Stakeholder Consensus on Proposed Part 53 Major Topics

February 24, 2025

The NRC is developing a new licensing framework for commercial nuclear reactors, as mandated by the Nuclear Energy Innovation and Modernization Act. It published a draft rule in the Federal Register Notice 89 FR 86918 in October 2024 (NRC–2019–0062, RIN 3150–AK31 "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors"). Stakeholders, NRC staff, Commissioners, and members of Congress paid particular attention to several topics and specific requests for comments in the draft. There is broad consensus among engaged stakeholders on major topics that the NRC staff should revise in the final Part 53 rule.

Introduction

In 2019, Congress passed the Nuclear Energy Innovation and Modernization Act (NEIMA), mandating that the Nuclear Regulatory Commission (NRC) establish a technology-inclusive licensing framework for advanced reactors. In response, the NRC developed new regulations under the proposed Title 10 of the Code of Federal Regulations Part 53 (Part 53) to fulfill NEIMA's directive.

The Commission approved the Part 53 rulemaking plan in October 2020 (SECY-20-0032). Following extensive stakeholder engagement, which concluded on August 31, 2022, NRC staff submitted the draft proposed rule to the Commission on March 1, 2023 (SECY-23-002). The Commission partially approved the draft proposed rule on March 4, 2024 (SRM-SECY-23-0021), with additional clarifications and exceptions. During this process, Congress enacted the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024 (ADVANCE Act), signed into law on July 9, 2024, further reinforcing the need for regulatory modernization to support advanced nuclear deployment. On October 31, 2024, the NRC published the proposed Part 53 rule in the Federal Register for public comment (Docket ID NRC-2019-0062).

Stakeholders still have concerns about the current draft of Part 53. Fifteen organizations participated in a workshop consensus process that culminated in this document. Participants included non-governmental organizations, government agencies, national laboratories, consultants, technology developers, and industry groups. Our efforts included expert elicitation, two focused workshops, and three individual breakout sessions, where key regulatory issues were identified and discussed in depth.

This comment focuses on select aspects of the proposed Part 53 rule where there was strong stakeholder consensus on changes or clarifications. We do not provide input on every provision for several reasons. In some cases, there was insufficient time to fully assess the implications of certain provisions. In other areas, key stakeholders—including non-governmental organizations, industry organizations and national laboratories—are submitting detailed, standalone comments. Additionally, some topics did not generate a clear consensus. As a result, this comment prioritizes the most critical regulatory issues identified in our extensive consultations. Many stakeholders will submit comments that reference this comment and further expand on or provide further basis for the recommendations in this comment. Some participants expect to directly endorse this comment, while others are unable to due to organizational policies.

From this engagement, we have identified broad stakeholder consensus on several key areas. In no particular order, the following tables present stakeholder perspectives and recommended changes to ensure Part 53 better aligns with NEIMA's intent.

Outcome and Endorsements

Stakeholders approached the topics discussed from different perspectives; however, their respective reasoning converged to a consensus on multiple topics without major objections. Consensus represents general agreement, although unanimous agreement was achieved on almost every topic. The following sections provide brief context along with the consensus perspective on key regulatory issues.

The following organizations and individuals are signatories to this comment:

- **The Breakthrough Institute**
- **Nuclear Innovation Alliance**
- **N. Prasad Kadambi, Ph.D., P.E.**

Additional stakeholders may reference this comment or provide further basis for its recommendations in their own submissions.

Table 1. Specific Request for Comment – Part 53, Subparts C and D—Earthquake Engineering

Affected Section	Comment/Basis	Recommendation
1. Proposed § 53.480 would establish requirements related to seismic design considerations.	*Specific Request for Comment: The NRC is seeking comment on whether the proposed requirements for earthquake engineering provide appropriate flexibility in addressing seismic risks while also ensuring that the regulations continue to adequately address seismic hazards. Please provide your considerations and rationale for your recommendation.* Limiting the scope of § 53.480 to safety-related structures, systems, and components (SR SSCs) aligns with existing NRC frameworks, enhances regulatory efficiency, and ensures that seismic risk management remains risk-informed and performance-based. This approach provides necessary flexibility while maintaining safety and supporting the licensing of advanced reactors, including microreactors, in accordance with the ADVANCE Act. The Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy (ADVANCE) Act of 2024 emphasizes streamlined licensing and siting requirements for microreactors, including flexible approaches to seismic analysis. Additional guidance may be needed to support applicants in demonstrating compliance	Limit the scope of 53.480 to safety-related structures, systems, and components (SR SSCs). The NRC should ensure § 53.480 is consistent with the ADVANCE Act's goals by incorporating graded approaches for seismic design, particularly for microreactors where traditional seismic standards may be overly restrictive.

Affected Section	Comment/Basis	Recommendation
	through a graded approach. Items like USGS seismic data and alternative sources are examples of acceptable methods for seismic hazard assessment, expanding options for advanced reactor developers.	

Table 2. Specific Request for Comment – Part 53, Subpart F—Emergency Preparedness and Security Programs

Affected Section	Comment/Basis	Recommendation
1. The proposed framework for part 53 would incorporate the changes to NRC regulations from the final rulemaking on "Emergency Preparedness for Small Modular Reactors and Other New Technologies" (the EP for SMR/ONT rule) by including references to § 50.160, "Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities," and by making conforming changes within § 50.160. a. The proposed framework for part 53 would also introduce a graded approach to physical protection requirements that includes the criterion in § 53.860(a)(2)(i) to	*Specific Request for Comment: The NRC is seeking comment on the sufficiency and clarity of requirements in proposed part 53 related to the assessments needed to support graded emergency planning and security. If a comment indicates that there is an issue with the sufficiency or clarity of the proposed regulations, please describe the reasons why, including, if applicable, any scenario for which the proposed regulations are not sufficient and possible ways to clarify the requirements.* *Specific Request for Comment: The NRC is specifically seeking comment on possible challenges arising from the interactions between the proposed regulations and related*	There are opportunities to further risk-inform 50.160, particularly related to the evaluation of changes to the emergency plan. This does not affect the clarity of Part 53 directly, but is an opportunity to further risk-inform the rule in the spirit of NEIMA and the ADVANCE Act, beyond what may have been possible in the deterministic Part 50 framework. 1. Modify 10 CFR 50.160 and 10 CFR 53.855 to be technology-inclusive and enable mobile reactors. 2. Clarify the definition of "commercial operation" to align with the operational

Affected Section	Comment/Basis	Recommendation
establish a class of licensees that would not be required to protect against the design-basis threat (DBT) of radiological sabotage.	*assessments for grading the requirements for emergency planning and security.* 50.160(c)(2) is not sufficiently technology-inclusive to meet the mandate of NEIMA. It requires that an emergency exercise be conducted prior to initial fuel loading. This is in conflict with deployable reactors, particularly microreactors, that may have fuel loaded and operation tested prior to transportation to the intended site. SECY-24-0008 and other NRC documents provide background on this concept. 50.160 does not provide sufficient flexibility for reactors that may be mobile or re-deployable. It is unclear how emergency preparedness should be addressed for reactors that are on mobile platforms. One example are ships that use a reactor for propulsion and power. Ships that are powered by a reactor could visit many ports. The use of "initial" in the existing version of 50.160 was intended to avoid confusion that a licensee must show compliance before each fuel loading, but may be overly limiting for reactors that could ultimately operate in more than one location. The result could be similar to the use of "initial" in relation to license renewals that had to be removed. The NRC historically considers fuel loading as the point of commercial operation, which	realities of microreactors and factory-fueled transportable reactors. *50.160(c)(2) - A holder of a combined license issued under part 52 of this chapter before the Commission has made the finding under § 52.103(g) of this chapter, must establish, implement, and maintain an emergency preparedness program that meets the requirements of paragraph (b) of this section, as described in the approved emergency plan and license, and conduct an initial exercise to demonstrate this compliance within 2 years before the scheduled date for ~~initial loading of fuel~~ power production. [as written in the existing 50.160]* 3. Revise the requirement for two independent physical mechanisms to prevent criticality (as drafted in this proposed rule) to allow for technology-inclusive approaches without impacting protection. 4. Revise existing guidance to clarify how uncertainty should be considered for risk-informed decision-making. 5. Provide further clarity that 1-rem is not a strict threshold. The spectrum of events, along with protective actions, should be considered to determine appropriate emergency preparedness.

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	does not align with advanced reactor deployment models. For transportable microreactors, commercial operation should be defined as the generation of electricity, process heat, or other usable energy at the intended deployment site, not at the point of initial fueling. Removal of physical mechanisms to prevent criticality in fueled manufactured reactors may occur during initial testing at the manufacturing facility. The version of 50.160 in the proposed rulemaking does not adequately address these concerns. The recommended clarification ensures consistent regulatory treatment across different reactor technologies and prevents unnecessary constraints on innovative deployment models. Part 53 also introduces a stricter requirement for two independent physical mechanisms to prevent inadvertent criticality, which goes beyond established NRC regulatory precedent and consensus standards. Existing criticality safety standards (e.g., ANSI/ANS-19.13) already provide adequate protection and align with defense-in-depth (DID) principles. The justification provided by NRC staff for this stricter requirement is overly broad and does not align with risk-	

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	informed, performance-based (RIPB) principles. Security events are not part of the design basis licensing. Significant security events should be considered relative to protective actions for risk insights and defense in depth. Consideration and planning for these events do not necessitate being bound to a 1-rem threshold. The NRC has already approved bounding events in the Decommissioning Rulemaking that exceed a 1-rem threshold with a site boundary emergency planning zone. The proposed changes will improve regulatory clarity, ensure consistency with existing safety principles, and remove barriers to innovation in advanced nuclear technology.	
2. DG-5076, "Guidance for Technology-Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants," ; The NRC is also planning to issue a draft revision of RG 1.242, "Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities,"	*Specific Request for Comment: The NRC is interested in comments on the need for additional rule language or guidance to address graded approaches for emergency planning and security programs under the scenarios described for part 53 applicants and licensees:* *In developing comments, the NRC urges stakeholders to consider various scenarios that might arise when implementing graded approaches for security and emergency planning for various reactor designs:*	Additional guidance to address graded approaches for emergency planning and security programs under the scenarios described for part 53 applicants and licensees is needed. Revisions should be made to guidance to clarify that the spectrum of events should be categorized to potential offsite impacts and evaluated against protective actions as appropriate.

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	• *The potential consequences from security events up to and including the DBT of radiological sabotage are bounded by unlikely and very unlikely event sequences such that security events do not need separate analyses in the EPZ size determination;* • *The potential consequences from security events up to and including the DBT are not bounded by unlikely and very unlikely event sequences but could otherwise support a reduced EPZ size consistent with considerations discussed in RG 1.242 and NUREG-0396, "Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants"; or* • *The potential consequences from security events up to and including the DBT are not bounded by unlikely and very unlikely event sequences and warrant consideration of increasing the size of the EPZ.* To facilitate the implementation of a truly risk-informed, performance-based framework under Part 53, NRC should provide additional guidance as needed on applying graded emergency planning and security approaches. This balances regulatory flexibility in the rule language while providing applicants clarity. Any new or updated guidance should account for varying reactor technologies, deployment models, and security risks while maintaining a	Clarify that the existence of sequences that have the potential for offsite consequences is not a direct indicator that a reduced-size EPZ is not appropriate. A reduced-size EPZ is based on risk insights and the potential for protective actions to mitigate consequences, not based on a strict dose threshold. Significant security events, up to the DBT, should be considered relative to protective actions for risk insights and defense in depth.

Affected Section	Comment/Basis	Recommendation
	predictable and transparent regulatory framework. Significant security events, up to the DBT, should be considered relative to protective actions for risk insights and defense in depth. Consideration and planning for these events does not remove the potential for a reduced size EPZ, or necessitate being bound to a 1-rem threshold. The NRC has already approved bounding events in the Decommissioning rulemaking that exceed a 1-rem offsite dose with a reduced-size emergency planning zone.	

Table 3. Specific Request for Comment – Part 53, Subpart F—Integrity Assessment Program Requirements

Affected Section	Comment/Basis	Recommendation
1. The NRC is proposing to include a new set of programmatic requirements for an Integrity Assessment Program that would ensure these phenomena are addressed early in the life of a commercial nuclear plant licensed under part 53. The requirements would be provided in § 53.870.	*Specific Request for Comment: The NRC is seeking comment on whether the proposed requirements under the Integrity Assessment Program appropriately complement design requirements to address concerns regarding aging, cyclic or transient load limits, and degradation mechanisms related to chemical interactions, operating temperatures, effects of irradiation, and other environmental factors. In addition, the NRC is interested in*	Staff should remove the proposed integrity assessment program (§ 53.870) from the regulatory text.

Affected Section	Comment/Basis	Recommendation
	views on whether, and if so how, degradation mechanisms are or could be addressed in other programs. The proposed Integrity Assessment Program aligns with precedent set in 10 CFR Part 50.65 (Maintenance Rule), which requires monitoring of SSC functionality to address aging and performance degradation. The proposed Integrity Assessment Program risks duplicating existing processes, such as the Reliability Integrity Management Expert Panel, the LMP Integrated Decision Panel (LMPIDP), and the SFCP IDP. These panels already address aging, degradation mechanisms, and design reliability, creating potential overlap and inefficiency. Additionally, over the course of the public meetings held on the proposed Part 53 rule, NRC staff gave verbal feedback that applicants could use RG 1.246. That being said, staff should address integrity assessment programs in existing and potential future guidance for cases where an applicant's risk evaluation indicates a need for such a program.	

Table 4. Specific Request for Comment – Part 53, Subpart G—Decommissioning

Affected Section	Comment/Basis	Recommendation
1. SECY-24-0011, "Final Rule: Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning (3150-AJ59; NRC-2015-0070)."	*Specific Request for Comment: What aspects of this draft final rule, if any, should be incorporated in a part 53 final rule and why?* The NRC has acknowledged the need for a more technology-inclusive decommissioning framework. Delaying the incorporation of these updates into Part 53 contradicts that objective and may create unnecessary regulatory uncertainty for advanced reactor developers. The decommissioning proposed rule, which has been in the works since 2014, includes much-needed changes to the current regulations. Those changes should be incorporated in Part 53. Incorporating these updates into Part 53 should not slow down the ongoing decommissioning rulemaking (SECY-24-0011). Rather, it ensures that Part 53 reflects the latest regulatory thinking without unnecessary delays.	We agree with the NRC approach of modifying current decommissioning requirements to be more technology inclusive. We concur that site-specific decommissioning cost estimates will be needed, at least initially, for advanced reactor technologies. The NRC should include the March 3, 2022 proposed changes to decommissioning regulations in the proposed Part 53. The NRC's proposal is to "consider" future revisions to Part 53 to align the regulations. Instead, the NRC should incorporate those much-needed changes now, and revise Part 53 in the future if the need for further alignment emerges. The inability of the NRC to process the ongoing decommissioning rulemaking for current reactors in a timely manner is not an acceptable rationale for including outdated and inefficient decommissioning requirements in the new advanced reactor regulation.
2. Proposed § 53.1060(b) in subpart G would require that, "No later than 30 days after the Commission publishes notice in the Federal Register under § 53.1452(a), the licensee must submit a report containing a	*Specific Request for Comment: The NRC is seeking comment on whether commercial nuclear plant COL holders under part 53 should have the same requirement as COL*	It is acceptable that COL holders under Part 53 have the same requirements as COL holders under Part 52. This is another reason for the NRC to consider making Parts 50/52 to be transferable to Part 53.

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certification that financial assurance for decommissioning is being provided in an amount specified in the licensee's most recent updated certification, including a copy of the financial instrument obtained to satisfy § 53.1040." *This is similar to the current requirement in § 50.75(e)(3) for part 52 COL holders.*	*holders under part 52 to demonstrate that they have financial assurance in place no later than 30 days after the Commission issues the notice of intended operation under § 53.1452.* Aligning financial assurance requirements between Part 52 and Part 53 ensures a stable and predictable regulatory framework for licensees, preventing unnecessary discrepancies between licensing pathways. Demonstrating financial assurance within 30 days of the notice of intended operation helps ensure that COL holders have the necessary resources to support safe operation and eventual decommissioning, mitigating financial risk to the NRC and the public. It may be more appropriate to require financial assurance within 30 days of initial fuel loading. However, as discussed in other sections of this comment, that may not be technology-inclusive as it relates to mobile or re-deployable reactor concepts. Allowing the transferability of Parts 50/52 to Part 53 would streamline regulatory processes, reducing unnecessary burdens on applicants while maintaining essential safety and financial oversight. This approach supports a flexible and efficient licensing regime for advanced reactors.	

Table 5. Specific Request for Comment – Part 73, Section 73.100—Physical Security

Affected Section	Comment/Basis	Recommendation
1. Proposed § 73.100 and implementing guidance in DG-5076 (proposed RG 5.97), "Guidance for Technology Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants."	*Specific Request for Comment: Does the NRC's proposed approach in § 73.100 provide a sufficient level of detail to be readily understood and easily applied to the licensing and oversight of new and advanced power reactors, or should the NRC consider moving some objective and measurable security performance standard recommendations from the draft implementing guidance in DG-5076 into proposed § 73.100? If so, which objective and measurable security performance standard recommendations should be moved from DG-5076 to § 73.100?* Keeping objective and measurable security performance standards in DG-5076 rather than codifying them in §73.100 allows for more adaptable implementation, ensuring the NRC can update guidance as needed without requiring formal rulemaking. Similar security provisions exist in §73.55(s)(2)(ii)(A)(4), and §73.100 provides sufficient detail for licensing and oversight. Ensuring consistency in terminology (e.g., "Reasonable Assurance" vs. "High Assurance") across NRC regulations will improve clarity and reduce confusion.	Yes, § 73.100 provides a sufficient level of detail to be readily understood and easily applied to the licensing and oversight of new and advanced power reactors. Leave objectives and standards in implementing guidance. Make any necessary revisions to DG-5076 to ensure it applies to Part 53.

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	The decision to keep standards in DG-5076 aligns with NRC's broader approach to security rulemaking. Given staff's focus on §73.100, necessary updates to DG-5076 should ensure its applicability to Part 53 while maintaining consistency with existing security frameworks.	

Table 6. Specific Request for Comment – Part 73, Section 73.110—Cybersecurity

Affected Section	Comment/Basis	Recommendation
1. Proposed § 73.110. a. Under proposed § 73.110(a), licensees would need to ensure that digital computer and communications systems are adequately protected against a potential cyberattack that would, for example, result in adverse impacts to the physical security digital assets used by the licensee to prevent unauthorized removal of material per § 53.860(a). b. Detailed implementing guidance in DG-5075 (proposed RG 5.96), "Establishing Cybersecurity Programs for Commercial Nuclear Plants licensed under 10 CFR part 53,"	*Specific Request for Comment: If a cyberattack were to compromise the availability, integrity, or confidentiality of data or systems associated with security systems/measures for the protection of SNM at a commercial nuclear reactor licensed under part 53, do the potential consequences warrant requiring cybersecurity for such material?* Given the critical importance of safeguarding Special Nuclear Material (SNM) and the potential consequences of a cyberattack on security systems, it is imperative to require robust cybersecurity measures to protect these systems. A compromise in the availability,	In Rule Text (§ 73.110): The rule should focus on broad, high-level performance objectives to maintain flexibility across different reactor designs and technologies. The language would outline the general requirement for cybersecurity protections without specifying how to achieve them, ensuring it remains applicable to all future reactor types. This would provide a flexible, high-level mandate that applies to a range of technological solutions and reactor types without becoming prescriptive. **In Guidance (DG-5075 or similar):** The implementing guidance (such as DG-

Affected Section	Comment/Basis	Recommendation
would be available to assist applicants and licensees.	integrity, or confidentiality of data or systems related to security could lead to significant risks, including unauthorized removal of SNM or breaches in the facility's physical security, which could have severe national security, environmental, and public safety implications. As such, the NRC should require a cybersecurity framework for systems and digital assets responsible for the physical protection of SNM. The NRC can, and must, do this in a risk-informed, performance-based, and technology-neutral way within the final Part 53 rule. By housing the more specific technical details in guidance rather than rule text, the NRC ensures that the rule remains flexible and RIPB, while still providing sufficient clarity for stakeholders on how to meet the cybersecurity performance objectives. This structure allows for future technological advancements and reactor designs to adapt to emerging threats without the need for frequent regulatory updates.	5075) would provide the technical details and measurable performance standards to support the rule's high-level requirements. The guidance would outline specific actions and strategies that licensees could implement to meet the cybersecurity objectives of § 73.110.

Table 7. Specific Request for Comment – Part 53, Subpart B—Comprehensive Risk Metrics

Affected Section	Comment/Basis	Recommendation
1. Subpart B—Comprehensive Risk Metrics	*Specific Request for Comment: The NRC is seeking comment on the use of comprehensive risk metrics and associated risk performance objectives in part 53 as one of several performance standards. The IEFR and ILCFR and the QHOs represent comprehensive risk metrics and associated risk performance objectives that the NRC has used for decades in a variety of capacities. What other performance standards could be used to address the comprehensive risks posed by proposed commercial nuclear plants?* Comprehensive risk metrics and associated risk performance objectives have the potential to improve the process and outcomes of a risk-informed, performance-based licensing framework. However, applicants need clear guidance from NRC to create and define their own comprehensive risk metrics (CRMs). NRC needs to clarify the proposed requirements for applicant-defined CRM and associated risk performance objectives in Part 53 to avoid creating regulatory uncertainty. NRC's existing risk metrics took significant time to develop, are based on decades of operating experience, and require buy-in from the Commission, NRC management and staff, applicants, and external stakeholders before use. Clarity on the conditions for NRC approval of applicant-defined risk metrics is needed. Without clear guidance on CRMs, the requirement will create a barrier for applicants	Revise the terminology from a Comprehensive Risk Metric (CRM) to a Comprehensive Safety Metric (CSM) to emphasize that the purpose of the metric is to evaluate the overall safety of the facility. This will also help emphasize that applicants have flexibility in how they meet safety objectives and that the NRC takes an integrated view of the effects of all regulatory requirements on overall plant safety rather than prescribing a specific metric or methodology (e.g., QHOs and PRA). This includes both qualitative and quantitative evaluations of safety. Specific recommendations related to CRMs include: 1. Revise the terms associated with CRMs. Define a "Comprehensive Safety Metric" (CSM) for the figure of merit that will be assessed during licensing and "Comprehensive Safety Assessment" (CSA) for the methodology used to evaluate and demonstrate compliance with the figure of merit. 2. Clarify in the preamble the relationship between existing NRC risk objectives, CSM, and CSA to clarify the basis for assessing and evaluating comprehensive risk while ensuring that CSMs are not the sole basis for regulatory decision-making. 3. Emphasize that the overall goal of CSM is to help ensure the outcome of "adequate

Affected Section	Comment/Basis	Recommendation
	compared to existing licensing frameworks or force applicants to default to existing metrics. It is important that the preamble and rule are clear and consistent in relation to the definition and use of the term “risk” in the context of safety, and NRC expectations of appropriate levels of risk. The comprehensive risk metrics enable quantitative assessment of the “total, overall risk from the facility” and the associated risk performance objectives. The preamble and proposed rule mixes regulatory terminology related to risk. The proposed rule is not clear or consistent in relation to expectations of levels of risk, using multiple terms, including “appropriate” levels of risk, “overall” risk, and “acceptable” risk. Clarity on these definitions of risk is important for applicants and staff to understand how to develop and use comprehensive risk metrics. Part 53 introduces new requirements for applicant evaluation of plant risks that differ and are not analogous to the existing regulatory requirements in Part 50 or 52 that do not utilize a comprehensive metric of overall risk. The use of quantitative risk requirements as the licensing basis in Part 53 is a fundamental change that reflects a different regulatory approach to consideration of licensing evaluations and different	protection of public health and safety" as the key figure of merit when evaluating existing or proposed metrics. 4. Enable applicant definition and use of CSM that do not increase regulatory burden (e.g., align with accepted industry practices for safety and risk evaluations completed during design) and allow applicants to select metrics (e.g., QHOs, CDF, LERF) and evaluation methodologies (e.g., PRA, AERI) that meet the overall intent of the CSM. 5. Remove explicit references to QHOs in the rule text to prevent QHOs from becoming a de facto regulatory requirement that requires applicant compliance or demonstrated equivalence with the QHOs. QHOs should, however, still be an acceptable option for applicants who choose to use them as their CSM. 6. Revise rule text (e.g., 53.220) to focus on applicant completion of an "Integrated Safety Assessment" rather than mandating specific evaluation methodologies (e.g., PRA) be used when demonstrating the overall safety of a facility. Substantially more interaction on this topic (i.e., beyond the proposed rule comment period) is necessary and supported by the Commission in SRM-SECY-23-0021 to ensure both staff and external stakeholders' understanding of the development, use, and

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	regulatory requirements. The preamble to Part 53 states that a "comprehensive risk metric or set of metrics with associated risk performance objectives is not, by itself, an indicator of "adequate protection." It is important that the discussion and application of CRMs in Part 53 reflect the position that the CRM is one tool to help characterize plant safety. The NRC Safety Goals, including the QHOs, which have been previously used to derive quantitative risk metrics, are not intended to serve as the sole basis of licensing decisions but can enable NRC to quantify levels of "acceptable risk" and the regulatory basis for "safe enough." The challenge of the CRM in the current proposed rule is that the CRM could become interpreted as a risk-based requirement instead of a performance-based requirement. If the CRMs are used as the only metric for an appropriate level of risk, it may become unclear what additional protection is required outside a comprehensive evaluation of safety that includes all other regulatory requirements in the framework. This risks creating contradicting interpretations of acceptable safety within Part 53 if not clearly implemented by applicants and staff. A broader evaluation of plant safety that encompasses the intent of the CRM should be used to indicate that the evaluation of a	implementation of CSM. Without additional interaction and guidance on CSM, it is not clear if this requirement will function as intended, or if the requirement will functionally limit the usefulness of the licensing framework due to uncertainty on use between applicants and staff.

Affected Section	Comment/Basis	Recommendation
	comprehensive risk of a facility includes the effects of other regulatory requirements on plant safety and is not the only requirement for regulatory decision-making. The Comprehensive Risk Metric could be changed to a Comprehensive Safety Metric (CSM) to help clarify the focus of the metric and evaluations on overall plant safety. Applicant definition and demonstration of compliance with a metric that meets the risk performance objectives will help ensure an acceptable level of safety relative to applicants, which demonstrates compliance with existing risk metric and show that the facility is "safe enough."	
2. § 53.220 Safety criteria for licensing-basis events other than design-basis accidents. Design features and programmatic controls must be provided for each commercial nuclear plant such that identification and analysis of licensing-basis events (LBEs) other than DBAs in accordance with § 53.240 demonstrate the following: (a) Plant SSCs, personnel, and programs provide the necessary capabilities and maintain the necessary reliability to address LBEs other than DBAs in accordance with §§ 53.240 and 53.450(e), and provide measures for defense in depth in accordance with § 53.250; and	§ 53.220 is problematic due to the unclear language	**Rule Text Revision – § 53.220:** ● Remove all areas that include "other than DBAs" throughout to avoid confusion. ● Revise "comprehensive risk metrics" language to improve regulatory certainty and mitigate confusion. **Proposed Revision:** *Replace 53.220 as follows:* § 53.220 Safety Criteria for an Integrated Safety Assessment Design features and programmatic controls for NSRSS SSCs must be provided for each commercial nuclear plant to assure adequate protection of public health and safety. This is achieved through an integrated safety

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(b) The analysis of risks to public health and safety resulting from LBEs other than DBAs under § 53.450(e) includes comprehensive risk metrics that satisfy associated risk performance objectives that are acceptable to the NRC and provide an appropriate level of safety.		assessment, which must consider the necessary capabilities and reliability of design features and programmatic controls ~~to address LBEs~~ in accordance with 53.450(e), provide measures for defense in depth in accordance with § 53.250

Table 8. Specific Request for Comment – Part 53, Subpart B—Defense in Depth

Affected Section	Comment/Basis	Recommendation
1. § 53.250 Defense in depth. (a) Measures must be taken for each commercial nuclear plant to ensure appropriate defense in depth is provided to compensate for uncertainties in the analysis of the safety criteria such that there is reasonable assurance that the safety criteria in this subpart are met over the life of the plant. (b) The uncertainties that must be addressed under paragraph (a) of this section include those related to the state of knowledge and modeling capabilities, the ability of barriers to limit the release of radioactive materials from the facility during LBEs other than DBAs, the reliability and performance of	*Specific Request for Comment: The NRC is seeking comment on the inclusion of the proposed requirements to assess and provide defense in depth.* Defense-in-depth is an "attribute that could assist in establishing the acceptability or license-ability of a proposed advanced reactor design" without requiring it in the rule. Applicants should have the flexibility to identify safety functions, design criteria, and other characteristics that meet performance-based safety requirements. As defined in the draft rule text, defense-in-depth is not a performance-based requirement.	Retain § 53.250(a) and remove § 53.250(b) and (c). The risk-informed approach outlined in (a) appropriately compensates for uncertainties, while (b) and (c) introduce unnecessary prescriptive elements that limit applicant flexibility. In response to the NRC's request for comment, we recommend that the role of inherent safety features in defense-in-depth (DID) be emphasized in guidance rather than rule language. Specifically: ● The principle that no single barrier should be relied upon for non-design basis

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plant SSCs and personnel, and the effectiveness of programmatic controls. (c) The safety analysis may not rely upon a single engineered design feature, human action, or programmatic control, no matter how robust, to address the range of LBEs other than DBAs.	A risk-informed approach is used in 53.250(a) and (b), which indicates that defense-in-depth is to compensate for uncertainties. Section 53.250(c), however, takes a deterministic approach by requiring that no single barrier be used to address licensing basis events other than design basis accidents, even if there is reasonable assurance that the uncertainty in (a) and (b) has been addressed. The proposed change to § 53.250 would be consistent with the Commission decision in SRM-SECY-19-0036 that "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."	licensing events should be addressed in guidance rather than codified in rule. ● NRC should clarify in the preamble that inherent safety features can be relied upon for DID, ensuring that applicants can use them effectively without rigid prescriptive requirements. ● The existing regulatory framework, including RG 1.174, provides sufficient guidance on DID without additional process-level requirements. This approach preserves regulatory flexibility while maintaining a risk-informed, performance-based framework for advanced reactor licensing.

Table 9. Specific Request for Comment – Part 53, Subpart C—Probabilistic Risk Assessment

Affected Section	Comment/Basis	Recommendation
1. § 53.450	A systematic evaluation of risk is prudent and necessary. However, the proposed rule currently unnecessarily limits the options to evaluate risk by arbitrarily prescribing that	Allow for the use of an alternative risk assessment to the probabilistic risk assessment methodology (PRA) in all current and proposed licensing frameworks, based upon

Affected Section	Comment/Basis	Recommendation
	applicants use PRA. Part 53 needs to be technology-inclusive to license all kinds of reactors, and it is essential for the developers to apply using a flexible risk evaluation methodology, especially the advanced reactors and microreactors. The term "risk evaluation" was used to replace "PRA" in Enclosure 2 to the SRM (ML2406A050). Additionally, ADVANCE Act Section 208 requires the NRC to develop strategies and guidance for risk analysis methods, including alternatives to PRA. Part 53 is mandated by NEIMA to be a risk-informed performance-based framework. As such, this risk-informed performance-based requirement must be included in Part 53. This requirement is aimed at micro-reactors. However, as a technology-inclusive licensing framework, Part 53 must be able to support this requirement. There is no alternative requirement that would prevent this requirement from being applied to all technologies. *SEC. 208. REGULATORY REQUIREMENTS FOR MICRO-REACTORS. (a) MICRO-REACTOR LICENSING.—The Commission shall— (1) not later than 18 months after the date of enactment of this Act, develop risk-informed and performance-based strategies*	technologically and actuarially plausible risk parameters and reasonable uncertainty margins. Proposed Rule Text Revision – § 53.450: ~~Requirement to have a probabilistic risk assessment (PRA).~~ A ~~PRA~~ *Risk evaluation* of each commercial nuclear plant must be performed to 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, or more restrictive alternative criteria adopted under § 53.470. Definition of Risk evaluation methods : Approaches for systematically evaluating engineering systems to perform risk analysis, including alternatives to PRA. Conforming Changes: In line with this recommendation and changing the PRA requirement to "risk evaluation," there must be conforming changes to: 53.450(b), 53.450(c), 53.450(e), 53.1239(a)(18), 53.1416(e)(1), 53.1416(f)(1), 53.1416(g)(1), 53.1545(3), 53.800, and any other related provisions.

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	and guidance to license and regulate micro-reactors pursuant to section 103 of the Atomic Energy Act of 1954 (42 U.S.C. 2133), including strategies and guidance for— (A) staffing and operations; (B) oversight and inspections; (C) safeguards and security; (D) emergency preparedness; ***(E) risk analysis methods, including alternatives to probabilistic risk assessments;*** Finally, the Kairos-Hermes construction permit application (approved) did not use a strict PRA approach, indicating that developers and the NRC are open to alternative approaches. To limit to only PRA is arbitrary and does not align with past licensing decisions, the intent of NEIMA, the ADVANCE ACT, and other NRC policies.	
2. § 53.450(b)	This section outlines specific uses for the Probabilistic Risk Assessment (PRA), mandating its application in various aspects of plant design, safety classification, defense-in-depth evaluation, and event identification. While the intent aligns with ensuring robust safety evaluations, the language is overly prescriptive, potentially stifling flexibility and innovation in safety analysis methodologies. To align with risk-informed, performance-based, and technology-inclusive principles, the regulation should encourage the use of PRA as one of several tools, allowing	**Recommendation**: In line with the recommendation in Table 9.1 and changing the PRA requirement to "risk evaluation," there must be conforming changes to 53.450(b). Revise the language to reflect that PRA is the primary tool but allow flexibility for alternative approaches. Specify performance outcomes rather than prescribing exact methods. **Proposed Revision to § 53.450(b):** *Risk evaluation methods must be used* ~~The PRA in combination with other generally~~

Affected Section	Comment/Basis	Recommendation
	applicants to justify alternative methods that achieve equivalent safety outcomes. This approach would maintain safety rigor while fostering innovation and efficiency. While PRA is a proven and valuable tool, mandating its use may preclude alternative, equally robust methods better suited to specific designs or scenarios. Performance-based language focuses on achieving safety outcomes without mandating how they are achieved, encouraging licensees to adopt best-fit methodologies. Flexibility supports technology inclusivity and innovation, particularly for advanced reactor designs. Our recommendations emphasize the role of risk insights in decision-making without making PRA the sole determinant, allowing for engineering judgment and other analytical methods to complement risk assessment.	~~accepted approaches for systematically evaluating engineered systems must be used~~. …
3. § 53.450(c)	To align with risk-informed, performance-based, and technology-inclusive principles, the regulation should encourage the use of PRA as one of several tools, allowing applicants to justify alternative methods that achieve equivalent safety outcomes. This approach would maintain safety rigor while fostering innovation and efficiency.	**Recommendation**: In line with the recommendation in Table 9.1 and changing the PRA requirement to "risk evaluation," there must be conforming changes to 53.450(c). Revise the language to reflect that PRA is a tool, but allow flexibility for alternative approaches. Specify performance outcomes rather than prescribing exact methods.

Affected Section	Comment/Basis	Recommendation
3. § 53.450(e)	This section mandates comprehensive analyses for licensing-basis events (LBEs) other than design-basis accidents (DBAs), prescribing the identification, evaluation, and risk categorization of LBEs using specific methodologies. While the intent is to ensure robust safety measures, the highly prescriptive nature of this section creates several concerns: 1. Over-Reliance on PRA: Like § 53.450(b), this section mandates the use of PRA in combination with other approaches, which may unnecessarily restrict flexibility in safety evaluations. 2. Excessive Detail: The level of prescriptive detail limits the ability of applicants to tailor methods and criteria to specific reactor designs or innovative technologies. 3. Potential Burden: The requirements for defining evaluation criteria and demonstrating compliance through exhaustive analysis of event sequences may create unnecessary regulatory burdens, especially for advanced and non-traditional reactor designs. To better align with risk-informed, performance-based, and technology-inclusive principles, this section should emphasize outcomes and safety objectives while allowing flexibility in methodologies.	**Recommendation**: In line with the recommendation in Table 9.1 and changing the PRA requirement to "risk evaluation," there must be conforming changes to 53.450(e). Revise the language to reflect that PRA is a tool, but allow flexibility for alternative approaches. Specify performance outcomes rather than prescribing exact methods. Additionally, the NRC should provide clarity on the definition of an "appropriate level of safety." A more defined performance objective should be explicitly addressed, either in the rule or accompanying guidance to reduce regulatory uncertainty.

Affected Section	Comment/Basis	Recommendation
	Additional clarity is needed on the definition of an "appropriate level of safety." This term is used differently in the proposed rule than in existing rules and guidance. While NRC staff have indicated openness to proposals, a more defined standard—such as ensuring safety is "comparable to what has been licensed in the past"—should be explicitly addressed, either in the rule or accompanying guidance.	
4. Subpart C—Probabilistic Risk Assessment	*Specific Request for Comment: The NRC is seeking comment on what additional guidance, if any, is needed regarding PRA acceptability for Part 53 applicants and licensees.* Guidance on risk evaluation methodologies should strike a balance between predictability and flexibility. While updating certain guidance documents—such as RG 1.233, RG 1.174, RG 1.200, and RG 1.247—may be beneficial, additional prescriptive guidance should only be developed on an as-needed basis to avoid inadvertently limiting innovation. Regulatory guidance often becomes a de facto requirement, restricting flexibility instead of preserving the intent of a performance-based framework. Instead of mandating specific methods, NRC should focus on defining clear performance outcomes, allowing applicants to	Guidance should be considered on the level of detail necessary depending on what method of risk evaluation applicants use under a Part 53 application. This includes but is not limited to if an all-hazards PRA is required, content of application guidance, and principal design criteria. The following guidance documents may be helpful to be updated with the changes outlined in the recommendations above: - RG 1.233 (LMP) - RG 1.174 (CDF and LERF) - RG 1.200 (LWR PRA standard to calculate CDF/LERF) - RG 1.247 (nLWR PRA Standard to calculate QHOs) - And any others as needed. Additional guidance may be helpful to applicants on what criteria must be met if risk

Affected Section	Comment/Basis	Recommendation
	choose the most appropriate risk evaluation approach. Consistent with the ADVANCE Act and Commission direction, alternative risk evaluations beyond PRA should be optionally usable in Part 53. Moreover, the NRC does not necessarily need to preemptively define acceptable methods. Instead, it should document licensing decisions and lessons learned to provide clarity over time. Applicants should not be forced to conform to a single approach like draft guide DG-1414 if alternative methods can demonstrate an appropriate level of safety. Ultimately, the goal should be to provide sufficient predictability without limiting developers to a rigid framework, ensuring that Part 53 remains technology-inclusive and adaptable to diverse reactor designs.	evaluation other than PRA are used for Part 53. Examples may include maximum hypothetical accidents or AERI-like approaches. This guidance should be developed to preserve knowledge gained over time through licensing actions.

Table 10. Specific Request for Comment – Part 53, Subparts H and I—Probabilistic Risk Assessment Information

Affected Section	Comment/Basis	Recommendation
1. Proposed § 53.1239(a)(18) in subpart H and the related references to this proposed requirement for the holders of OLs and COLs would require a description of the PRA required by § 53.450(a), and its results to be included in FSARs. *a. However, guidance documents may further clarify the division of PRA-related information needed to be in the FSAR, in other possible licensing basis documents, and controlled as plant records subject to inspections and audits.*	*Specific Request for Comment: The NRC is seeking comment on the appropriate placement of PRA-related information among various licensing basis documents and plant records. In addition to the placement of PRA-related information, the NRC is seeking comment on the appropriate control of that information and on the routine submittal of updates to the NRC.* To align with risk-informed, performance-based, and technology-inclusive principles, the placement and control of risk evaluation-related information should be prioritized: 1. Transparency and accessibility for safety evaluations. 2. Flexibility to integrate evolving risk insights. 3. Efficiency in information management and NRC oversight. These recommendations provide a balanced framework for managing risk evaluation-related information, ensuring it is accessible, up-to-date, and appropriately integrated into regulatory processes without stifling innovation or imposing unnecessary burdens.	The placement, control, and routine submittal of risk evaluation-related information should align with the applicant's integrated safety assessment, chosen risk evaluation methodology, and overall approach to meeting performance objectives. Given this variability, it is difficult to provide a single directive for the NRC. For applicants using the Licensing Modernization Project (LMP), Regulatory Guide 1.253 already provides clear expectations on PRA-related information. However, this guidance is specific to LMP users, and a similar framework should be available for alternative methodologies without imposing rigid requirements. A general principle should be established to guide applicants while preserving flexibility. The approach should prioritize transparency for safety evaluations, adaptability to evolving risk insights, and efficiency in information management and NRC oversight. This ensures that information is appropriately integrated into regulatory processes without creating unnecessary burdens or restricting

Affected Section	Comment/Basis	Recommendation
		technological diversity.

Table 11. Specific Request for Comment – Part 53, Subpart E—Construction and Manufacturing

Affected Section	Comment/Basis	Recommendation
1. Proposed § 53.610(b)(1)(iii) would require procedures that describe how construction will be controlled so as not to impact other features important to the design (e.g., dewatering, slope stability, backfill, compaction, and seepage). (iii) Procedures must be in place prior to the start of construction activities that describe how construction will be controlled so as not to impact other features important to the design, such as dewatering, slope stability, backfill, compaction, and seepage.	*Specific Request for Comment: The NRC is seeking comment on whether such specific requirements are useful or whether these requirements could be met through other requirements proposed in part 53 or already present in other relevant regulations (e.g., quality assurance requirements in appendix B to part 50).* Basis: ● The existing quality assurance framework under Appendix B to Part 50 is already well-established and effective for licensing under Parts 50 and 52. ● Supply chain oversight operates across all regulatory frameworks, making duplication in Part 53 unnecessary. ● Industry stakeholders have recommended removing § 53.610 to avoid supply chain inefficiencies.	Remove § 53.610 from the proposed rule language to reduce redundancy. Quality assurance requirements are already established in Appendix B to Part 50 and function effectively under Parts 50 and 52. The same framework should apply to Part 53 rather than introducing duplicative requirements. Additionally, the NRC should consider the acceptance of alternative quality assurance programs, including internationally recognized standards such as ISO 9001, as long as they meet the necessary safety and reliability criteria.

Affected Section	Comment/Basis	Recommendation
	• A flexible approach that allows for alternative QA programs would enhance international alignment and maintain regulatory consistency without compromising safety.	

Table 12. Specific Request for Comment – Part 53, Subparts E and H—Manufacturing Licenses

Affected Section	Comment/Basis	Recommendation
1. The proposed requirements governing manufacturing are set forth in subpart E, and the proposed requirements governing the licensing processes are contained in subpart H.	*Specific Request for Comment: The NRC is seeking comment on whether the proposed regulations are sufficient to govern various scenarios for the possible manufacturing and deployment of manufactured reactors.* Part 70 already governs the handling, processing, and loading of nuclear fuel, ensuring appropriate safety measures. There is no demonstrated need for additional requirements under Part 53. Stakeholders have provided justification for why Part 70 is sufficient in separate comments. While the NRC has not previously applied Part 70 to factory fuel loading of a manufactured reactor, it provides an established, structured approach.	Apply Part 70 provisions and cut § 53.620(d) from the proposed rule.

Affected Section	Comment/Basis	Recommendation
	Rather than creating new requirements, aligning with Part 70 ensures consistency and avoids unnecessary regulatory duplication, which could delay innovation. Similar applications, such as work at PNNL related to Project PELE, have successfully complied with existing regulations rather than requiring new rulemaking.	
2. The proposed regulations in subpart H allow holders of or applicants for a COL to reference an ML but do not include such a provision for the holder of or applicant for a CP or OL.	*Specific Request for Comment: The NRC seeks comment on whether part 53 should include provisions for an applicant for or a holder of a CP or an OL to reference an ML and, if so, how this should be done.* The ability to reference an ML in a CP or OL application could improve efficiency, reduce duplication of work, and promote design-centered licensing. There are ongoing policy proposals and rulemakings that should be considered to ensure consistency. For example, consideration should be made related to fueled manufactured reactors.	Part 53 should include provisions for an applicant for or a holder of a CP or an OL to reference an ML.
3. Proposed § 53.1295 states that the holder of an ML could not begin manufacture of a manufactured reactor less than 6 months before the expiration of the license.	*Specific Request for Comment: The NRC seeks comment on whether it is necessary or appropriate to revise the 3-year restriction in part 52 on when manufacturing activities*	Yes, revise to 6 months to match Part 53.

Affected Section	Comment/Basis	Recommendation
	could begin in relation to license expiration and, if so, what that restriction should be. Aligning Part 52 with Part 53 promotes regulatory coherence and simplifies compliance for applicants. A 6-month restriction is a more practical timeframe while still allowing sufficient oversight. There is no prior experience to suggest that a longer restriction is necessary. Additionally, the NRC's existing timely renewal provisions could address concerns about license continuity, reducing the need for an extended restriction.	
4. Proposed § 53.1288 provides the finality provisions for MLs and includes, as does existing § 52.171, limitations on the NRC's imposition of new requirements on either the design or the requirements for the manufacture of a manufactured reactor.	*Specific Request for Comment: The NRC is seeking comment on the proposed finality provisions for MLs and specifically if and how finality for manufacturing processes might be requested and used.* Aligning with § 52.171 ensures a stable and predictable framework without introducing unnecessary deviations. The existing provisions in Part 52 have been effective, and there is no clear reason to modify them for Part 53. Keeping the language as it allows applicants to request and use finality for manufacturing processes as needed.	It is acceptable to align §53.1288 with § 52.171 on the proposed finality provisions for MLs.
5. The proposed regulation includes provisions for loading of fuel into	*Specific Request for Comment: A specific topic on which the NRC is seeking comment is*	The NRC needs to apply Part 70 provisions and cut § 53.620(d).

Affected Section	Comment/Basis	Recommendation
manufactured reactors at a manufacturing facility prior to transporting the fueled reactor to its deployment site, as suggested by some stakeholders. The proposed rule addresses this matter by allowing an applicant to combine an ML with a part 70 license, which would authorize possession of a manufactured reactor in which the licensee has loaded unirradiated fuel provided at least two independent criticality prevention mechanisms are in place, each of which is sufficient to prevent criticality assuming optimum neutron moderation and neutron reflection conditions.	*on the potential benefits of and issues with including the requirements of subpart H of part 70 within the proposed regulations for loading fuel into manufactured reactors at the manufacturing facility.* *If a comment indicates that the proposed regulations are not sufficient, please describe the reasons why, including the plausible scenarios for which the proposed regulations would not work or could be made to work better.* Part 70 already provides an established framework for fuel handling and security, making § 53.620(d) redundant. Aligning with Part 70 ensures uniform treatment of fuel-related activities across regulatory frameworks. Stakeholders have separately provided justification that Part 70 is sufficient, and the NRC has not previously applied different standards in this context.	
6. Section 170, "Indemnification and Limitation of Liability," of the Act states that each license under section 103 shall have as a condition of the license a requirement that the licensee have and maintain financial protection of such type and in such amounts as the NRC shall require.	*Specific Request for Comment: The NRC is seeking comment on whether the proposed regulations should include amounts of required financial protections for MLs for fueled manufactured reactors, and, if so, what would be appropriate amounts of required financial protection.*	The proposed regulation should not include amounts of required financial protections for MLs for fueled manufactured reactors because it will be variant for different designs. The rule text must provide flexibility that is graded commensurate with risk. Additional clarity and direction can be provided for applicants in guidance as developed and when needed.

Affected Section	Comment/Basis	Recommendation
7. Some stakeholders have suggested that a fueled manufactured reactor with appropriate protections against criticality should not be categorized as a utilization facility under NRC regulations or Section 11cc. of the Act.	*Specific Request for Comment: The NRC is seeking comment on possible approaches where the NRC could find that a fueled manufactured reactor would not be a utilization facility, the basis for such a finding, and the potential benefits of and potential issues with such a finding.* The significantly lower risk profile of small, fueled manufactured reactors with robust safety measures justifies a reclassification. Aligning regulatory definitions with the technological advancements and risk profiles of these reactors promotes efficiency without compromising safety. This topic is considered in separate NRC whitepapers and policy option papers, public meetings, and stakeholder comments. This consensus comment does not try to reproduce those references.	The NRC should consider a framework where a fueled manufactured reactor, with appropriate protections against criticality, is not automatically classified as a utilization facility under NRC regulations or Section 11cc of the Atomic Energy Act. The NRC should engage further with stakeholders to further determine the most appropriate approach to implement this recommendation.
8. GENERAL – Subparts E and H—Manufacturing Licenses	*Specific Request for Comment:* *1. The NRC is seeking comment on whether provisions regulating the testing of fueled manufactured reactors in the manufacturing facility should be included in part 53 and, if so, what would be practical for the holder of an ML while*	1. The NRC should include provisions to regulate the testing of fueled manufactured reactors at the manufacturing facility in implementing guidance, with requirements tailored to the unique nature of these facilities.

Affected Section	Comment/Basis	Recommendation
	also providing adequate protection of public health and safety. *2. The NRC recognizes configuration changes are needed to perform nuclear physics testing and is seeking comment on what requirements should apply to the manufactured reactors and the manufacturing facility during such testing (e.g., limiting power levels).* *3. The NRC is seeking comment on what requirements in subpart H of part 53 should apply to applicants for a COL who would perform testing of fueled manufactured reactors at the manufacturing plant.* *4. Additionally, the NRC is seeking comment on whether several other requirements in part 53 could be modified for applications for a low power testing COL at a manufacturing facility.* *For example, the NRC is seeking comment on how portions of the ML facility used to support testing should fall within the requirements for construction activities under § 53.610; whether §§ 53.710 and 53.715 (SSC configuration control) must be implemented to ensure portions of the ML facility relied on to limit potential radiological consequences from LBEs are available to perform their safety functions; and whether the requirements of § 53.730 could be modified to reflect the conditions of low power physics testing.*	2. In guidance, the NRC should discuss the nuclear physics testing of manufactured reactors and outline safety, security, and oversight measures to ensure both effective validation and risk mitigation to ensure the rule language remains technology neutral and flexible. 3. The NRC should clarify which provisions of subpart H of part 53 apply to COL applicants conducting testing of fueled manufactured reactors at a manufacturing facility. NRC should also acknowledge that certain pre-criticality testing activities may be permissible under Part 70 without requiring a COL. 4. See the following: a. It would be helpful for the NRC to provide detailed guidance on what constitutes "low power testing" at a manufacturing facility and how it differs from full operational testing at a deployment site for future applicants. b. Staffing and oversight requirements (e.g., § 53.730) should be adapted to reflect the lower risk profile of low-power testing but still ensure

Affected Section	Comment/Basis	Recommendation
	5. The NRC is seeking comment on the potential benefits and issues with having a COL for each fueled manufactured reactor to be tested versus having a COL cover the testing of multiple fueled manufactured reactors. Testing requirements for fueled manufactured reactors must balance regulatory clarity, safety, and flexibility while avoiding unnecessary duplication with existing frameworks. Establishing clear provisions in guidance rather than prescriptive rule language ensures technology neutrality and adaptability. Recognizing the distinction between subcritical and critical testing is crucial—subcritical testing may align with Part 70 provisions, whereas critical testing may require additional licensing, such as a Class 104 license. A licensing framework that allows for the testing of multiple reactors under a single authorization, where appropriate, would improve efficiency while maintaining necessary oversight.	sufficient engineering expertise is available. c. The NRC should engage with stakeholders to further clarify the roles and responsibilities of ML holders versus COL applicants during the testing phase. 5. The NRC should pursue a licensing framework that allows a single license (not necessarily a COL) to cover the testing of multiple fueled manufactured reactors, provided they meet consistent design and safety criteria. This approach should distinguish between subcritical testing—potentially allowable under Part 70—and critical testing, which may necessitate a different licensing pathway, such as a Class 104 license under the AEA. Clear regulatory criteria should be established to define when a separate license is required, ensuring both flexibility and regulatory certainty.

Table 13. Specific Request for Comment – Part 53, Subparts H and I—Changes to Manufacturing Licenses

Affected Section	Comment/Basis	Recommendation
1. Proposed § 53.1530 would not allow the holder of an ML or the holder of a COL using a manufactured reactor to make changes to the design of the manufactured reactor without requesting a license amendment from the NRC. The proposed requirements do not include a specific mention of the manufacturing processes for which the NRC could possibly provide finality under proposed § 53.1288.	*Specific Request for Comment: The NRC is seeking comment on the appropriate change control provisions for MLs, including whether criteria could be developed to determine when a license amendment request would not be required and whether those criteria should address changes in manufacturing processes as well as changes in the design.* A well-defined, risk-informed approach to license amendment criteria is essential to ensure regulatory efficiency while maintaining safety and security. Not all design or manufacturing changes warrant a full license amendment—distinguishing between safety-significant and non-safety-significant modifications allows for a more practical and responsive regulatory framework.	We recommend that the NRC develop clear and risk-informed criteria to determine when a license amendment request is required, specifically focusing on changes that have a direct impact on safety, security, or regulatory compliance. This would help minimize unnecessary amendments for non-safety-significant adjustments while ensuring that changes that affect reactor safety are properly evaluated. Design changes may not require a license amendment: ● Cosmetic or aesthetic features ● Administrative systems ● Maintenance tracking tools ● Etc. Design changes that may require a license amendment: ● Primary cooling system ● Control systems ● Containment ● Core Design ● Etc. Additionally, the NRC should clarify the procedures for evaluating changes to manufacturing processes. For non-safety-significant adjustments, these should be

Affected Section	Comment/Basis	Recommendation
		subject to notification to the NRC with supporting documentation but should not trigger the need for a full license amendment request. However, any changes to the reactor design that impact safety or compliance must still undergo the standard approval process. Finally, we suggest that periodic audits of manufacturing facilities be conducted to verify adherence to approved designs and processes. This would allow for continued oversight without unnecessarily hindering operations. Conforming changes should be made to § 53.1530, § 53.1288, and any other relevant provision within the proposed rule to better accurately reflect these recommendations.

Conclusion

The successful deployment of advanced nuclear technologies depends on a regulatory framework that is risk-informed, performance-based, and technology-inclusive. While Part 53 represents an important step toward modernizing reactor licensing, our engagement with diverse stakeholders has highlighted areas where improvements are necessary to ensure clarity, efficiency, and effectiveness of implementation.

The NRC should incorporate these recommendations to align Part 53 with NEIMA's intent, reduce unnecessary regulatory burdens, and provide a clear pathway for innovative nuclear technologies. By addressing stakeholder concerns and refining the rule, the NRC can create a regulatory environment that supports the safe, timely, and cost-effective deployment of advanced reactors.

We appreciate the opportunity to contribute to this rulemaking process and look forward to continued engagement with the NRC and other stakeholders to ensure that Part 53 meets the statutory requirements and enables the commercialization of innovative nuclear technologies.

If you have any questions regarding this joint comment, please contact Adam Stein (adam@thebreakthrough.org)