the single failure more effective	Delete the requirement. If the requirement is not deleted, then it should be revised as follows: *"~~Measures must be taken for each commercial nuclear plant to ensure appropriate~~ Defense in depth must be ~~is~~ provided to compensate for uncertainties in the performance of safety functions ~~such that there is high confidence~~ to provide reasonable assurance that the safety criteria in 53.210 ~~this subpart~~ are met over the life of the plant. The uncertainties to be considered include those related to the state of knowledge and modeling capabilities, and the ability of barriers to limit the radionuclide release ~~of radioactive materials from the facility during routine operation and for licensing basis events, and those related to the~~*

		when it is applied to SR SSCs relied upon for DBAs in meeting 53.210? Thus, the requirement is adding regulatory burden, without an increase in safety. Thus, this prescriptive application of a single failure protection is inconsistent with the basis for the Commission direction in SRM-SECY 19-0036 to not apply deterministic criteria when they are not needed based on risk insights. This requirement uses language that is prescriptive, yet open-ended, rather than using performance-based language that is clear and measurable. Consequently, this requirement reduces regulatory predictability and flexibility. Specifically, the phrase "Measures must be taken" prescribes the feature rather than defining the desired outcome.	*~~reliability and performance of plant SSCs and personnel, and programmatic controls~~. <u>Defense in depth measures may include increased safety margin and redundant layers of protection.</u> ~~No single engineered design feature, human action, and or programmatic control, no matter how robust, should be exclusively relied upon to meet the safety criteria of § 53.220 or the safety functions defined in accordance with § 53.230.~~"* (If the sentence on "No single engineered design features…" is not deleted, then it should be only applicable to 53.210 and conditions as follows "<u>this does not apply when strict, prescriptive application of deterministic criteria such as the single failure criterion is unnecessary to provide for reasonable assurance of adequate protection of public health and safety.")</u>
B-8	53.260 Normal Operations	The creation of a design requirement for ALARA in 53.260(b) is inconsistent with the Commission's intention that "*the ALARA concept is intended to be an operating principle rather than an absolute*." 56 Fed. Reg. 23359, 23366 (May 21, 1991). The requirement, however, treats ALARA as the latter, and in fact expands the ALARA principle beyond what is currently in place for the operating reactors. A design requirement for ALARA is not necessary since 53.260(a) already establishes a design requirement through the dose standard for normal operations (0.1 rem) in Part 20. ALARA is also already achieved by operational considerations through Part 20, which is applicable to all Part 53 licensees even if it is not explicitly stated in Part 53.	Delete the requirement 53.260(b) for a design requirement for ALARA.

		Thus, the effect of establishing an ALARA design requirement in 53.260(b) is to establish a regulatory philosophy of regulating to an undefined and limitless "safer than safe" standard that increases regulatory burden without increasing safety, and distract licensees and the NRC from items that are more important to safety.	
B-9	53.270 Protection of Plant Workers	The creation of a design requirement for ALARA in 53.270(b) is inconsistent with the Commission's intention that "*the ALARA concept is intended to be an operating principle rather than an absolute*." 56 Fed. Reg. 23359, 23366 (May 21, 1991). The requirement, however, treats ALARA as the latter, and in fact expands the ALARA principle beyond what is currently in place for the operating reactors. A design requirement for ALARA is not necessary since 53.270(a) already establishes a design requirement through the dose standard for occupational doses in Part 20. ALARA is also already achieved by operational considerations through Part 20, which is applicable to all Part 53 licensees even if it is not explicitly stated in Part 53. Thus, the effect of establishing an ALARA design requirement in 53.270(b) is to establish a regulatory philosophy of regulating to an undefined and limitless "safer than safe" standard that increases regulatory burden without increasing safety, and distract licensees and the NRC from items that are more important to safety.	Delete the requirement 53.270(b) for a design requirement for ALARA.
B-10	53.280 Quality Assurance	The NRC preliminary rule language splits up QA requirements and relocates them in different subparts of the rule. In doing so, there is significant duplication in the proposed QA requirements, and in several cases, there are	Add the following requirement: *"<u>53.280 Quality Assurance.</u>*

		differences in language applying the exact same QA criterion. The Part 53 QA requirement language, in some instances, significantly deviates from the Part 50 Appendix B QA requirement language. This is likely to cause unintended consequences in a number of ways. First, this may require existing Appendix B QA suppliers to create another new QA program to meet Part 53 QA requirements. Second, prescribing QA requirements for NSRSS SSCs deviates from the approach for existing reactors, which have flexibility to establish QA programs based upon the safety significance, and prescribes the level of QA even if it is more than is necessary for less safety significant SSCs. This all results in reduced clarity, predictability and flexibility in the regulations, while increasing regulatory burden without an increase in safety.	*Applicants, licensees, permit holders and design approval holders must meet the QA requirements in 10 CFR Part 50 Appendix B for all safety-related functions of SSCs."* Alternatively, include a comprehensive set of more performance-based QA requirements that are compatible with Part 50 Appendix B, only applicable to safety-related SSCs, and allow flexibility to use international standards (e.g., ISO-9001) to comply with the requirements. If this approach is taken, the NRC should consider also making these more performance-based QA requirements available to Parts 50 and 52 to an optional alternative to Appendix B.

Attachment B
Detailed Comments on NRC's Comprehensive Preliminary Part 53 Rule Language

Detailed Comments on Subpart C – Design and Analysis Requirements

Comments are based on NRC's released version on August 10, 2021 (ML21202A162).

Comment Number	NRC Preliminary Requirement	Industry Comment	Proposed Resolution
C-1	53.400 Design Features	It is important to define the purpose for, and relationship between, the types of technical features (design features, human actions and programs) that are needed for nuclear facilities. While 53.400 states that design features, human actions and programs work together in performing the safety functions to meet the safety criteria, there is still a lack of clarity on the relationship between these elements in the Part 53 safety framework. The NRC appears to have reversed the hierarchy of the "design features" and the "principal [functional] design criteria", as determined through the definitions of these terms. The design features flow from the PDC, since the design features apply only to SSCs, and PDC could be accomplished through human actions or programs.	Revise to improve clarity as follows: *"The combination of design features, human actions and programs necessary and sufficient to perform the safety functions in 53.230 during the relevant licensing basis events in 53.240 must be provided for each commercial nuclear plant such that~~, when combined with associated programmatic controls and human actions,~~ the plant will satisfy the safety criteria defined in §§ 53.210 and 53.220. ~~Design features must ensure that the safety functions identified in § 53.230, of limiting the release of radioactive materials from the facility, are fulfilled during licensing basis events~~."* Change the requirement title to align with the hierarchical flow of "design features" and the "principal [functional] design criteria": "53.410~~400~~ Design Features"
C-2	53.410 Functional Design Criteria for Design Basis Accidents;	The NRC is establishing a requirement that all SSCs relied upon to meet the functional design criteria must establish programmatic controls. However, a requirement here for programmatic controls would duplicate the programs required in other parts of Part 53, and thus is not necessary. Duplication of requirements reduces regulatory	Revise the requirement as follows: *"~~Functional~~ Principal design criteria must be defined for each design feature required by § 53.400 relied upon to demonstrate compliance with the safety criteria defined in § 53.210,*

	53.420 Functional Design Criteria for Licensing Basis Events other than Design Basis Accidents; 53.425 Design Features and Functional Design Criteria for Normal Operations	clarity and predictability, and increases regulatory burden, in terms of demonstrating compliance, without an increase in safety. It is noted that the Part 53 "functional design criteria" serve the same underlying purpose as "principal design criteria" in Parts 50 and 52. The NRC establishes three requirements related to functional design requirements (53.410, 53.420 and 53.425). The language in each of these is nearly identical, and thus the repetition and duplication reduces regulatory clarity and predictability, and increases regulatory burden without an increase in safety. The NRC appears to have reversed the hierarchy of the "design features" and the "principal [functional] design criteria", as determined through the definitions of these terms. The design features flow from the PDC, since the design features apply only to SSCs, and PDC could be accomplished through human actions or programs. It is important to note that while normal operations should be considered in establishing PDC, it does not need to be considered in developing design features, since normal operations is not included in the LBEs established in 53.240 and is not related to meeting the safety criteria in 53.210 or 53.220.	*53.220, and 53.260*. *Principal design criteria are the necessary and sufficient design, fabrication, construction, testing and performance requirements for SR and NSRSS SSCs that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public.* *~~Corresponding programmatic controls and interfaces must be established in accordance with this and other subparts to achieve and maintain the reliability and capability of SSCs relied upon to meet the established functional design criteria and the safety criteria required in § 53.210 and to maintain consistency with analyses required by § 53.450~~.*" Change the name of the requirement, to align with the hierarchical flow of "design features" and the "principal [functional] design criteria, as follows: "53.400~~410~~ ~~Functional~~ Principal Design Criteria ~~for Design Basis Accidents~~" Delete 53.420 and 53.425, as the requirements were incorporated into the proposed revision.
C-3	53.430 Design Features and Functional Design Criteria for	53.430 increases regulatory burden relative to that which exists for existing reactors. Part 20 is a performance-based approach to protecting occupational workers and does not require the establishment of design features or principal design criteria for protection of plant workers.	Delete 53.430, as this would be a significant increase in regulatory burden, as compared to the regulation of existing reactors.

	Protection of Plant Workers	This is an increased burden compared to Part 50/52 as it will require a significantly greater level of detail in the application, which is not needed to make a safety determination, and which will be subject to formal NRC review, approval and oversight. Protection of plant workers is more efficiently achieved in Part 20 which only regulates the operational program for radiation protection, rather than establishing a design approach equivalent to what is needed for design basis accidents.	
C-4	53.440 Design Requirements.	The requirement (b), to qualify SSCs for their service conditions over the plant lifetime, negates the need for an Integrity Assessment Program in 53.850. The requirement (c), to evaluate possible degradation mechanisms over the plant lifetime can be reassigned to provide further clarification for the need to qualify materials in (b). The requirement (d), to consider safety/security interface, duplicates 73.58, which is significantly more detailed than the requirement here. Duplication of requirements reduces clarity and predictability and increases regulatory burden without an increase in safety. The design requirements for fire protection are prescriptive, rather than performance-based, in that they mandate specific features of the design to address fire protection. However, fire hazards are already considered in the LBEs in 53.240, and thus the design would already need to have considered these in (a) of this requirement. The requirement for considering fuel and waste appears to be in the wrong place in Part 53. These relate to understanding all of the sources of radionuclides that	Revise the requirement as follows: *"(b) The materials used for safety related and non-safety related but safety significant SSCs must be qualified for their service conditions over the plant lifetime. Qualification must consider ~~(c)~~ possible degradation mechanisms related to service time ~~aging~~, fatigue, chemical interactions, operating temperatures, effects of irradiation, and other environmental factors that may affect their performance ~~of safety related and non-safety related but safety significant SSCs must be evaluated and used to inform the design and the development of integrity assessment programs under § 53.850~~.* *(d) Consider safety and security interfaces according to 73.58* ~~must be considered together in the design process such that, where possible, security issues are effectively resolved through design and engineered security features~~."

		could be released to the environment, and is a first order consideration in the safety paradigm, not a downstream consideration during the design requirements stage.	Delete 53.440(f) related to design features related to fire protection. Relocate the 53.440(i) requirement related to fuel and radionuclides outside the reactor to 53.205 (proposed in comment B-2) as this is a first order consideration in the safety of the plant.
C-5	53.450 Analysis Requirements.	53.450 prescribes a very specific use of the PRA that would only permit licensing approaches that utilize PRA in what the NRC has called a "leading" role. Unfortunately, these prescriptive requirements would allow only one of the four risk-informed approaches described in the NEI September 2021 white paper "*Technology-inclusive, Risk-informed, Performance-based Approaches for Development of Licensing Bases Under Part 53.*" This is problematic because the only allowed approach has never been used before to license a nuclear reactor, and approaches that have licensing precedent are excluded. A prescriptive approach to the PRA requirement is not necessary, since all of the risk-informed approaches in the NEI paper would be able to meet the other Part 53 requirements. Thus, the prescription of details for the PRA in rule language would increase the amount of PRA that must be used for <u>all</u> advanced reactors. Such detail is typically found in guidance rather than rule language, and in fact the requirements for PRA in 53.450 are far more detailed that equivalent requirements in Parts 50 and 52, which are consistent with the NRC's PRA Policy Statement.	Revise the PRA requirement as follows: *"(a) Requirement to have a probabilistic risk assessment. A probabilistic risk assessment (PRA) of each commercial nuclear plant ~~[reminder – plant definition to include multi-module and multi-source]~~ must be performed to <u>incorporate risk insights into the design, as appropriate.</u> ~~identify potential failures, susceptibility to internal and external hazards, and other contributing factors to event sequences that might challenge the safety functions identified in § 53.230 and to support demonstrating that each commercial nuclear plant meets the safety criteria of § 53.220~~.* *(b) <u>Completeness of the PRA. The completeness and quality of the PRA should be commensurate with the completeness of the design, where a complete PRA is not expected to be performed until the nuclear plant has completed construction and is authorized to load fuel.</u> ~~Specific uses of analyses. The PRA, other generally accepted risk-informed approaches for systematically evaluating~~*

		Unnecessary detail in the requirements for the PRA reduces flexibility, without any increase in clarity or predictability. The details in the PRA requirements also increases regulatory burden, since it will likely increase the amount of information from the PRA that must be included in the licensing basis, with no increase in safety. The requirements for fire protection and aircraft impacts should be conditioned on the applicability of these types of events to the nuclear facility. Some designs, such as microreactors, should not need to consider aircraft impacts because the consequences do not pose an undue risk to the public. Similarly, for some plants a fire hazard may not pose an undue risk to the public. The requirement to mitigate BDBEs does not belong in the requirement for analyses, and it duplicates the requirements to address BDBEs through QHOs in 53.220. The BDBE mitigation requirement references 50.155, which is LWR-specific and not technology-inclusive. The requirement 53.460(c) related to confidence that human actions will be performed as assumed in the analysis are out of place there and would be more appropriate here in 53.450. Flexibility for bounding analyses, including in Part 5X should also be included here.	*~~engineered systems, or combination thereof must be used:~~* *~~(1) In determining the licensing basis events, as described in § 53.240, which must be considered in the design to determine compliance with the safety criteria in Subpart B of this part.~~* *~~(2) For classifying SSCs and human actions according to their safety significance in accordance with § 53.460 and for identifying the environmental conditions under which the SSCs and operating staff must perform their safety functions.~~* *~~(3) In evaluating the adequacy of defense-in-depth measures required in accordance with § 53.250.~~* *~~(4) To identify and assess all plant operating states where there is the potential for the uncontrolled release of radioactive material to the environment.~~* *~~(5) To identify and assess events that challenge plant control and safety systems whose failure could lead to the uncontrolled release of radioactive material to the environment. These include internal events, such as human errors and equipment failures, and external events, such as earthquakes, identified in accordance with Subpart D of this part.~~* *(c)-Maintenance and upgrade of analyses. The PRA, another generally accepted risk-informed approach for systematically evaluating engineered systems, or a combination thereof must be maintained and upgraded in*

			conformance with generally accepted methods, standards, and practices. The PRA must be upgraded every four years until the permanent cessation of operations under § (a) 53.## of this chapter." *(d) Qualification of analytical codes. The analytical codes used in modeling plant behavior in analyses of licensing basis events (e.g., thermodynamics, reactor physics, fuel performance, mechanistic source term) must be qualified for the range of conditions for which they are to be used.* *(e) Analyses of licensing basis events other than DBAs. Analyses must be performed for licensing basis events including anticipated operational occurrences, and BDBEs ~~unlikely event sequences, and very unlikely event sequences with estimated frequencies well below the frequency of events expected to occur in the life of the commercial nuclear plant. The licensing basis events must be identified using insights from a PRA, other generally accepted risk-informed approaches for systematically evaluating engineered systems, or combination thereof to identify and analyze equipment failures and human errors. The analyses must address event sequences from initiation to a defined end state and demonstrate that the functional design criteria required by § 53.420 provide sufficient barriers to the unplanned release of radionuclides to satisfy evaluation criteria defined for licensing basis events, to satisfy the safety criteria of § 53.220, and~~*

			~~provide defense in depth as required by § 53.250.~~ The methodology used to identify, categorize, and analyze licensing basis events must include a means to identify event sequences deemed significant for controlling the risks posed to public health and safety. <u>The analysis of LBEs other than DBAs must address event sequences from initiation to a safe stable end state and may credit SR and NSRSS SSCs and all reasonable human actions that are available to meet the safety criteria of 53.220. The analysis may demonstrate compliance with the safety criteria using realistic models and assumptions.</u> Applicants may elect to perform a single or multiple bounding analyses and evaluations to demonstrate the design appropriately mitigates the consequences of accidents; in taking this approach, applicants must demonstrate that the bounding evaluation(s) adequately envelope conditions for the full range of LBEs. *(f) Analysis of design basis accidents. The analysis of DBAs ~~licensing basis events required by § 53.240 and § 53.450(e) must include analysis of design basis accidents that address possible challenges to the safety functions identified in accordance with § 53.230. Design basis accidents must be selected from those unlikely event sequences with within a frequency range of at least less than one hundred years and greater than one in 10,000 years as identified using insights from a PRA, other generally accepted risk-informed~~*

			~~approaches for systematically evaluating engineered systems, or combination thereof to identify and analyze events considering equipment failures, human errors, and uncertainties. The events selected as design basis accidents should be those that, if not terminated, have the potential for exceeding the safety criteria in § 53.210. The design-basis accidents selected~~ must be performed using ~~deterministic~~ methods that address event sequences from initiation to a safe stable end state and assume only the safety-related SSCs identified in § 53.460 and human actions addressed by § 53.8xx (reference to concept of operations sections of Subpart F) are available to perform the safety functions identified in accordance with § 53.230. The analysis must conservatively demonstrate compliance with the safety criteria in § 53.210. *(g) Other required analyses. ~~If not addressed within the PRA, other generally accepted risk-informed approach for systematically evaluating engineered systems, or combination thereof under paragraph (b),~~ Analyses must be performed to assess <u>the following hazards, if applicable to the facility</u>:* *(1) fire protection measures to demonstrate reasonable assurance that no fire or explosion in any plant area can:* *(i) prevent equipment from performing its safety function to meet § 53.230, or* *(ii) challenge the safety criteria in §§ 53.210 and 53.220.*

			(2) measures provided to protect against aircraft impacts as required by 10 CFR 50.150, and ~~*(3) measures to mitigate specific beyond design basis events as required by 10 CFR 50.155.*~~ *(f) Human actions needed to prevent or mitigate licensing basis events must be capable of being reliably performed under the postulated environmental conditions present and be addressed by programs established in accordance with Subpart F of this part to provide confidence that those actions will be performed as assumed in the analysis performed in accordance with § 53.450 to provide reasonable assurance of meeting the safety criteria in §§ 53.210 and 53.220."*
C-6	53.460 Safety Categorization and Special Treatment.	While the NRC does not need to prescribe the specific safety categories that all nuclear facilities must use, the set of safety categories established in this requirement is reasonably flexible. However, modifications are needed to some of the details related to human actions and special treatment, which should not be required in the manner that 53.460 establishes. The issue with creating safety-related and safety-significant human actions is that they do not share the same nature as SSCs, and thus the requirements that apply to safety-related SSCs (e.g., design criteria) likely are not applicable to humans, and requirements applicable to humans (e.g., training programs) are not applicable to SSCs. Thus, while an SSC or a human action, or combination of both, could be used to perform a safety	Revise the requirement as follows: *"(a) SSCs ~~and human actions~~ must be classified according to their safety significance. The categories must include "Safety Related" (SR), "~~Non-Safety Related but~~ Safety Significant" (~~NSR~~SS), and "Non-Safety Significant" (NSS), as defined in subpart A of this part.* *(b) For SR and ~~NSR~~SS SSCs ~~and human actions~~, the conditions under which they must perform their safety function in § 53.230 must be identified. ~~Special Treatment (e.g., functional design criteria and programmatic controls) must be established in accordance with this and other Subparts to provide appropriate confidence that the SSCs will perform under the~~*

		function, the requirements should not treat an SSC and a human action the same manner. Furthermore, the requirement (c) related to the confidence that human actions will be performed as assumed in the analysis are out of place and would be more appropriately included in 53.450. The language appears to be trying to add clarity by applying *"special treatment"* to safety-related and NSRSS SSCs. However, the NRC does not define the differences in the special treatments between these types of SSCs. Thus, it is possible, or even likely, that NSRSS SSCs will receive an equivalent regulatory burden as SR SSCs. The application of the term "special treatment" to SR and NSRSS SSCs reduces regulatory predictability and is not necessary. While the NRC appears to be applying the term "special treatment" to describe how Part 53 requirements apply to SR and NSRSS SSCs, such an approach was not necessary in Parts 50 and 52. The NRC's Part 53 definition of "special treatment" effectively says that it is "requirements that apply to certain SSCs." Thus, the definition provides no clarity or regulatory stability. The approach in Parts 50 and 52 is to state within specific requirements whether they apply to safety-related or risk-significant SSCs. The same can be done in Part 53, where the requirements specify to which category of SSCs they apply, and in fact most Part 53 requirements already do this. Thus, the use of the term "special treatment" creates confusion and provides no regulatory benefit.	*~~service conditions and with the reliability assumed in the analysis performed in accordance with § 53.450 to provide reasonable assurance of meeting the safety criteria in §§ 53.210 and~~* *~~53.220.~~* *~~(c) Human actions to prevent or mitigate licensing basis events must be capable of being reliably performed under the postulated environmental conditions present and be addressed by programs established in accordance with Subpart F of this part to provide confidence that those actions will be performed as assumed in the analysis performed in accordance with § 53.450 to provide reasonable assurance of meeting the safety criteria in §§ 53.210 and 53.220.~~*"
C-7	53.470 Application of	This requirement is confusing in that it is not clear what the alternative criteria are supposed to be. Nor is it clear	Delete 53.470.

	Analytical Safety Margins to Operational Flexibilities.	what benefit in operational flexibility would result from using the alternative criteria. The requirement is also essentially unused throughout the rest of Part 53. There is only one instance of use in the ability for relaxed change control criteria in 53.1322, which has little operational benefit. The requirement appears to limit the flexibility to use more streamlined requirements for advanced reactors, such as the alternative requirements for SMR EP and Security that are being developed separately from the Part 53 rulemaking. That should not be the case since additional requirements for more restrictive criteria are not imposed on designs licensed to the same alternative requirements through Parts 50 and 52, and the alternative requirements themselves will determine what criteria must be met to utilize them. Thus, the creation of this confusing and unnecessary requirement in 53.470 reduces regulatory clarity and predictability because applicants do not know what purpose it serves or operational benefits it offers. It also could be used inappropriately to force more strict criteria on designs to achieve the same operational flexibility that is provided in Parts 50 and 52 without an equivalent requirement in those parts.	
C-8	53.480 Design Control Quality Assurance.	The NRC preliminary rule language splits up QA requirements and scatters them in different subparts of the rule. In doing so, there is a lot of duplication of the QA requirements, and in several cases, there are differences in language for the exact same QA criterion.	Delete 53.480 and all other requirements on QA so that all QA requirements can be established together, in Subpart B, in a manner compatible with Part 50 Appendix B as follows: *"53.280 Quality Assurance.*

		The NRC has inserted multiple QA requirements related to design control, as found in 53.480, 53.490 and 53.740. The Part 53 QA requirement language, in some instances, significantly deviates from the Part 50 Appendix B QA requirement language. This is likely to cause unintended consequences in a number of ways. First, this may require existing Appendix B QA suppliers to create another new QA program to meet Part 53 QA requirements. Second, prescribing QA requirements for NSRSS SSCs deviates from the approach for existing reactors, which have flexibility to establish QA programs based upon the safety significance and prescribes the level of QA even if it is more than is necessary for less safety significant SSCs. This all results in reduced clarity, predictability and flexibility in the regulations, while increasing regulatory burden without an increase in safety.	*Applicants, licensees, permit holders and design approval holders must meet the QA requirements in 10 CFR Part 50 Appendix B for all safety-related SSCs."* Alternatively, include a comprehensive set of more performance-based QA requirements that are compatible with Part 50 Appendix B, only applicable to safety-related SSCs, and allows flexibility to use international standards (e.g., ISO-9001) to comply with the requirements.
C-9	53.490 Design and Analyses Interfaces.	The NRC has multiple QA requirements related to design control, as they are found in 53.480, 53.490 and 53.740. 53.490 would expand the NRC's regulatory footprint to cover activities and documents, such as procedures and calculations, resulting in much more information being included on the DOCKET. This is contrary to NRC statements that recent applications provided more information than is necessary to make a safety decision, and has led to less efficient reviews. This further contradicts the NRC efforts in ARCAP and other areas to right-sized level of detail in applications. Additionally, the specific language in 53.490 is unclear about under what conditions assessments would be	Remove 53.490 as it is not necessary to require that such information, be included in the licensing basis for Part 53 applications. Such information is not currently needed in the licensing basis for reactors licensed under Parts 50 and 52.

		required and why. The NRC also has not stated the benefit, nor justified the need for more details to be under their regulatory control. The over-broad reach of 53.490, particularly linking it to 53.800 makes it a significant burden increase. Thus, this requirement will reduce regulatory clarity and predictability, while increasing regulatory burden, in terms of demonstrating compliance, without an increase in safety.	

Attachment B
Detailed Comments on NRC's Comprehensive Preliminary Part 53 Rule Language

Detailed Comments on Subpart D – Siting Requirements

Comments are based on NRC's released version on January 21, 2021 (ML21012A278).

Comment Number	NRC Preliminary Requirement	Industry Comment	Proposed Resolution
D-1	Subpart E	While we are willing to support the NRC approach to include siting requirements in Part 53, rather than continue to point to Part 100, the NRC preliminary rule language is identical to the current requirements. Thus, the NRC does little more than relocate the siting requirements from one part to another and does not endeavor to establish a more modern technology-inclusive, risk-informed and performance-based approach to siting that is more appropriate for Part 53. By doing so, the NRC is injecting further ambiguity in its regulations by having the same requirement in two separate locations. If the NRC is to integrate these standards in Part 53, they should be tailored to reflect the reduced risk of the advanced reactor designs. Otherwise, if no changes to Part 100 are anticipated, then a cross reference would appear to be sufficient. We believe an incremental approach to Part 53 is a missed opportunity to achieve transformational changes that result in a more efficient regulatory framework to protect the public health and safety. Part 53 should completely reevaluate the approach to siting by recognizing that it is largely the same as it was originally conceived in 1960s/1970s, and that	The NRC should pursue a more modern technology-inclusive, risk-informed and performance-based approach to siting. Such approach should consider how safety, security, EP and siting could be better integrated to establish a more efficient Part 53 framework. Specifically, the NRC should consider the NEI proposed approach to modernize siting requirements, submitted in the February 11, 2021 comments, which would require (NEI §53.4(b)) that the characteristics of the site that have a significant impact on the ability of the facility to meet the public protection criteria in NEI §53.2 and NEI §53.3 and the location of the site boundary (NEI §53.4(b)) be part of the facility characteristics. It would also require the establishment of design features and human actions (NEI §53.4(e)) to protect against manmade hazards related to the site (NEI §53.4(d)(3)) such that the public protection criteria are met. The NEI proposal would achieve a more efficient, less burdensome regulatory framework, that is enabled by better

		Part 53 is being built upon more a more modern and flexible regulatory framework. A more modern technology-inclusive, risk-informed and performance-based approach to siting was proposed by NEI in the comment letter submitted February 11, 2021 that better aligns with the Part 53 framework. The essence of that proposal was to integrate siting with safety, security and EP to achieve a more holistic and efficient regulatory framework.	integrating safety, security, EP and siting, resulting in an effectively higher level of safety than is currently achieved in Parts 50 and 52. This is accomplished by establishing the site boundary, in lieu of the low population zone and exclusion area boundary as the key boundary, in alignment with the on-going SMR Emergency Preparedness rulemaking, streamlining the licensing basis of the facility. This would avoid the need to establish a requirement for distance from a population center, since it is not necessary, nor does it include specific requirements for the seismic and geologic criteria, since it is not needed for a technology-inclusive, performance-based and risk-informed approach.
D-2	53.500 General Siting	It is unclear what the NRC is attempting to accomplish with this requirement, since the requirement essentially duplicates all of the requirements in Subpart D at a high level. If the NRC's intent is to establish the purpose of Subpart D, then the requirement should be written to state that this is a purpose statement, which clarifies the collective nature of Subpart D requirements and the outcome achieved by meeting the collective requirements, and that this is not a requirement that an applicant and licensee must explicitly meet. Establishing a high-level requirement that duplicates all the other requirements in Subpart D, without	Revise the requirement as follows: *"The purpose of Subpart D is to ensure that appropriate considerations ~~must be~~ are given to the siting of each advanced nuclear plant ~~such that, when combined with associated design features and programmatic controls, the plant will satisfy the first and second tier safety criteria defined in §§ 53.220 and 53.230. A~~ This is accomplished by meeting the set of requirements in Subpart D that ensure the siting assessment for each advanced nuclear plants ~~must be performed and must~~*

		stating that this requirement does not need to be met, but is met implicitly by meeting the other requirements in Subpart D reduces regulatory clarity and predictability, and increases regulatory burden without an increase in safety.	*ensures that 1) external hazards and site characteristics that might contribute to the initiation, progression, or consequences of licensing basis events analyzed in accordance with § 53.240 are identified and addressed by design features, human actions ~~or~~ programs or a combination thereof ~~matic controls~~; and 2) ~~. The siting assessments must address~~ the potential adverse impacts that an advanced nuclear plant may have on nearby environs as a result of normal operations or radiological accidents as required by Part 51, "Environmental protection regulations for domestic licensing and related regulatory functions," of this chapter are addressed."*
D-3	53.510 External Hazards 53.520 Site Characteristics 53.530 Population-related considerations 53.540 Siting interfaces 53.550 Environmental Considerations	Per comment D-1, these requirements should be completely reconsidered and established in a more modern technology-inclusive, risk-informed and performance-based approach to siting. Such approach should consider how safety, security, EP and siting could be better integrated to establish a more efficient Part 53 framework.	See proposed resolution to comment D-1. Additional specific comments are not provided as Subpart D should be considered a work in progress.

Attachment B
Detailed Comments on NRC's Comprehensive Preliminary Part 53 Rule Language

Detailed Comments on Subpart E – Construction and Manufacturing

Comments are based on NRC's released version on February 11, 2021 (ML21042B855).

Comment Number	NRC Preliminary Requirement	Industry Comment	Proposed Resolution
E-1	Subpart E	The requirements in Subpart E are confusing, since it combines together a variety of concepts without clear distinctions between the general construction requirements that are applicable to all types of license holders (CP, COL, ML and LWA), and those niche requirements that are only applicable to a certain type of license holder (e.g., ML). Most of the requirements in Subpart E are unnecessary as they are not needed to validate that the as-built design features of the facility conforms to the license and regulations. The requirements are also overly prescriptive in the process that must be used, rather than creating a performance-based framework that focuses on the desired outcome. In fact, many of the required management and control features either duplicate QA program controls, or are related to managing business risk (e.g., on-schedule construction or avoiding re-work, OSHA worker safety). The focus of the NRC requirements should be only those items that are necessary and sufficient to ensure the as-built design features of the facility (outcome of the construction activity) conforms to the license and regulations. Several of the management and control requirements duplicate other requirements. For example, the requirement for design and analyses is accomplished through requirements in Subpart C, which must be met in	The NRC should recognize that achieving sufficient confidence that the as-built design features of the facility are in conformance with the license and regulations is primarily achieved by the QA program and startup testing. Thus, the NRC should delete most of the requirements in this section as they are not necessary. For those requirements that are retained, the NRC should establish conditions under which they apply. Most requirements for management and control either duplicate other requirements, or are only necessary to manage business risk. The following requirements appear to be appropriate for NRC regulation of construction activities: • (6) Fitness for duty program • (8) Radiation protection program (not needed until fuel or radioactive sources will be brought on site) • (9) Information Security • (10) Cyber Security • (11) Posting of Requirements

		order to receive authorization from the NRC to begin construction. Other requirements are not applicable during the entire course of construction, but are only applicable when certain construction activities begin, some of which are not enabled until either the NRC approves the OL (for construction under a CP) or the ITAAC are closed and NRC authorizes fuel loading (for construction under a COL). The NRC preliminary rule language splits up QA requirements and scatters them in different subparts of the rule. In doing so, there is a significant amount of duplication of the QA requirements, and in several cases, there are differences in language of the exact same QA criterion. As there is no central location for these QA requirements, the opportunities for redundancy or inconsistency between requirements escalates dramatically. The Part 53 QA requirement language, in some instances, significantly deviates from the Part 50 Appendix B QA requirement language. This is likely to cause unintended consequences in a number of ways. First, this may require existing Appendix B QA suppliers to create another new QA program to meet Part 53 QA requirements. Second, prescribing QA requirements for NSRSS SSCs deviates from the approach for existing reactors, which have flexibility to establish QA programs based upon the safety significance, and prescribes the level of QA even if it is more than is necessary for less safety significant SSCs. This all results in reduced clarity, predictability and flexibility in the regulations, while increasing regulatory burden without an increase in safety.	• Control of SNM and sources (should only reference applicable requirements, e.g., Parts 30, 40) • Physical security (only needed when SNM is brought on site) • Fire protection (only needed when SNM is brought on site) • Protection of operating reactors on site (only needed when construction site is located near operating reactors) Delete 53.610(a)(7) QA requirements and all other requirements on QA so that all QA requirements can be established together, in Subpart B, in a manner compatible with Part 50 Appendix B as follows: *"53.280 Quality Assurance.* *Applicants, licensees, permit holders and design approval holders must meet the QA requirements in 10 CFR Part 50 Appendix B for all safety-related SSCs."* Alternatively, include a comprehensive set of more performance-based QA requirements that are compatible with Part 50 Appendix B, only applicable to safety-related SSCs, and allows flexibility to use international standards (e.g., ISO-9001) to comply with the requirements.

		It is noted that the NRC is continuing to work on a framework for addressing transportable reactors that may have fuel loaded at the factory, and transported with loaded fuel.	The requirements that remain in Subpart E should be organized to clearly distinguish those that are generally applicable to all types of license holders (CP, COL, ML and LWA), and those that are only applicable to a certain type of license holder (e.g., ML). For each requirement, the type of license holder for which the requirement is applicable should be stated. No additional specific comments are provided on requirements related to transportable reactors built in a factory. Prior input was provided in NEI's July 2021 paper on Manufacturing Licenses, and the NRC has not provided an update in this area.
E-2	53.600 Construction and Manufacturing Scope and Purpose	It is unclear what the NRC is attempting to accomplish with this requirement, since the language essentially duplicates all of the requirements in Subpart E at a high level. If the NRC's intent is to establish the purpose of Subpart E, then the requirement should be written to state that this is a purpose statement, which clarifies the collective nature of Subpart E requirements and the outcome achieved by meeting the collective requirements, and that this is not a requirement that an applicant and licensee must explicitly meet. Establishing a high-level requirement that duplicates all the other requirements in Subpart E, without stating that these requirements do not need to be met, but are met implicitly by meeting the other requirements in Subpart E	Revise the requirement as follows: *"The purpose of Subpart E is to ensure that the constructed and manufactured (i.e., as-built) design features of the nuclear facility ~~is~~ conform to the license and regulations. This is accomplished by meeting the set of requirements in Subpart E. This subpart applies to those construction and manufacturing activities authorized by a Construction Permit (CP), Combined License (COL), Manufacturing License (ML) or a Limited Work Authorization (LWA) under subpart H of this regulation. ~~The term construction, as defined in § 53.xyz, refers~~*

		reduces regulatory clarity and predictability, and increases regulatory burden without an increase in safety. The statement that connects construction and manufacturing activities to design features and programmatic controls in a way of satisfying safety criteria is not accurate. As established in Subpart B, the safety of the plant is fully and solely accomplished by the combination of design features, human actions and programs. The role of the manufacturing and construction activities is to ensure the as-built facility conforms to the license and requirements for the design features. Since there is no radiological hazard until after the facility is constructed and manufactured, these activities do not directly satisfy safety criteria, but rather it is the design features of the as-built plant that satisfy safety criteria (in combination with human actions and programs). Thus, the acceptance standards for construction and manufacturing are not those activities that satisfy the safety criteria (they inherently do because there is no radiological hazard during construction and manufacturing), but rather that the activities result in an as-built facility that conforms to the license and regulations for safety-related and safety-significant design features and SSCs. It is noted that Subpart A includes specific definitions for construction and manufacturing, thus, these definitions do not need to be duplicated again in this requirement.	~~*to those activities contributing to meeting the first and second tier safety criteria defined in §§ 53.210 and 53.220, respectively, that are conducted on-site to build the nuclear facility in support of subsequent operations. [Note - Definition of construction to exclude items currently excluded by 50.10(a)(2)]. The term manufacturing, as defined in § 53.xyz, refers to those activities conducted at one or more facilities under a ML for transport to a licensed location for installation and operation.*~~ ~~*These requirements are intended to provide assurance that construction and manufacturing activities are managed and conducted such that when combined with associated design features and programmatic controls, the plant will satisfy the first and second tier safety criteria required in §§ 53.210 and 53.220 throughout the plant's lifecycle."*~~

Attachment B
Detailed Comments on NRC's Comprehensive Preliminary Part 53 Rule Language

Detailed Comments on Subpart F – Requirements for Operations

Comments are based on NRC's released versions on April 26, 2021 (ML21106A001 and ML21106A002), and October 18, 2021 (ML21267A006). Note that comments relating to staffing, training, personnel qualifications and human factors are initial comments, and that there may be additional comments on human-related requirements identified later after performing a more thorough review. These comments did not include a review of 53.760 through 53.781.

Comment Number	NRC Preliminary Requirement	Industry Comment	Proposed Resolution
F-1	53.700 – Operational Objectives	It is unclear what the NRC is attempting to accomplish with this requirement, since the requirement essentially duplicates all of the requirements in Subpart F at a high level. If the NRC's intent is to establish the purpose of Subpart F, then the requirement should be written to state that this is a purpose statement, which clarifies the collective nature of Subpart F requirements and the outcome achieved by meeting the collective requirements, and that this is not a requirement that an applicant and licensee must explicitly meet. Establishing a high-level requirement that duplicates all the other requirements in Subpart F, without stating that this requirement does not need to be met but is met implicitly by meeting the other requirements in Subpart F reduces regulatory clarity and predictability, and increases regulatory burden without an increase in safety.	Revise the requirement as follows: *"The purpose of Subpart F is to ensure that each licensee ~~shall~~ defines, implements, and maintains controls for plant SSCs, responsibilities of plant personnel, and plant programs during the operating life of each advanced nuclear plant such that the ~~first and second tier~~ safety criteria defined in §§ 53.210 and 53.220 are satisfied. This is accomplished by meeting the set of requirements in Subpart F that ensure each licensee ~~shall~~ maintains the ~~capabilities and reliabilities of~~ facility structures, systems, and components; ~~to ensure that the safety functions identified in § 53.230 will be performed if called upon during normal operations and licensing basis events. Each licensee shall ensure~~ that plant personnel have adequate knowledge and skills to perform their assigned duties; and ~~that support the performance of the safety functions identified in § 53.230. Each licensee shall~~ that the*

			implementation of plant programs during operations are in accordance with the license and the regulations ~~sufficient to ensure that the safety functions identified in § 53.230 will be performed if called upon during normal operations and licensing basis events~~."
F-2	53.710 Transition from construction/manufacturing to operation	This requirement is not necessary. For a licensee that constructed the plant under a Construction Permit, the items addressed in this requirement are confirmed by the NRC as part of the approval of the Operating License. For a licensee that constructed the plant under a Combined Operating License, the items addressed in this requirement are confirmed by the NRC as part of the completion of ITAAC and NRC approval to load fuel.	Remove this requirement as it duplicates other requirements.
F-3	53.720 Maintaining capabilities and availability of structures, systems, and components.	This requirement establishes an equivalent to Technical Specifications for NSRSS SSCs. It is noted that all of the risk-informed approaches in the NEI September 2021 white paper "*Technology-inclusive, Risk-informed, Performance-based Approaches for Development of Licensing Bases Under Part 53*" could meet this requirement, without the need for prescriptive detail in the requirement for PRA 53.450.	No change proposed, although edits are needed to conform to changes in terms that occurred elsewhere, and references to other requirements that may have changed numbering.
F-4	53.730 Maintenance, repair and inspection programs.	This requirement establishes requirements applicable to SR and NSRSS SSCs. It is noted that all of the risk-informed approaches in the NEI September 2021 white paper "*Technology-inclusive, Risk-informed, Performance-based Approaches for Development of Licensing Bases Under Part 53*" could meet this	No change proposed, although edits are needed to conform to changes in terms that occurred elsewhere, and references to other requirements that may have changed numbering.

		requirement, without the need for prescriptive detail in the requirement for PRA 53.450.	
F-5	53.740 Design control.	The NRC has multiple QA requirements related to design control, as they are found in 53.480, 53.490 and 53.740. This requirement duplicates other requirements. For example, 73.58 deals with safety/security interfaces and addresses many of the subjects described in 73.740. QA requirements address design control, including for design changes. Furthermore, this is a design related requirement, so it should not be in the Subpart for Operations.	Remove 53.740 as it duplicates other requirements, such as QA requirements (see our proposal for 53.280) and 73.58. If there is anything in this requirement that is not already in other requirements, then it should be included in 53.440 for design requirements.
F-6	53.800 Programs.	It is unclear what the NRC is attempting to accomplish with this requirement, since the requirement essentially duplicates all of the requirements in Subpart F 800-series at a high level. If the NRC's intent is to establish the purpose of Subpart F, then the requirement should be written to state that this is a purpose statement, which clarifies the collective nature of Subpart F requirements and the outcome achieved by meeting the collective requirements, and that this is not a requirement that an applicant and licensee must explicitly meet. Establishing a high-level requirement that duplicates all the other requirements in Subpart F 800-series, without stating that this requirement does not need to be met, but is met implicitly by meeting the other requirements in Subpart F reduces regulatory clarity	Revise the requirement as follows: *"<u>The purpose of programs, which are the administrative measures and controls that are relied upon by the NRC, is to provide reasonable assurance that the plant is design, construction, maintenance and operation meet the safety criteria in 53.210 and 53.220 for the lifetime of the plant. This is accomplished by meeting the 800-series set of requirements in Subpart F that ensure that</u> programs ~~must be provided for each advanced nuclear plant such that~~, when combined with associated design features and human actions, ensure the plant will satisfy the ~~first and second tier~~ safety criteria defined in §§ 53.210 and 53.220. ~~Programs must~~*

		and predictability, and increases regulatory burden without an increase in safety. As part of the NRC's efforts to develop a regulatory philosophy for Part 53, it is important to define the purpose for the types of technical features (design features, human actions and programs) that are needed for nuclear facilities. The role of programs, and their interface with design features and human actions, is an area that lacks clarity.	*~~also support continued assurance that the safety functions identified in § 53.230 are maintained during normal operations and licensing basis events. The required plant programs must include but are not necessarily limited to the programs described in the following sections of this Subpart~~."*
F-7	53.810 Radiation Protection.	This requirement duplicates requirements in 10 CFR Part 20, and such duplication should be avoided as it could lead to unintended consequences and increased regulatory burden, without an increase in safety.	Replace the requirement with the following: *"Each licensee under this part must develop and implement a Radiation Protection Program in accordance with 10 CFR Part 20."*
F-8	53.820 Emergency Preparedness	The NRC's approach to allow flexibility for the use of more performance-based EP requirements being developing in the parallel SMR EP rulemaking to establish 50.160, and also allow more traditional Emergency Preparedness requirements in 50.47 and Part 50 Appendix E is appropriate. *Note that the NRC's latest language for this requirement is from June 2021 (ML21145A028).*	No specific comments are provided since the NRC is still working on the requirement. Beyond what the NRC is already considering, the NRC should also consider whether safety, security, EP and siting could be better integrated to establish a more efficient Part 53 framework.
F-9	53.830 Security Program	The NRC's general approach to allow flexibility for the use of more performance-based security requirements, incorporating and expanding upon the parallel SMR Security rulemaking, and also allow more	Comments were previously provided by NEI in July 2021. No additional comments are provided since the NRC is still working

		traditional Security requirements in 73.55 is appropriate. As discussed in previous comments by NEI submitted in July 2021, and which are also supported by prior USNIC comments, the NRC appears to be headed in the direction of establishing alternative Security requirements that are more technology-inclusive, risk-informed and performance-based, and thus more appropriate for Part 53. However, it is noted that much work still remains in order to fully work out the detail of the alternative Security requirements in 73.100, 73.110, and 73.120. *Note that the NRC's latest language for this requirement is from June 2021 (ML21145A043).*	on the requirement and has not released an update on the security requirements. Beyond what the NRC is already considering, the NRC should also consider whether safety, security, EP and siting could be better integrated to establish a more efficient Part 53 framework.
F-10	53.840 Quality Assurance.	The NRC preliminary rule language splits up QA requirements and locates them in different subparts of the rule. In doing so, there is a significant amount of duplication in the QA requirements, and in several cases, there are differences in language of the exact same QA criterion. The Part 53 QA requirement language, in some instances, significantly deviates from the Part 50 Appendix B QA requirement language. This is likely to cause unintended consequences in a number of ways. First, this may require existing Appendix B QA suppliers to create another new QA program to meet Part 53 QA requirements. Second, prescribing QA requirements for NSRSS SSCs deviates from the approach for existing reactors, which have flexibility	Delete 53.840 and all other requirements on QA so that all QA requirements can be established together, in Subpart B, in a manner compatible with Part 50 Appendix B as follows: *"53.280 Quality Assurance. Applicants, licensees, permit holders and design approval holders must meet the QA requirements in 10 CFR Part 50 Appendix B for all safety-related functions of SSCs."* Alternatively, include a comprehensive set of more performance-based QA requirements that are compatible with

		to establish QA programs based upon the safety significance, and prescribes the level of QA even if it is more than is necessary for less safety significant SSCs. This all results in reduced clarity, predictability and flexibility in the regulations, while increasing regulatory burden without an increase in safety.	Part 50 Appendix B, only applicable to safety-related SSCs, and allows flexibility to use international standards (e.g., ISO-9001) to comply with the requirements.
F-11	53.850 Integrity Assessment Programs.	53.850 applies aging management requirements that are similar to those in Part 54 for License Renewal. However, there is no need to establish an aging management program for the initial license period, since requirements in 53.440 ensures that the SSCs will be able to perform their safety functions over the lifetime of the plant. Thus, this requirement both duplicates other requirements and applies requirements that are not applicable until license renewal, increasing regulatory burden without an increase in safety.	Remove this requirement since it duplicates other requirements and applies requirements that are not applicable until license renewal.
F-12	53.860 Fire Protection.	This requirement establishes requirements applicable to SR and NSRSS SSCs. It is noted that all of the risk-informed approaches in the NEI September 2021 white paper "*Technology-inclusive, Risk-informed, Performance-based Approaches for Development of Licensing Bases Under Part 53*" could meet this requirement, without the need for prescriptive detail in the requirement for PRA 53.450.	No change proposed, although edits are needed to conform to changes in terms that occurred elsewhere, and references to other requirements that may have changed numbering.
F-13	53.870 Inservice Inspection/Inservice Testing.	This requirement establishes requirements applicable to SR and NSRSS SSCs. It is noted that all of the risk-informed approaches in the NEI September 2021 white paper "*Technology-inclusive, Risk-informed, Performance-based Approaches for Development of*	No change proposed, although edits are needed to conform to changes in terms that occurred elsewhere, and references to other requirements that may have changed numbering.

		Licensing Bases Under Part 53" could meet this requirement, without the need for prescriptive detail in the requirement for PRA 53.450.	
F-14	53.880 Criticality Safety Program.	The NRC requirement for a criticality safety program appears to be in addition to criticality design requirements. If this is the case, then the NRC is requiring a criticality program in Part 53, where such a program is not required for existing reactors that meet criticality design requirements. The NRC's requirement for criticality, referencing 70.24 is interesting, since most nuclear power plants utilize 50.68, since design controls are more efficient than monitoring to maintain sub-criticality. Requirements related to emergency procedures and radiation protection duplicate other requirements.	Revise the requirement to improve clarity, predictability and efficiency and as follows: "(a) Each licensee under this part must (1) maintain sub-criticality of SNM, except when it is inside the reactor and the reactor is being operated, by design and administrative controls to maintain k-effective below 0.98 at a 95 percent probability 95 percent confidence level at optimum moderation; (2) have a criticality safety program, or ~~.~~ ~~The program must address the requirements in~~ (3) meet the requirements of 10 CFR 70.24 of this chapter for maintaining a monitoring system capable of detecting a criticality, ~~having emergency procedures, and providing radiation protection for plant workers~~. Change the name of the requirement as follows: *"53.880 Criticality accident requirements ~~safety program~~."*

F-15	53.890 Facility Safety Program. 53.892 Facility Safety Program Performance. 53.894 Facility safety program plan. 53.896 Review, Approval, and Retention of Facility Safety Program Plans	It is unclear what problem the NRC is trying to solve with this requirement. The NRC, in a public meeting, explained that the intent of this requirement is for the NRC to more efficiently handle the large number of generic issues given the variety of reactor designs to which the requirements would apply. However, the reduction in NRC oversight through this requirement is questionable at best. Our assessment of this requirement is that it would impose an enormous amount of regulatory burden on licensees. First, it effectively duplicates most other programs required by the NRC. On top of this, it requires a periodic safety review, which is inconsistent with Commission policy and has never been needed for the existing reactors. This would circumvent backfit protections and force unwarranted continuous upgrades to the plant. The NRC has claimed that it would reduce regulatory burden on licensees. Industry asked, around March of 2021 for the NRC to provide details on how this could reduce burden and to provide examples of past generic issues both under the current approach to address them in Part 50 and how they would be addressed by the Facility Safety Program. The NRC has not provided any additional perspective on how this could reduce regulatory burden. Thus, this requirement imposes enormous regulatory burden without any increase in safety.	Remove this requirement, as it imposes enormous regulatory burden without any increase in safety.

		We recognize that more flexible rule language could result in more applications that do not rely on established guidance. However, what we are proposing could also make it easier for the NRC staff to conduct the review of these applications, because a focus on the acceptance criteria makes it easier for the NRC to determine whether the design meets the requirements. This is in contrast to a prescriptive one-size-fits-all requirement, which makes it clear that something must be provided, but leads to subjectivity in the decision on what is good enough. Therefore, performance-based requirements meet the intent of NEIMA, to enable the deployment of these innovative technologies by reducing regulatory burden, not increasing.	
F-16	53.900 Procedures and Guidelines	It is unclear what problem the NRC is trying to solve with this requirement. Existing reactors were all developed, implemented and maintained utilizing an integrated set of procedures, guidelines and related supporting activities to support normal operations and respond to possible unplanned events, all without a specific NRC requirement for a program to do it. This requirement would significantly expand the NRC's regulatory footprint to cover activities and documents, such as procedures and calculations, resulting in much more information being included on the DOCKET and unnecessary cost being imposed on licensees. The operating experience of existing reactors demonstrates that the NRC does not need to require and control a program for this information.	Delete this requirement as it would significantly increase regulatory burden without an increase in safety.

		Further, this is contrary to NRC statements that recent applications provided more information than is necessary to make a safety decision, and has led to less efficient reviews. This further contradicts the NRC efforts in ARCAP and other areas to right-sized level of detail in applications.	
F-17	General – Human Actions	There is a lack of clarity on the purpose of the requirements related to human actions (staffing, training, personnel qualifications and human factors) in 53.750 through 53.781. While the NRC has done a good job establishing the safety paradigm for the design, there is a lack of clarity on how the design fits within the overall safety paradigm, which also includes human actions and programs. The NRC's identification of human actions as safety-related and non-safety-related but safety significant (see comment A-15) creates issues in that it establishes a framework in which human actions and SSCs are treated in the same manner. However, this is not realistic, because they function in very different ways. The plant safety functions are ultimately performed by SSCs, and the human actions are relied upon in the safety case only to the extent that they are needed to ensure the SSCs perform the safety function. For example, for SSCs that perform safety functions through an action, such as opening valves and turning on pumps to prevent overheating. In contrast, SSCs that perform safety functions through passive and inherent operation do not rely on human actions. Another consideration is about which human actions require an NRC license to operate the plant,	The NRC should define the purpose of the design features, human actions and programs, and how these interface with each other. With respect to human actions, the NRC should establish the need for requirements, including the limited scope for requiring operator licenses or certificates (E.g., requirements are only needed for human actions that manipulate reactor controls necessary to prevent a design basis accident).

		which should be limited to actions that manipulate controls that are necessary to prevent a design basis accident.	
F-18	73.750 General staffing, training, personnel qualifications, and human factors requirements	53.750(b) *Definitions.* The discussion text notes that the list of definitions is adapted from 55.4, and that "some (or all) of the definitions in 53.750(b) may be relocated to the definitions section at 53.020." There is some inconsistency between new definitions needed in Part 53 and those carried over from 55.4. It will be important that a comprehensive list of definitions be developed for 53.020 in the next iteration so that stakeholders have adequate opportunity to consider the full set of definitions and their implications. The discussion text (2nd full paragraph) notes the introduction of "certified operator", and that operators will only be referenced as "senior licensed operators", "licensed operators", or "certified operators". Definitions for these terms are provided.	Include a comprehensive list of definitions in 53.020 in the next iteration, and ensure alignment between the definitions adapted from 55.4 and nomenclature of Part 53.
F-19	53.753 – Defining, fulfilling, and maintaining the role of personnel in ensuring safe operations	The introductory text in 53.753 points to human actions "needed to fulfill safety functions, prevent or mitigate licensing basis events, or otherwise meet the safety criteria in 53.210 and 53.220 and, if applicable, any alternative criteria used in accordance with 53.470." As noted in comment A-15, classifying actions as safety-related or NSRSS and then treating SSCs and human actions in these categories is problematic. Also, as noted in comment H-10, these specific	The language in 53.753 should be modified to address human actions as proposed in comment A-15 and to allow the use of other risk-informed and more traditional approaches.

		requirements for 53.210, 53.220, and 53.470 derive from the PRA-based requirements of Subparts B and C. These requirements are based on the PRA-based approach addressed in the Licensing Modernization Project and do not permit use of other risk-informed approaches or more traditional approaches that may be more appropriate for very simple design, especially those designs where a manufacturing license might be sought.	
F-20	53.753(a) *Human factors engineering design requirements.*	53.753(a) is consistent with 50.34(f)(2)(iii) in the requirement that the design "must reflect state-of-the-art human factors principles..." The challenge is that in this area the state-of-the-art may be evolving rapidly so identifying the point in time at which the state-of-the-art is to be referenced makes the requirement ambiguous. Providing a reference, such as the state-of-the-art at the time the application was submitted, could provide reference to a time frame that would provide a degree of certainty for the applicant and the NRC reviewer. The scope of 53.753(a) goes beyond the control room design and includes "facility design […] for safe and reliable performance in all settings that human activities are expected for performing or supporting the continued availability of plant safety or emergency response functions." The "Discussion" note summarizes this is intended to include Emergency Response Facilities. The wording here is very broad and open for interpretation. Part 50 limits the HFE program to the "control room design" but NUREG-	Modify 73.753(a) to include a time reference (E.g., 6 months before the application is submitted) for determining the state-of-the-art to be addressed in the application. Ensure that 53.753(a) is not expanding the scope to areas of the facility design to which HFE is not warranted. Also ensure guidance addresses the variations in HFE needed based on the safety significance of the design features.

		0696, 0711 and 0737 Supplement 1 provide guidance that includes the ERFs.	
F-21	53.753(b) *Human system interface design requirements.*	53.753(b) simply refers to "operators" which is not consistent with the discussion text in 53.750. Presumably, the requirement in 53.753(b) applies to all types of operators, but the clarity noted in 53.750 is absent.	Modify the reference to "operators" to be consistent with the discussion text in 53.750 OR make clear that 53.753(b) refers to all types of operators or a specific subset of operators.
F-22	53.753(b)(3), (4), (5)	53.753(b)(3), (4), and (5) are design requirements and it is not clear why they are provided in Subpart F. Presumably, they should be in Subpart B or C, and should address the requirements in terms of what is needed for SR, NSRSS SSCs. These requirements may need to be modified to address other risk-informed or more traditional analysis methods.	Modify the requirements in 53.753(b)(3), (4), and (5) to put them in a more appropriate location in Part 53, presumably Subpart B or C, and to address requirements for SR and NSRSS SSCs, including any modifications needed to address other risk-informed or more traditional analysis methods.
F-23	53.753(b)(6)	53.753(b)(6) is a design requirement and it is not clear why it is provided in Subpart F. It should be located in either Subpart B or C and should address specific requirements in Subparts B and C so that the monitoring requirements (e.g., measurement sensitivity) are clear, rather than simply including a broad requirement for in-plant radiation and airborne radioactivity monitoring "as appropriate."	Modify the requirement in 53.753(b)(6) to put it in a more appropriate location in Part 53, presumably Subpart B or C, and reference specific requirements in Subparts B and C so that the expectation for monitoring, and for what purpose, is clear.
F-24	53.753(c) 53.753(d)	These items do not appear to be in 50.34, but are included in NUREG-0711. NRC should not include in regulations details that currently reside in guidance. The "Discussion" note for (d) alludes to considering emergency response functions within the scope of this rule. This would be a significant expansion of scope from the equivalent guidance in NUREG-0711.	Delete rule language as necessary to ensure that 53.753(c) and 53.753(d) do not include details currently in, or that goes beyond, guidance in NUREG-0711.

F-25	53.753(e) *Programmatic requirements.*	53.753(e) requires a program for evaluating and applying operating experience, and is adapted from 50.34(f)(3)(i). Part 53 creates a program to accomplish the Part 50 requirement, whereas Part 50 did not require a program to accomplish the purpose. Requiring a program adds administrative burden without a benefit to safety.	Revise the requirement to focus on the purpose and avoid adding unnecessary regulatory burden by: "(e) ~~*Programmatic*~~ *Evaluating Experience requirements*. A description of <u>how</u> the ~~program~~ <u>administrative procedures are provided</u> for evaluating and applying operating experience ~~must be provided~~."
F-26	53.753(g) *Training and examination programs.*	EDITORIAL COMMENT – The text in (g) does not describe a regulatory requirement. Presumably, this is simply an editorial issue and the actual requirement is to provide the description of the proposed programs for the positions described in 53.753(g)(1)(i – iii) and (g)(2)(i-iii).	Consider editorial revisions to 54.753(g) to clarify what is being required.
F-27	53.755 Conditions for operations staffing for operating or combined licenses under this part	53.755(a) stipulates that licensees must meet the requirements of 53.760 through 53.769 OR 53.770 through 53.779. 53.760 through 53.769 provide the requirements for staffing using licensed operators and senior licensed operators while 53.770 through 53.779 provide the requirements for staffing using certified operators. 53.755(b) provides two options by which a licensee may comply with 53.770 through 53.779 in lieu of 53.760 through 53.769 (certified operators versus licensed operators and senior licensed operators). Option A lists five criteria that must be satisfied. The first four each require demonstration that the subject of the criterion be satisfied without "reliance on human actions for event mitigation." The fifth criterion states the "plant response to licensing basis	53.755(b) needs significant further development and refinement of both Options to demonstrate they are viable. Guidance-level detail is needed to determine how and whether Criteria for Options A and B can be met.

		events is not reliant on human actions to guarantee the performance of structures, systems, and components that function through inherent characteristics or have engineered protections against human failures (e.g., system misalignments). Relying on "inherent characteristics" seems an intellectually satisfying concept but the practicality of demonstrating the inherent characteristics is as yet unproven, and it has been challenged by ACRS members. Thus, it is not clear how or whether criterion 5 under Option A could even be demonstrated. Guidance on demonstrating the viability of inherent characteristics would be essential to implementing Option A. As noted in the discussion text, Option B builds upon the general philosophical approach used for considering unmitigated hazards in DOE STD 1224, Section 2.7. In reviewing this Section, it is clear that the guidance is more involved, with it referencing DOE STD 3009-2014, Section 3.2.2. While this approach is useful for DOE, it is untried and unproven for application in NRC regulation. Implementing the approach would require regulatory guidance and much more specific requirements than specified under Option B so that the requirement is unambiguous and not left open to interpretation by individual reviewers. In summary, while being able to implement 53.770 through 53.779 and make use of certified operators is potentially very desirable, meeting the requirements for either Option A or Option B appears to be very challenging and perhaps totally impractical. This	

		warrants significant further discussion between the NRC and stakeholders.	
F-28	53.755(d)	53.755(d) addresses operator requalification. The requirement is for the program to be implemented "upon commencing the administration of licensed operator and senior licensed operator licensing examinations..." The discussion text notes that the requalification training programs "only need to be put into effect when the associated examination programs begin producing individuals who require those continuing programs. However, it is not clear from the language in 53.755(d). This requirement needs to be clarified. Also, 53.755(d) requires that the approved operator requalification program shall be subject to the requirements of Subpart I, "Maintaining and Revising Licensing Basis Information During Operations." The title of Subpart I is incorrect. Further, it is not clear how the criteria in 53.1322 or 53.1333 could be relevant to changes to the operator requalification program requirements. 53.755(g) addresses changes to the approved staffing plan and stipulates that those changes would be subject to the requirements of Subpart I. As with 54.755(d), it is not clear how the criteria in 53.1322 or 53.1333 could be relevant to changes to the staffing plan.	Clarify the requirement on when the requalification training programs needs to be put into effect, specifying it in the language of 53.755(d) rather than in the discussion text. Clarify how the change processes in Subpart I are applicable to the requalification program or the staffing plan. The discussion text of 53.755(g) does note that changes to Subpart I would be required and that linking changes to programs required within 53.750 – 53.799 is a subject where the NRC work is continuing to determine whether this will be appropriate and future changes to this approach are possible. It is strongly recommended that these issues be resolved and appropriate change control processes be defined.

Attachment B
Detailed Comments on NRC's Comprehensive Preliminary Part 53 Rule Language

Detailed Comments on Subpart H – Licenses, Certifications, and Approvals

Comments are based on NRC's released versions on August 10, 2021 (ML21202A178), and October 18, 2021 (ML21267A004).

Comment Number	NRC Preliminary Requirement	Industry Comment	Proposed Resolution
H-1	General	Subpart H is overly complex and appears to be substantially longer than equivalent requirements in Parts 50 and 52 combined. This leads to a reduction in regulatory clarity, and introduces the potential for similar requirements having unintentional differences. The use of fractions, such as "½", in the numbering of requirements is confusing. There are enough whole numbers that can be utilized to avoid this numbering convention, especially considering the requirement numbering system already goes all the way up to "1572".	Streamline the requirements in Subpart H to reduce the duplication of language, and eliminate unnecessary details. NEI provided a proposal for achieving such streamlining in Attachment 1 of the February 11, 2021 letter (see NEI 53.35 thru 53.39). Eliminate the use of fractions, such as "½", in the numbering of requirements (here and in other locations).
H-2	53.1110 Combining applications 53.1120 Elimination of repetition	The discussion comment for 53.1110 notes the language comes from 50.31 and 52.8. We agree that these two requirements are essentially identical to 50.31 and 50.32. However, 53.1110 and 53.1120 do not contain additional language that is in 52.8. Specifically, 52.8(c) could have an administrative benefit, potentially lessening burden on either an applicant or the staff.	Include the following language from 52.8(c) that provides additional flexibility: *"The Commission may combine in a single license the activities of an applicant which would otherwise be licensed separately."*
H-3	53.1165 Site suitability reviews	If 53.1165 were to be included, it would be the same as Part 50 App. Q and Part 2, Subpart F. The NRC is seeking stakeholder input as to whether these provisions should be included in Part 53.	More discussion is needed to determine whether this requirement should be included. If there is no potential need for this requirement, for example it is duplicated by provisions for early site permits, then it would not appear to be necessary in Part 53.

		Because these provisions have not been used in recent applications, it is recommended that they not be included in Part 53.	
H-4	53.1180 Early site permits 53.1183 Filing of applications	The discussion comment for these requirements notes the language comes from 52.12 and 52.15, and we agree with this assessment. However, there is not a 53.118x comparable to 52.16 on "Contents of applications, general information." It is not clear if this is an oversight or a deliberate omission.	If not including the requirements from 52.16 in a 53.118x was deliberate, we suggest addressing this in the staff's discussion table, or including a reference to where in Part 53 the information is required. If not including 52.16 was an oversight, then it should be included in the next release of Subpart H.
H-5	53.1185 Contents of applications; technical information	53.1185 is nominally identical to 52.17; however, there are some differences that have major implications: 1. 53.1185(a)(ix) requires an analysis of LBEs associated with potential designs and their results, as described in 53.240, considered in the design to determine compliance with the safety criteria in 53.210 and 53.220. It is noted that the analysis description must address 53.450(e) and (f). Taken together, these requirements are considerably more burdensome than the requirements in 52.17(a)(1)(ix). Additionally, to meet the 53.1185(a)(ix) requirements would require use of the PRA-based methods required in Subparts B and C, and at a level of design maturity that would appear to go beyond what has been required for previously issued ESPs under Part 52. The PRA-based requirements in 53.1185(a)(ix) would not permit other risk-informed methods or more traditional analysis approaches that would satisfy the requirements under 52.17.	The requirements for 53.XX in Subpart D should be replaced with a reference to the location of a comprehensive set of more performance-based QA requirements that are compatible with Part 50 Appendix B, only applicable to safety-related SSCs, and allow flexibility to use international standards (e.g., ISO-9001) to comply with the requirements. In Comment B-10 we recommend this be a new requirement 53.280 that is accompanies by deleting all other QA requirements in Part 53. Delete the references to 53.450(e) and (f) consistent with comment C-5 to delete these detailed prescriptive uses of PRA from the rule.

		2. External hazards are required to be addressed under Subpart D. In 53.1185(a)(xi), reference is made to 53.XX which is a new QA section that is to be added to Subpart D. 53.1185(a)(xi) requires a description of the quality assurance program required by 53.XX. this is similar to 52.17(a)(1)(xi) which points to 10 CFR 50, Appendix B. It is not clear what will be included in the Subpart D QA program requirements. However, this would appear to be another separate QA program, rather than being incorporated into a more comprehensive Part 53 QA program.	
H-6	53.1191 Extent of activities permitted	Editorial Comment: 53.1191 points to 53.1185(c) regarding a site redress plan. However, 53.1185(c) points to 53.1170, with the redress plan requirement being in 53.1170(b)(3)(iii). It is not clear why 54.1191 does not simply point to 53.1170.	Consider changing the reference from 53.1185(c) to 53.1170(b)(3)(iii).
H-7	53.1199 Finality of early site permit determinations	53.1199 does not include the provision on information requests from 52.39(f), which other than for requests seeking to clarify compliance with the current licensing basis of the ESP, requires that information requests to the holder be evaluated before issuance to ensure that the burden to be imposed is justified in view of the potential safety significance of the issue. The evaluations are to be in accordance with 50.54(f). It appears that this might be in 53.1360, but this is not clear.	A limit on information requests similar to 52.39(f) should be included in 53.1199 OR elsewhere in Part 53, with appropriate reference here, to ensure similar rigor in evaluating information requests before they are issued.
H-8	53.1223 Filing of applications	As described in the discussion of 53.1223, it is essentially identical to 52.135(a). However, the requirements in 52.135(b) on submitting the application, and 52.135(c) on review fees being set forth in Part 170, are not included. While these are administrative matters, being specific in	Include, either in 53.1223 or another provision in Part 53, the requirements in 52.135(b) and (c). If these requirements have been deliberately omitted, discussion of these issues

		the regulation is important to ensure the application is submitted properly and to specify the review fee regulation.	should be included in the staff's discussion table for the next release of Subpart H.
H-9	53.1225 Contents of applications; technical information	53.1225 includes general expectations on submitting "major portions" of a design for a Standard Design Approval. The text notes that the scope of the application for which approval is sought must include all functional design criteria as can be identified at that stage of design. Such applicants must identify conditions related to interfaces with systems outside the scope of the major portion of the standard design for which NRC staff approval is ought and the remainder of the standard design. While these requirements are, in principle, understandable, their implementation given the PRA-based requirements in the balance of 53.1225 warrant further explanation and guidance.	Develop regulatory guidance and examples, potentially including tabletop exercises, to clarify implementation of the expectations for approving major portions of a SDA.
H-10	53.1225 Contents of applications; technical information 53.1235 Contents of applications; technical information	53.1225 and 52.1235 provide the "Contents of applications; technical information" for Standard Design Approvals and Standard Design Certifications. The general structure of these requirements is consistent with 52.137 for SDAs and 52.47 for DCs. However, the specific requirements in 53.1225 and 53.1235 derive from the PRA-based requirements in Subparts B and C. These requirements are based on the PRA-based approach addressed in the Licensing Modernization Project and do not permit use of other risk-informed approaches or more traditional approaches that may be more appropriate for very simple designs.	53.1225 and 53.1235 should be significantly revised to permit use of other risk-informed and more traditional approaches.
H-11	53.1229 Finality of standard	The discussion of 53.1229(a) – (c) states that it is identical to 52.145. However, 52.145 does not include a provision	NRC should provide the rationale for including 53.1229(d), specifically addressing challenges

	design approvals; information requests.	akin to 53.1229(d) which states "The Commission will require, before granting a construction permit, combined license, operating license, or manufacturing license which references a standard design approval, that information supporting required design and analysis application content be completed and available for audit if the information is necessary for the Commission to make its safety determinations, including the determination that the application is consistent with the design approval information. This information may be acquired by appropriate arrangements with the design approval applicant." It is not clear why this requirement was added nor, and it may require actions that are not practical or significantly increase regulatory burden without a commensurate increase in safety.	that have been experienced with Part 52 that suggest this requirement is warranted. If the significance of the issue being addressed is already addressed through other requirements and is not justified by the potential cost for an applicant to implement the requirement, then it should be deleted from Part 53.
H-12	53.1162 Relationship Between Sections	53.1162(e)(4) addresses factory installation of fuel, which industry had indicated was a desirable capability. However, in NEI submitted a paper on Manufacturing Licenses on July 16, 2021 identifying a number of desirable capabilities, such as criticality testing, that are not addressed in either 53.620 or 53.1162(e)(4).	Include in either 53.620 or Subpart H, requirements addressing the capabilities discussed in the NEI July 2021 paper on Manufacturing Licenses.
H-13	53.1245 Contents of applications for manufacturing licenses; technical information in final safety analysis report	53.1245(b) "*Design Information*" points to 53.1235 "Contents of applications; technical information" for Standard Design Certifications. As noted in comment H—10, the specific requirements for 53.1235 derive from the PRA-based requirements of Subparts B and C. These requirements are based on the PRA-based approach addressed in the Licensing Modernization Project and do not permit use of other risk-informed approaches or more traditional approaches that may be more appropriate for very simple design, especially those designs where a manufacturing license might be sought.	53.1245 should be significantly revised to permit use of other risk-informed and more traditional approaches. The NRC should not impose an ITAAC-like process for CPs. Such a process is not necessary since the plant cannot load fuel without first getting NRC approval for an OL. There is no "one size fits all" description of the roles of various types of organizations. More

		The NRC is seeking stakeholder input in the following areas: (1) "The staff is soliciting stakeholder views on the translation of ITAAC from a standard design certification through possible licensing paths involving CPs/OLs. The staff is proposing to track the ITAAC as technical requirements through a process such as conditions on a CP. The reviews of an OL application would then confirm the conditions without introducing other ITAAC processes from Part 52." (2) "Stakeholder feedback: a designer a manufacturer, and an applicant for a facility license could all be different entities. Is there a specific model the staff should focus on, given the potential applicant deployment strategies?"	discussion is needed to understand the NRC's perceived need to add terms such as "designer", "manufacturer" and "owner/operator".
H-14	53.1246 Contents of applications for manufacturing licenses; other application content	The last sentence of 53.1246 states "[N]onetheless, an application for a manufacturing license that references a standard design certification that includes the installation of fuel at the factory must discuss severe accident mitigation design alternatives for the reactor module while at the factory and must also discuss severe accident mitigation alternatives for the factory itself." The NRC staff is interested in stakeholder views related to SAMDA evaluations for manufacturing license applicants.	The requirement in 53.1245(e) *Special considerations for factory fueling* impose the requirements of Subpart H of Part 70. Requirements in 53.1246 should not go beyond the Part 70 requirements.
H-15	53.1247 Standards for review of applications, referral to ACRS, and issuance of a	In the NRC discussion table, it is noted that this section does not address the potential removal of the manufactured module from the operating site. The NRC also notes "[A]s previously mentioned, the staff is interested in stakeholder insights related to a licensing model for possible stages in the manufacture, transport,	Part 53 should address all aspects of the possible stages listed in the discussion table. This is particularly important as those stages may relate to micro reactors.

	manufacturing license	storage (at site), installation, operation, removal, storage (at site), transport, refurbishment, and disposal of a reactor module. Part 53 might not address the back end of this cycle."	
H-16	53.1264 Contents of applications for construction permits; general information	This requirement supplements the general information required under 53.1130 and is specific to the information to be submitted to demonstrate financial qualifications. The technical requirement to demonstrate financial qualifications is in 53.1561. Under the discussion comments for 53.1561, the staff notes that their approach is to have technical requirements in a Subpart other than where the contents of applications are specified. While this is, in concept, a sound approach, there need to be references to the technical requirement in the content requirement. Absent this linkage, the regulation becomes unnecessarily difficult to follow and implement.	In the application content requirements, provide references back to the technical requirements that relate to the content being required.
H-17	53.1265 Contents of applications for construction permits; technical information in preliminary safety analysis report	53.1265(b) *Design information* generally requires design information equivalent to that required for a standard design certification as defined in 53.1235(a)(2)-(19). However, as noted in comment H—10, the specific requirements for 53.1235 derive from the PRA-based requirements of Subparts B and C. These requirements are based on the PRA-based approach addressed in the Licensing Modernization Project and do not permit use of other risk-informed approaches or more traditional approaches that may be more appropriate for very simple designs, especially those designs where a manufacturing license might be sought.	53.1265 should be significantly revised to permit use of other risk-informed and more traditional approaches. The revisions to 53.1265 also should address conforming changes to 53.1265(b)(2) on *Planned Research*, and (3) *Programmatic controls and interfaces*.

H-18	53.1268 Issuance of construction permits	53.1268(a)(4)(ii) points to 53.210 and 53.220. 53.210 incorporates the 25 rem requirement in 50.34(a)(1) while 53.220 incorporates the QHOs into the rule, rather than continuing to use the Policy Statement, and both effectively impose the PRA-based requirements from Subparts B and C. As other risk-informed and more traditional approaches are included in Part 53, conforming changes in the requirements of 53.1268 should be included.	Conforming changes to 53.1268 should be made consistent with incorporating other risk-informed and more traditional approaches into Part 53.
H-19	53.1275 Contents of applications for operating licenses; technical information in final safety analysis report	53.1275(a) *Site information.* The text in this requirement does not indicate that the information should reflect current information consistent with 50.34(b)(1). As written, it is simply duplicating the site information required for a CP. 53.1275(b) *Design information* generally requires design information equivalent to that required for a standard design certification as defined in 53.1235(a)(2)-(19). However, as noted in comment H—10, the specific requirements for 53.1235 derive from the PRA-based requirements of Subparts B and C. These requirements are based on the PRA-based approach addressed in the Licensing Modernization Project and do not permit use of other risk-informed approaches or more traditional approaches that may be more appropriate for very simple designs. 53.1275(d) *Integrity assessment program.* Industry has previously commented (see comment F-11) that the integrity assessment program required in 53.850 should be removed since it duplicates other requirements and applies requirements that are not applicable until license renewal.	53.1275(a) should be revised to reflect submission of current information. 53.1275(b) should be significantly revised to permit use of other risk-informed and more traditional approaches. 53.1275(d) should be removed.

		53.1275(m) *Quality assurance.* Industry has previously commented (see B-10, F-5 and F-10) that all of the QA requirements in Part 53 be established together, in Subpart B, in a manner compatible with Part 50 Appendix B for all safety-related SSCs, or alternatively in a requirement that allows the flexibility to use international standards (e.g., ISO-9001). 53.1275(o) *Security Program.* Industry has previously commented (see F-9) on the Security Program efforts. To the extent that the additional content required in 53.1275(o) goes beyond the on-going efforts, they should be included in those efforts so that the full scope of security issues are addressed in the security plan in 53.830. 53.1275(w) *Facility safety program.* Industry has previously commented (see comment F-15) that the facility safety program required in 53.890, and the associated requirements in 54.892-53.896, should be deleted, because they impose enormous regulatory burden without any increase in safety.	53.1275(m) should be revised to reference a QA requirement consistent with comments B-10 and F-10. Ensure all of the issues raised in 53.1275(o) are addressed in the security plan required in 50.810. 53.1275(w) should be removed.
H-20	53.1276 Contents of applications for operating licenses; other application content.	53.1276(3) *Availability controls.* This requirement addresses information derived from the PRA-based requirements of Subparts B and C, which are based on the PRA-based approach addressed in the Licensing Modernization Project and do not permit use of other risk-informed approaches or more traditional approaches that may be more appropriate for very simple designs. Additionally, the language refers to the two-tier structure that has been removed from Subpart B.	Revise the text to remove reference to the "second-tier safety criteria". Revise, or delete, 53.1276(3) to address other risk-informed or more traditional approaches.

H-21	53.1289 Contents of applications for combined licenses; technical information in final safety analysis report	53.1289(a) The penultimate sentence states the "Commission will require, before issuance of a combined license, that information supporting required siting, design and analysis application content be completed and available for audit if the information is necessary for the Commission to make its safety determination." While there is a similar sentence in 53.1235 for a standard design certification, it is a modification of the language in 52.47. However, there does not appear to be a sentence in 52.79 that is similar to the language in 52.1289(a). The specific requirement is not objectionable but the basis for including it is not clear.	Recommend including an explanation for adding the sentence in the next iteration of the discussion table for Subpart H.
H-22	53.1289(a)(1) *Design Information*	53.1289(a)(1) *Design information* requires design information equivalent to that required for a standard design certification as defined in 53.1235(a)(2)-(19). However, as noted in comment H—10, the specific requirements for 53.1235 derive from the PRA-based requirements of Subparts B and C. These requirements are based on the PRA-based approach addressed in the Licensing Modernization Project and do not permit use of other risk-informed approaches or more traditional approaches that may be more appropriate for very simple designs. 53.1289(a)(4) *Integrity assessment program.* Industry has previously commented (see comment F-11) that the integrity assessment program required in 53.850 should be removed since it duplicates other requirements and applies requirements that are not applicable until license renewal. 53.1289(a)(12) *Quality assurance.* Industry has previously commented (see B-10, F-5 and F-10) that all of the QA	53.1289(a)(1) should be significantly revised to permit use of other risk-informed and more traditional approaches. 53.1289(a)(4) should be removed. 53.1289(a)(12) should be revised to reference a QA requirement consistent with comments B-10 and F-10.

		requirements in Part 53 be established together, in Subpart B, in a manner compatible with Part 50 Appendix B for all safety-related SSCs, or alternatively in a requirement that allows the flexibility to use international standards (e.g., ISO-9001). 53.1289(a)(14) *Security program.* Industry has previously commented (see F-9) on the Security Program efforts. To the extent that the additional content required in 53.1289(a)(14) goes beyond the on-going efforts, they should be included in those efforts so that the full scope of security issues are addressed in the security plan in 53.830. 53.1289(a)(22) *Facility safety program.* Industry has previously commented (see comment F-15) that the facility safety program required in 53.890, and the associated requirements in 54.892-53.896, should be deleted, because they impose enormous regulatory burden without any increase in safety.	Ensure all of the issues raised in 53.1289(14) are addressed in the security plan required in 50.810. 53.1289(a)(22) should be removed.
H-23	53.1290 Contents of applications for combined licenses; other application content	53.1290 (a)(3) *Availability controls.* This requirement addresses information derived from the PRA-based requirements of Subparts B and C, which are based on the PRA-based approach addressed in the Licensing Modernization Project and do not permit use of other risk-informed approaches or more traditional approaches that may be more appropriate for very simple designs. Additionally, the language refers to the two-tier structure that has been removed from Subpart B.	Revise the text to remove reference to the "second-tier safety criteria". Revise, or delete, 53.1290(a)(3) to address other risk-informed or more traditional approaches.
H-24	53.1306 Inspection during construction	The timelines for specific actions provided in 53.1306(a) and (c)(3) and in 53.1307(a) are reasonable for large plants or plants that have long construction periods owing to design-specific considerations. However, for small, simple plants, the overall construction schedules may be	Consider revisions to reporting timelines in 53.1306 and 53.1307 that would be linked to the licensee's construction and ITAAC completion schedules.

	53.1307 Operation under a combined license	significantly shorter than what has been experienced for large plants. Some of the timelines could create administrative burdens (reporting uncompleted ITAAC 225 days before the scheduled date for initial fuel load) if the pace of construction compresses the time between specific actions and the scheduled initial fuel load date. While it is reasonable to specify timelines for the actions listed in these regulations, the specific times may not be practical. A reporting schedule based on the ITAAC completion schedule for each plant submitted under 53.1306(a), could provide a schedule that supports NRC's interests but does not impose unrealistic burdens for the licensee.	

Attachment B
Detailed Comments on NRC's Comprehensive Preliminary Part 53 Rule Language

Detailed Comments on Subpart I – "Maintaining and Revising Licensing Basis Information"

Comments are based on NRC's released versions on August 10, 2021 (ML212025A175), and August 31, 2021 (ML21243A106 for 53.1322).

Comment Number	NRC Preliminary Requirement	Industry Comment	Proposed Resolution
I-1	53.1311 Application for amendment of license	The second sentence in 53.1311 is significantly more prescriptive than equivalent language in 50.90. While the analyses to support an amendment under 50.90 would address the equivalent topics using the approaches in the original Part 50 or 52 application, it is not clear why the NRC is including this level of specificity in 53.1311.	The level of detail in the second sentence of 53.1311 should be made consistent with a performance-based regulation.
I-2	53.1312 Public notices; State consultation	The introductory paragraph in 53.1312 does not include all of the information in the introductory paragraph in 50.91. Some of the process information in 50.91 would appear to be important (such as the requirement to publish the opportunity for a hearing at least 30 days before the requested amendment is issued by the Commission). It is not clear why the NRC is not including this process information.	The introductory information in 50.91 that has not been included in 53.1312 should be reviewed for legal significance. If found to be significant, then it should be included in 53.1312.
I-3	53.1321 Updating final safety analysis reports	The specific language in these requirements presumes the licensee has made use of the PRA-based approach in Subparts B and C. The requirements do not reflect other risk-informed approaches or more traditional approaches.	The language in 53.1321(a)(2)-(4) should be modified to reflect FSAR updates where other risk-informed approaches or more traditional approaches have been used in supporting licensing of the plant.
I-4	53.1322 Evaluating changes to facility as described in final safety analysis reports	This requirement is only applicable to one type of risk-informed approach in which the safety case is based almost entirely on the PRA, and therefore cannot be applied to other risk-informed approaches. It is further noted that it appears that the outcome of the change control criteria here would be identical to the use of the	Replace the change control criteria in 53.1322(a) with technology-inclusive equivalents of the change control criteria in 50.59. NEI proposed a set of technology-inclusive change control criteria in the proposed 53.41 in Attachment 1 of the

		criteria in 50.59, so that there is no regulatory advantage other than the ability to solely use the PRA to evaluate changes. The experience from implementing 50.59 is that the guidance is crucial to understanding how the change control criteria will be applied, and the guidance for 50.59 took significant resources and years to develop. No such guidance has been provided for 53.1322, and so the PRA-based criteria could be found to be undesirable once the details are developed in guidance. Even if some licensees desire to solely use the PRA to evaluate whether changes need prior NRC approval, a requirement must be more inclusive and flexible. The 10 percent change criterion, in 53.1322(a)(2)(ii) and (iii), is likely to be overly burdensome given the frequency and cumulative risk values for many event sequences. A more realistic target to achieve the desired change threshold should be defined. The scope in 53.1322(a) does not include "conduct tests or experiments not described in the final safety analysis report (as updated)" which is included in 50.59(c)(1). The basis for not including this phrase is not clear. Absent a compelling reason, Part 53 should not be more restrictive that Parts 50 and 52. It is not clear why the last sentence of this requirement has been included. As noted in the sentence, the information is already required by 53.1321. Redundant requirements are unnecessary and contribute to clutter in the regulation.	February 11, 2021 letter that would work in the NRC's preliminary rule language. If the NRC feels it necessary to include PRA-based change control criteria, then the NRC would need to develop guidance with the implementation details to accompany rule language in order for stakeholders to determine whether there are any benefits to that approach. Even if the NRC includes a PRA-based version of change control criteria, the NRC should include it as an alternative to the 50.59-like change control criteria so that licensees have the option to use whichever criteria works best for their licensing approach. Include the "tests and experiments" phrase in 53.1322(a). Delete the last sentence.

I-5	53.1332 Updating program documents included in licensing basis information	In the discussion comments for this requirement the staff requests stakeholder views on the benefits of a common approach versus the current practice of establishing program-specific requirements for reporting and change control. The industry notes that there can be benefits to a common approach. However, the varied topics and differing nature of content in the numerous programs being required under Part 53 argues for program-specific requirement for reporting and change control. A common approach would likely have the effect of imposing unduly onerous requirements on some of the simpler programs, particularly for very small and very simple designs.	53.1332 should be revised to address high-level requirements, leaving the details to programs-specific reporting and change control, supported by appropriate regulatory guidance. A single change control process for programs could be considered in the future, if the NRC were to create a transformational regulatory framework which integrated safety, security, EP and siting, based upon a more holistic safety paradigm that more fully integrates design features, human actions and programs. Until such a transformational framework is pursued, the NRC should not attempt to create a single change control process for programs in Part 53.
I-6	53.1333 Evaluating changes to programs included in licensing basis information	In the discussion comments for this requirement the staff requests stakeholder views on the benefits of a common approach versus the current practice of establishing program-specific requirements for reporting and change control. This would apparently extend to the 53.1333 requirements for evaluating changes to programs included in licensing basis information. As discussed in comment I-5 for 53.1332, the varied topics and content of the numerous programs being required under Part 53 argues for a program-specific requirement for reporting and change control. Additionally, the requirements in 53.1333(a)(4) establish PRA-based change control criteria. As discussed in comment I-5 for 53.1322, Part 53 should not use PRA-	53.1333 should be revised to address high-level requirements for reporting and change control, leaving the details to programs-specific reporting and change control, supported by appropriate regulatory guidance. Revise 53.1333(a)(4) to be based upon 50.59-like change control criteria. If the NRC feels it necessary to include PRA-based change control criteria, then the NRC would need to develop guidance with the implementation details to accompany rule language in order for use to determine whether there are any benefits to that approach. Even if the NRC includes a PRA-based version of change control criteria, the

		based change control criteria, and 50.59-like criteria are recommended.	NRC, the NRC should include it as an alternative the 50.59-like change control criteria so that licensees have the option to use whichever criteria works best for their licensing approach.

Attachment B
Detailed Comments on NRC's Comprehensive Preliminary Part 53 Rule Language

Detailed Comments on Subpart J – "Reporting and Other Administrative Requirements"

Comments are based on NRC's released version on August 24, 2021 (ML21225A224).

Comment Number	NRC Preliminary Requirement	Industry Comment	Proposed Resolution
J-1	53.1521 Immediate Notification Requirements for Operating Commercial Nuclear Plants	The discussion of this requirement states that it was taken from 50.72. However, it does not specify the 1-hour activation time for the data links (formerly ERDS) in 50.72(a)(4). Rather, details on activation of the data links are left to the emergency plans. Removing the activation time requirement would appear to be a relaxation so long as more restrictive requirements are not included elsewhere in Part 53. it is unclear whether this requirement is consistent with 50.72(a)(4) in the inclusion of the criteria for declaring an Emergency Class "for events of actual or potential substantial degradation of plant safety or security, probable risk to site personnel life, or site equipment damage caused by hostile action." It is not clear why these criteria have been included in 53.1521(a)(4) when they are not in 5072(a)(4). It also is not clear that this does not duplicate, or is in conflict, with other requirements or guidance on Emergency plans.	Ensure that provisions in Part 53, or associated guidance, do not impose an activation time for the data links more restrictive than the 1-hour specified in 50.72(a)(4). Ensure that the criteria for declaring an Emergency Class in 53.1521(a)(4) are not duplicated elsewhere in Part 53 and are not in conflict with other requirements related to Emergency Class declarations.
J-2	53.1530 Licensee Event Report System	The discussion of this requirement states that it was taken from 50.73. This is essentially identical to 50.73(a)(2)(viii)(B); h*owever, t*he staff poses the question: *"Do limits for these {meaning tritium and dissolved noble gasses} radionuclides need to be specified for non-LWRs?"*	We agree that these questions need to be addressed in order to determine if non-LWR alternatives need to be established for 53.1530(a)(2)(vii)(B) and 53.1530(b)(ii)(F). It is noted that these same requirements, in 50.73(a)(2)(viii)(B) and 50.73(b)(2)(ii)(F), apply to licensing non-LWRs under Parts 50 and 52,

		This is essentially identical to 50.73(b)(2)(ii)(F); however, the staff poses the question *"Is this identification system applicable to non-LWRs?"*	and these questions will also need to be addressed outside of Part 53.
J-3	53.1561 Financial Qualifications	The text for this requirement is at a very high level, simply stating that applicants "under this part must possess or have reasonable assurance of obtaining the funds necessary for the activities for which the permit or license is sought." The text notes that electric utilities are assumed to have such reasonable assurance. In the last sentence of the first paragraph of the staff discussion it is noted that "details on the require contents of applications to show an applicant is financially qualified for a license or permit will be in Subpart H." However, in the staff discussion for Subpart H, 53.1130, it is noted in the first sentence that 50.33(f) on financial qualifications is moved to Subpart J. The details on content for financial qualification are in 50.33(f) but are not included, even in a modified form, in either 53.1130 or 53.1561. Absent some level of detail on application content expected to demonstrate financial qualification, the applicant will be open to individual reviewer expectations, which could be variable from application to application and could exceed current content requirements in 5033(f).	The language in 53.1561 should be expanded to provide an appropriate level of content requirement for a Part 53 applicant. As a minimum, 53.1561 should reference requirements that provide the technical criteria for reporting (e.g., 53.1274 and 53.1287), similar to the referencing used in 53.1563. Additional details could be in guidance, and the detail in the regulations should not go beyond expectations for a Part 50 or 52 applicant.
J-4	53.1563 Licensee's Change of Status; Financial Qualifications	The text in 53.1563 is nominally identical to 50.76. However, 50.76 points to 50.33(f)(2) for details on the financial qualification information to be supplied. 53.1563 requires that the licensee "must provide the NRC with the financial qualifications information that would be required for obtaining an initial operating license" as specified in 53.1274 or 53.1287.	The inconsistency in which provision(s) provide the requirements for financial qualification information needs to be remedied. This is particularly a problem given the lack of detail in 53.1561.

J-5	53.1564 Creditor Regulations	The text in 53.1564(b) addresses, in part, application by a creditor to transfer the license covering a facility. It references 53.1309 and states the Commission will act upon such application pursuant to Subpart I. However, 53.1309 in not included in the release of Subpart I dated August 10, 2021. Rather, license transfers are addressed in 53.1340. Presumably, referencing 53.1309 is simply an editorial error.	Correct the reference to license transfer application from 53.1309 to 53.1340 OR provide the appropriate language in a 53.1309 in the next iteration.
J-6	53.1571 Insurance Required to Stabilize and Decontaminate Plant Following an Accident	53.1571(a) includes requirements on the minimum amount of insurance required for each reactor station site. In addition to the amounts specified in 50.54(w)(1), 53.1571(a)(1) includes "an amount based on plant-specific estimates of costs to stabilize and decontaminate a plant." This additional requirement is a sound addition to 53.1571(a), particularly for SMRs and non-LWRs. However, there is no discussion of the estimation process or acceptance criteria for this amount. Absent, a level of specificity, the acceptance of the estimated costs would be left to the discretion of an individual reviewer.	High-level language on the estimation process requirements and acceptance criteria should be developed and incorporated into the regulation, with more detail provided in regulatory guidance.

Attachment B
Detailed Comments on NRC's Comprehensive Preliminary Part 53 Rule Language

Detailed Comments on draft 5X

Comments are based on NRC's released version draft language for Part 5X (ML21270A005) released on October 18, 2021.

Comment Number	NRC Preliminary Requirement	Industry Comment	Discussion and Proposed Resolution
5X-1	General	As discussed in Attachment A comment II.2.A, with changes to two Part 53 requirements, and other conforming modifications, that removes detail that is historically in guidance and Policy Statements, the NRC can make Part 53 flexible to work for all risk-informed approaches.	The NRC should not pursue a separate Part 5X regulatory framework for the majority of risk-informed approaches, but rather the NRC should modify Part 53 requirements to allow it to be accessible to more than only one type of risk-informed approach. While Part 5X should be discontinued as a parallel framework, the requirements could be evaluated to determine whether any content from Part 5X should replace or supplement the current Part 53 language.
5X-2	50.210 - Applicability	This requirement specifies that the subsequent requirements replace technology-specific requirements for licensing Part 50 and 52. While each requirement can be evaluated individually, there is not sufficient information to evaluate Part 5X as a "framework" since it is missing significant context in terms of the other requirements that would be applicable. Furthermore, this contradicts the introductory text that says the NRC has not determined where to put this framework. This requirement clearly expresses that this framework is not compatible with the Part 53.	Provide more details on how the Part 5X requirements would replace or modify requirements in Part 50 (since it is built upon that framework). Also explain how the Part 5X requirements would replace or modify requirements in Part 53 (since most of Part 53 is generally applicable). The NRC should not preclude other risk-informed approaches from using Part 53.

5X-3	50.220- Definitions	The definitions in Part 53 work for all risk-informed approaches, and the technology-specific definitions introduced in Part 5X are not needed. The NRC has identified the need for a definition of Basic Component, which has not been identified in Part 53. The term basic component is used in Part 20, and Part 53 will need to develop a technology-inclusive equivalent.	Do not use these definitions in Part 53, as Part 53 definitions are already inclusive, with exception as noted in comments on Subpart A. Create a technology-inclusive definition of "basic component" for Part 53.
5X-4	50.230- Requirements	The Part 53 requirement on defense-in-depth already includes a performance-based approach to accomplish the same purpose as both the single failure criterion and defense-in-depth requirements here. The requirement for PRA here is more performance-based than the prescriptive PRA requirement found in Part 53. There is nothing in Part 53 that would depend upon the use of the PRA in the prescriptive manner provided, and thus this version of the PRA requirement could be used in Part 53 to allow all risk informed approaches to be used.	Do not use these requirements for single-failure criterion or defense-in-depth in Part 53, as the Part 53 DID requirement is more performance-based, inclusive and flexible, and achieves the same purpose. Comments on the NRC's Part 53 PRA requirement are provided in comment C-5; however, the PRA requirement here could also be considered as a replacement for the current 53.450 rule language.
5X-5	50.240- Principal Design Criteria	There is not a need for prescribing the process for identifying PDC. Part 53 already requires PDC, although the term used there is functional design criteria, and the Part 53 requirement is more performance-based, inclusive and flexible.	Do not use this requirement in Part 53, because Part 53 requirements for principal design criteria (although the NRC has called them functional design criteria) serve the same purpose and are more performance-based, inclusive and flexible.
5X-6	50.250 – Anticipated Operational occurrences and design basis accidents	Part 53 has more performance-based, inclusive and flexible versions of most of the requirements found here, with the following exceptions. The explicit discussion in (a)(6) to permit a single or bounding analyses provides additional clarity that this	Consider explicitly stating in Part 53 that bounding analysis may be used, with performance-based language. Do not use other requirements found here in Part 53, as they are not needed.

		approach is acceptable. However, the language that says these may not be realistic is confusing and could create unintended consequences. The requirements in (c) are ambiguous and the requirement to report "EACH" change and its estimated effect in a separate report annually seems excessive, and will result in significant increased regulatory administrative burden, without an increase in safety. This also appears to duplicate other requirements like Part 21 and the change control process.	
5X-7	50.260 Beyond Design Basis Events	This requirement effectively puts the beyond design basis events into the design basis. Specifically, the requirements go far beyond current BDBE requirements by stating that: 1. Applicants must identify design features for withstanding BDBE 2. Design features should be developed to establish supplementary protections against BDBE initiators 3. Must classify SSCs used to mitigate BDBE as safety-related 4. Requiring BDBE to meet 25 rem dose criteria (through requirements in 53.270) This is not consistent with the current regulatory treatment of BDBE through mitigation measures. Furthermore, the Commission directed the staff to remove design requirements for BDBE for new reactors in the Proposed Rulemaking for Mitigation of Beyond Design Basis Events in SRM-SECY-15-0065 (ML15239A767).	Do not use this requirement in Part 53, and modify current Part 53 language so that BDBE are not included in the design basis in Part 53, consistent with the Commission decision in SRM-SECY-15-0065 (ML15239A767). Part 53 should address BDBE with a requirement focused on mitigation. Comments on Subpart B, in particular B-4, discuss how current Part 53 rule language includes BDBE in the design basis.

5X-8	Severe Accidents	This requirement effectively puts severe accidents into the design basis. The requirements also go far beyond the current approach to severe accidents by stating that: 1. Requiring severe accidents to meet 25 rem dose criteria 2. Requiring design features to prevent severe accidents This is not consistent with the current regulatory treatment of severe accidents through the Policy Statement on Severe Accidents. Furthermore, the Commission directed the staff to remove requirements for SAMGs in the Proposed Rulemaking for Mitigation of Beyond Design Basis Events in SRM-SECY-15-0065 (ML15239A767).	Do not use this requirement in Part 53, and modify current Part 53 language so that severe accidents are not included in the design basis in Part 53, consistent with the Commission decision in SRM-SECY-15-0065 (ML15239A767). Severe accidents should continue to be addressed through the Policy Statement on Severe Accidents. Comments on Subpart B, in particular B-4, discuss how current Part 53 rule language includes severe accidents in the design basis.
5X-9	50.280 Functional Containment	A more expansive concept of functional containment is more technology-inclusive. However, Part 53 has a more technology-inclusive requirement in 53.230 for Safety Functions.	Do not use this requirement in Part 53, as Part 53 requirements for safety functions, which serve the same purpose is more performance-based, inclusive and flexible
5X-10	53.290 Design Requirements	It is noted that this requirement is still under development. The flexibility in meeting the requirements for Technical Specifications will lead to a more inclusive requirement. The Part 53 requirement, 53.720, includes an even more technology-inclusive requirement that does not specify criteria, but rather relies on the requirements in Subparts B and C to identify the LCOs related to meeting 53.210. This Part 53 requirement would also work for other risk-informed approaches, and is not dependent upon a specific use of the PRA (see comment F-3).	Do not use this requirement in Part 53, as the Part 53 requirement 53.720, is more performance-based, inclusive and flexible. See comment F-3.

Attachment C

NEI and USNIC Prior Submissions to NRC Regarding Part 53

Introduction

For over a year, since the rulemaking effort began, the Nuclear Energy Institute (NEI), the U.S. Nuclear Industry Council (USNIC), and our members, key stakeholder organizations, have been engaging with the U.S. Nuclear Regulatory Commission (NRC) staff, and have promptly identified our concerns and recommendations to the staff. We have anticipated constructive dialog and evolution of Part 53 toward the framework that is needed to enable the timely, efficient, and cost-effective deployment of the next generation of reactors to meet our nation's carbon reduction goals.

This Attachment C lists key submissions we have made to the NRC on Part 53 as active Stakeholders. Most documents were posted on the NRC web site, and any of these documents can be sent to NRC staff by contacting Marc Nichol at NEI at mrn@nei.org, or Cyril Draffin at USNIC at cyril.draffin@usnic.org. In addition, individuals at companies that are developing advanced nuclear reactors, most of which are NEI or USNIC members, have submitted input to the NRC on Part 53 preliminary rule language and approach NRC has been taking.

U.S. Nuclear Industry Council Submissions (from October 2019 to October 2021)

Key documents submitted to NRC

1. "*U.S. Nuclear Industry Council Comments on NRC's Rulemaking on "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors" (RIN-3150-AK31; NRC2019-0062)"* 15 July 2021 letter. Topics: stakeholder engagement, results of USNIC survey on Part 53, lack of roadmap and clarity on expectations of safety, perspective on rule development, key stakeholder input on topic of interest within the current Part 53 language (ALARA, QHOs, Quality Assurance, Subpart F, Decommissioning, Defense in Depth, Two Tiers, Reasonable Assurance of Adequate Protection) and going forward. Comment 055 of Cyril Draffin) (ML21196A499)
2. "*Unified Industry Position on the NRC's Rulemaking on "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors" (RIN-3150-AK31; NRC-2019-0062)*," Letter from D. True, et. al. to NRC J. Tappert, July 14, 2021. Topics include: Usefulness, Efficiency, Technology-inclusive, Risk-informed, Recognize Confidence in Licensee Controls, and Urgency. (ML21196A498)
3. "*U.S. Nuclear Industry Council (USNIC) Comments NRC Advisory Committee on Reactor Safeguards (ACRS) Future Plant Designs Subcommittee Meeting Preliminary Rule 10 CFR Part 53"* 17 March 2021, submitted 23 March 2021 by Cyril Draffin. Topics: Goals for Part 53, NEIMA expectations and objectives, rulemaking process, Adequate Protection Standard, Dose Consequence-Based Performance, Development and Application of Risk Insights, Evaluating Defense in Depth Adequacy, Quality Assurance (NRC-2019-0062-0065); (ML21083A151)
4. *"U.S. Nuclear Industry Council (USNIC) suggested update to Part 53 NRC Preliminary Language, with Discussion (2021-02-03)"* Preliminary language for "Subpart B - Technology-Inclusive Safety Requirements " table with NRC preliminary language, USNIC revised preliminary language, and discussion, 3 February 2021. Topics; § 53.200 to 53.260. (ML21035A003)

Attachment C

NEI and USNIC Prior Submissions to NRC Regarding Part 53

Additional presentations at NRC Part 53 meetings, NRC Stakeholder meetings, Advisory Committee on Reactors Safeguards meetings; and submissions to Regulations.gov

1. *"U.S. Nuclear Industry Council Comments for NRC Part 53 Public Meeting: Alternative Requirements for Commercial Nuclear Plants"* Cyril Draffin (slides 17-35), 28 October 2021 (ML21295A245)
2. *"U.S. Nuclear Industry Council Comments for NRC Part 53 Public Meeting: Subpart F: Operations - Staffing, Training, Personnel Qualifications (Licensing/Certification), and Human Factors*, Cyril Draffin (slides 31-34) 26 October 2021 (ML21295A241)
3. *Results of USNIC 2021 Advanced Nuclear Survey* (Cyril Draffin and Jeff Merrifield, slides 16-84), 26 August 2021 Stakeholders Meeting. Topics directly addressing Part 53: Importance, date needed, usefulness, delay, PRA, QHO, LMP, which Part to use (slides 24-37, with slide 32 addressing range in way PRA to be used) (ML21237A463)
4. *"U.S. Nuclear Industry Council (USNIC) Comments, NRC Advisory Committee on Reactor Safeguards (ACRS) Meeting, Future Plan Designs Subcommittee, Preliminary Rule 10 CFR Part 53",* Verbally by Cyril Draffin with submitted hard copy, 20 May 2021
5. *"U.S. Nuclear Industry Council Comments for NRC Part 53 Public Meeting Subpart A: Definitions and Subpart F Programs"* 6 May 2021, Cyril Draffin verbal comments
6. *"U.S. Nuclear Industry Council (USNIC) Comments, NRC Advisory Committee on Reactor Safeguards (ACRS) Meeting, Preliminary Rule 10 CFR Part 53",* Cyril Draffin, 05 May 2021
7. *"U.S. Nuclear Industry Council (USNIC) Comments, NRC Advisory Committee on Reactor Safeguards (ACRS), Future Plant Designs Subcommittee Meeting, Preliminary Rule 10 CFR Part 53",* Cyril Draffin, 22 April 2021 (NRC-2019-0062-0083)
8. *"U.S. Nuclear Industry Council Comments for NRC Part 53 Public Meeting"*, 08 April 2021. Topics: Human-System Consideration (Cyril Draffin, slide 42-44) Subpart B: Safety Requirements (Cyril Draffin and Jeff Merrifield, slide 63-74), Subpart C: Design and Analysis Requirements including PRA(Cyril Draffin and Dennis Henneke, slide 82-89), Subpart E: Construction and Manufacturing (Cyril Draffin and Steve Schilthelm, slide 101-104), Key Guidance (ML21088A279)
9. "*U.S. Nuclear Industry Council Comments for NRC ACRS Part 53 Meeting"* Cyril Draffin and Peter Hastings, 17 March 2021, to Advisory Committee on Reactor Safeguards (ACRS) Future Plant Designs Subcommittee 10 CFR Part 53 "Licensing and Regulation of Advanced Nuclear Reactors." (slides 19-30) Topic: General Discussions and Preliminary Proposed Rule Language
10. *"U.S. Nuclear Industry Council Comments for NRC Stakeholders meeting: Construction Permit Guidance"* Stakeholders meeting 25 February 2021, Cyril Draffin, Jeff Merrifield, Jeff Hawkins, Travis Chapman (slides 32-46)
11. *"Comments regarding Part 53",* Cyril Draffin, 22 February 2021 (NRC-2019-0062-0049)
12. *"U.S. Nuclear Industry Council Comments for NRC Part 53 Meeting"* 04 February 2021. Topics: Goals and Success Criteria (Cyril Draffin and Jeff Merrifield, slides 14-15), Key Concepts and Possible Structures (Cyril Draffin, Jeff Merrifield, Frank Akstulewicz, Dennis Henneke, Travis Chapman, Rebecca Norris, Ross Moore, slides 19-33), Approach to Rule language (Cyril Draffin and Jeff Merrifield, slides 43-44), Rule Language (Cyril Draffin and Jeff Merrifield, slides 48-49), Subpart D Siting Requirements (Cyril Draffin and Jeff Merrifield, slides 80-84). (ML21032A045)
13. *"U.S. Nuclear Industry Council Comments for NRC Part 53 Meeting: Section B (Technology-Inclusive Safety Requirements)"* 07 January 2021. Topics: Introductory Comments and Subpart C (Cyril Draffin, Jeff Merrifield, Steve Nesbit, slides 21-29), Subpart F (Cyril Draffin and Jeff Merrifield, slides 38-40), Subpart B: Technology-Inclusive Safety Requirements (Frank

Akstulewicz, Dennis Henneke, Rebecca Norris, Travis Chapman, Ross Moore, slides 46-54). (ML21006A000)

14. *"U.S. Nuclear Industry Council Comments regarding Part 53 at NRC Part 53 Rulemaking Meeting"* 18 November 2020. Topics: Rulemaking Strategy & Schedule (Cyril Draffin, slides 16-21), Safety Requirements (Cyril Draffin, slides 47-53). (ML20318A007)
15. *Comments regarding "10 CFR Part 53 "Licensing and Regulation of Advanced Nuclear Reactors"* Cyril Draffin, 22 September 2020.. Topics: Safety Criteria and Risk Metrics (slide 17), Life Cycle of a Facility (slide 21), QA (slide 24), Integration of various Requirements and Programs (slide 29), Initial licensing and throughout life cycle (slide 45), Perspective and Scope (slides 48-54) (ML20254A014)
16. *"U.S. Nuclear Industry Council Comments regarding Part 53 at NRC Stakeholders Meeting"* Cyril Draffin (5 slides) 20 August 2020
17. "10 CFR Part 53: Ideas for Risk-informed, Technology Inclusive Regulatory Framework for Advanced Reactors Rulemaking" Jeffrey Merrifield (17 slides), October 10, 2019

Nuclear Energy Institute Submissions (from August 2020 to October 2021)

Formal Comments and Papers Submitted to NRC

1. "*NEI Paper on Licensing Approaches for the NRC's Rulemaking on, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062),"* Letter from D. True to NRC M. Doane, September 28, 2021. Topic is on risk-informed licensing approaches and options to more efficiently make Part 53 inclusive to all licensing approaches. Attached NEI September 2021 White Paper *"Technology-inclusive, Risk-informed, Performance-based Approaches for Development of Licensing Bases Under Part 53."*
2. "*NEI Comments on the Preliminary Language for the Physical Security and Cyber Security Requirements included in the Proposed Risk-Informed, Technology Inclusive Regulatory Framework for Advanced Reactors Rule*," Letter from M. Nichol to NRC J. Tappert, August 31, 2021. Topics include: Physical Security, Cyber Security, Fitness for Duty and Access Authorization. (ML21244A331)
3. "*NEI Paper on Manufacturing License Considerations for Part 53, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062),"* Letter from M. Nichol to NRC K. Coyne, July 16, 2021. Topic: Subpart E, Manufacturing Licenses. Attached NEI July 2021 White Paper, "*Proposed Approach for Manufacturing License Requirement in 10 CFR PART 53."* (ML21197A103)
4. "*Unified Industry Position on the NRC's Rulemaking on "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors" (RIN-3150-AK31; NRC-2019-0062)*," Letter from D. True, et. al. to NRC J. Tappert, July 14, 2021. Topics include: Usefulness, Efficiency, Technology-inclusive, Risk-informed, Recognize Confidence in Licensee Controls, and Urgency. (ML21196A498)
5. "*Industry's Concerns about NRC Proposed Approaches to Part 53, and Alternative Discussion Draft for the NRC's Rulemaking on, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)*," Letter from M. Nichol to NRC J. Tappert, February 11, 2020. Topics include: Regulatory Functions, Safety Criteria and Safety Paradigm, Role of Probabilistic Risk Assessment (PRA), Performance-based safety, security, siting and emergency preparedness, Organization of documentation and technical requirements, Level of detail in regulations and use of guidance, Relationship with Part 50 and 52 licensing processes. Attachment 1 proposed a discussion

draft of Part 53 rule language that would better meet the vision and goals for Part 53. Attachment 2 provided details on topics such as: Safety Objectives and Two-Tier Criteria, ALARA, Overall Safety Construct, Occupational Exposures, Quantitative Health Objectives, Quantitative Frequencies, Probabilistic Risk Assessments, Defense-in-Depth, Siting, Facility Safety Program, Addressing Uncertainties, General Design Criteria, and Performance-based Language. (ML21042B889)

6. "*NEI Input on the NRC Rulemaking on, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)*," Letter from M. Nichol to NRC J. Tappert, December 23, 2020. Topics include: Success Criteria (a.ka., Project Requirements), Safety Criteria, Overall Safety Construct, ALARA, Occupational Exposures, Performance-Based Language, Administrative Requirements, Quantitative Frequencies, Beyond Design Basis Events, Addressing Uncertainties and General Design Criteria. (ML20363A227)
7. "*NEI Input on the NRC Rulemaking Plan on, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)*," Letter from M. Nichol to NRC J. Tappert, October 21, 2020. Topics include: Well Defined Vision and Objectives for the Final Rule, Systematic Approach to the Rulemaking, and Predictable and Meaningful Stakeholder Interactions. (ML20296A398)

<u>Presentations at NRC Meetings</u>

1. "*Change Control – 53.1322*," M. Nichol, September 15, 2021.
2. "*Part 53 Programs*," M. Nichol, September 15, 2021.
3. "Role of the PRA," M. Nichol, August 26, 2021.
4. "*Manufacturing Licenses*," M. Nichol, June 10, 2021, at NRC Part 53 meeting (starting slide 62)
5. *"Part 53 Graded Approach to PRA,"* M. Nichol, May 27, 2021.
6. *"Part 53,"* M. Nichol April 8, 2021. Part 53 meeting. Topics: Subpart C (slide 75), Subpart E: Construction and Manufacturing
7. *"Part 53 Rulemaking – NRC ACRS Meeting,"* M. Nichol, March 17, 2021. Topics includes: Vision and Goals, Fundamentals of Part 53, NEI Discussion Draft – Alternative Part 53 Rule Language, Safety, Design and Analysis, High-Level rule language, ALARA, Security, Siting, Quality Assurance, Probabilistic Risk Assessment, Defense in depth, Quantitative Health Objectives, Quantitative Frequencies, and Facility Safety Program.
8. "*Construction Permit Guidance*" (NEI slides 18-31, Stakeholders meeting), February 25, 2021
9. *"Part 53 Rulemaking,"* M. Nichol, 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)
10. *"Part 53 Rulemaking,"* M. Nichol, 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)
11. *"Part 53 Rulemaking,"* M. Nichol November 18, 2020. Topics include: Safety Criteria, Safety Objectives and AEA Standards, ALARA, Safety Paradigm. (ML20318A007, slides 37-45)
12. "*Part 53 Rulemaking*," M. Nichol, August 20, 2020.