

Bridging the Gap on 10 CFR Part 53



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Executive Summary

The Nuclear Regulatory Commission (NRC) is about to make a decision with important implications for the future of advanced nuclear energy and for the United States' ability to address its climate and energy security challenges. A flawed but fixable draft rule for licensing advanced reactors is coming before the NRC's five Commissioners this month. This moment requires the Commission to exercise its leadership role and provide clear and specific direction to NRC staff and management. With the right Commission direction, the capable NRC staff can modify the rule so that it will enable the safe and rapid deployment of gigawatts of new clean energy in the United States in the next two decades.

NRC is now positioned to create a new regulatory framework for advanced reactor licensing. Many stakeholders are concerned, however, that NRC's proposed new advanced reactor regulatory framework (10 CFR Part 53) is incorporating the same flawed structure and prescriptive analytic and programmatic requirements that make nuclear reactor licensing challenging today. The issues in the NRC's proposed approach are due, in part, to the challenges of preparing a novel rule subject to complex constraints in a short period of time and an imperfect approach to balancing regulatory predictability and flexibility in a new licensing rule.

The Nuclear Innovation Alliance (NIA) believes that while the current draft proposed rule would not facilitate the effective and efficient licensing of advanced reactors, the NRC could create a transformative new rule by making specific changes to the rule structure. Resolving the differences between NRC staff and external stakeholders requires rethinking how to balance regulatory predictability and flexibility while taking advantage of the extensive work the NRC staff has already done. Restructuring the draft rule to focus on ensuring applicant compliance with performance-based regulatory requirements applicable to all reactors would enable applicants to select the methods, programs, and design features that will ensure safety. A vast majority the draft proposed rule requirements can be retained but moved to regulatory guidance or non-mandatory appendices of the rule text to provide optional pathways for applicants that are interested in using a more prescriptive, predictable process. This solution represents a bridge from the current proposed draft Part 53 rule to a regulatory framework that resolves major differences between NRC staff and external stakeholders.

The NRC Commission is in the best position to redirect the Part 53 rulemaking process, and realign NRC staff and external stakeholders. The NRC staff is expected to submit the proposed draft Part 53 rule package to the NRC Commission for their review and approval in February 2023. The Commission can decide to change the structure of the rule to better align with a safety requirement framework described by NIA and others, and work with NRC staff to convert existing draft safety requirements and operational program requirements into optional regulatory guidance or non-mandatory appendices of the rule text for applicants. The NRC has the opportunity to create a regulatory framework in 10 CFR Part 53 that will provide both regulatory flexibility and predictability for advanced reactors and enables the commercialization and deployment of advanced nuclear energy.

Introduction to 10 CFR Part 53 and Advanced Reactor Regulation

Creating a new regulatory framework for advanced nuclear reactors has been described as a “once-in-a-generation” opportunity. Creating new, more effective and efficient regulations tailored to advanced nuclear reactors could enable the commercialization and deployment of advanced nuclear energy, facilitating the construction and operation of hundreds or thousands of new nuclear power plants that can help us meet our future clean energy needs. The Nuclear Regulatory Commission (NRC) is the independent federal agency that licenses and permits the construction and operation of nuclear reactors in the United States. The NRC must create a regulatory framework that can enable the safe and rapid deployment of gigawatts of new clean energy in the United States in the next two decades.

Creating a new regulatory framework for advanced reactors could also be described as a “once-in-a-generation” headache. The NRC was directed by the [2019 Nuclear Energy Innovation and Modernization Act \(NEIMA\)](#) to create a technology-inclusive, risk-informed, performance-based (TI-RIPB) regulatory framework for advanced reactors by 2027. A TI-RIPB framework would be applicable to all reactor technologies (technology-inclusive), use information from risk assessments to focus safety analyses on the most important issues (risk-informed), and ensure that plants are regulated based on how they perform and not just how they are designed (performance-based). If implemented correctly, a TI-RIPB regulatory framework could facilitate the effective and efficient licensing of advanced nuclear energy.

Congress charged NRC with creating this new regulatory framework to enable effective licensing of all reactor technologies – from multi-gigawatt large light water reactors that would operate for 100 years in a single location to single-megawatt transportable non-light water microreactors that would operate in a location for weeks at time before moving to the next site. The scope of the proposed rulemaking was unprecedented for NRC, and perhaps for any safety regulation agency. The NRC staff created a [draft plan to complete the rulemaking by 2027](#), but a number of stakeholders and policymakers requested that the NRC accelerate the rulemaking process to complete the new regulatory framework by 2024. The NRC staff and management responsible for creating the new regulatory framework would have less than 2 and a half years to draft a proposed rule that satisfied a set of complex and sometimes contradictory stakeholder objectives and constraints.

Development of a new regulatory framework was further complicated by limited direction. The NRC staff received limited initial guidance from Congress and the NRC Commission on the exact structure and content of the rule. NRC staff’s revised plans to complete this incredibly important and challenging regulatory framework was [approved by the Commission in October 2020](#). The plan outlined the Staff’s plan to leverage the existing NRC projects on advanced reactor licensing and existing Commission guidance on increasing operational flexibility for advanced reactors as the basis the new regulatory framework. The framework would be called “Part 53” based on its expected location in Title 10 of the Code of Federal Regulation. NRC staff thus began work on Part 53 as one of the potentially highest-impact and most challenging rulemaking activities in recent memory.

The Current State of the 10 CFR Part 53 Rulemaking Process

The past 28 months have seen dozens of public meetings held, hundreds of public comments submitted, and thousands of pages of preliminary draft text published as NRC staff worked to develop a proposed rule package for formal public comment. The NRC staff is finalizing a [proposed rule package for review](#) by

the NRC Commission (expected in late February 2023), but stakeholders already are assessing whether the draft proposed rule would create the more effective and efficient regulation that enables the commercialization and deployment of advanced nuclear energy. Numerous stakeholders have expressed concern that the preliminary draft of the proposed rule does not meet the intent of NEIMA, does not create a more effective and efficient licensing process, and is an unusable rule that will inhibit the deployment of advanced nuclear energy.

Significant concerns about preliminary drafts of the proposed rule have caused some stakeholders to call for the NRC staff to throw out all the work that has been done on Part 53 and restart the rule development process. While these calls are based on the desire to create a usable, effective, and efficient regulatory framework for advanced reactors, they are misplaced, as it is doubtful that the NRC staff would develop a significantly different rule without additional direction and guidance by the NRC Commission. Some stakeholders have expressed frustration in public meetings that they felt that the NRC staff was not incorporating or addressing specific comments on the draft proposed rule and that it seemed that the regulatory framework and structure were already finalized. NRC staff have repeatedly pushed against this criticism, citing instances of staff incorporation of public comments and future opportunities to make additional changes to the rule as part of the formal public comment period following publication of the proposed rule.

Re-starting the Part 53 rulemaking process risks further delaying the development of a new regulatory framework for advanced reactors and still does not guarantee the development of an effective rule. Satisfying both the intent and legal requirements of NEIMA to create a TI-RIPB regulatory framework by 2027 requires that the Commission provide clear direction and guidance to the NRC staff and an understanding of how to effectively resolve major differences between NRC staff and external stakeholders.

The [dozens of public meetings](#) and [hundreds of public comments](#) submitted during the Part 53 draft rule development process covered a wide range of technical topics, but the core regulatory question is how a new regulatory framework can balance predictability and flexibility. The Part 53 rule must be flexible so it can accommodate a wide range of advanced reactor technologies, but it also must be predictable to provide the conditions necessary for private companies to invest in the commercialization and deployment of advanced reactors. Existing regulatory frameworks for reactor licensing (10 CFR Part 50 and 10 CFR Part 52) are predictable because they use a combination of design requirements, safety analysis requirements, and operational program requirements to ensure safe design and operation of nuclear power plants. The design requirements in these frameworks, however, are specific to large light water reactor designs and have limited applicability to advanced reactor technologies.

When the NRC staff began development of Part 53, they leveraged guidance developed as part of the [Licensing Modernization Project](#) (a multi-year partnership between NRC and industry to develop new regulatory guidance for non-light water reactors) and replaced technology-specific design requirements with additional safety analysis requirements and operational program requirements. This process enabled applicability to any reactor technology (increasing flexibility) but still preserved the predictability of the existing regulatory frameworks. This initial framework is now characterized as “Framework A” within Part 53. NRC staff’s strategy, however, ran into challenges as stakeholders expressed concern that the new safety analysis requirements (e.g., probabilistic risk assessment) and operational program requirements (e.g., Facility Safety Program) would not be applicable and effective for some advanced reactor applicants.

The NRC staff attempted to further increase flexibility by creating alternative deterministic safety analysis requirements (“Framework B”), but stakeholders still expressed concern that the process was not sufficiently flexible. The challenge of balancing predictability and flexibility using a combination of design requirements, safety analysis requirements, and operational program requirements is the basis for many differences between NRC staff and external stakeholders on Part 53.

Creating a Pathway Forward on 10 CFR Part 53

Resolving the differences between NRC staff and external stakeholders requires a fundamental rethinking of how to balance regulatory predictability and flexibility. We must think about the underlying TI-RIPB requirements that ensure reactor safety instead of focusing on the design, safety analysis, and operational program requirements. Attempting to effectively regulate the wide range of advanced technologies covered by Part 53 using safety analysis or operational program requirements is impossible because the hazards, operational characteristics, and business models of these reactors will vary so widely. We need to focus, instead, on the TI-RIPB safety requirements that all advanced reactors will be expected meet. Requirements for on-site and off-site radiation doses for normal and accident conditions, chronic and acute radioactive effluent releases, and cumulative risk metrics will apply to all advanced reactor technologies. How applicants will demonstrate compliance with these requirements (using design features, safety analyses, and operational programs) can vary by applicant and technology, but the underlying requirements are universally applicable. The goal of the regulator thus would shift from ensuring compliance with design, safety analysis, and operational program requirements to instead confirming that an applicant satisfactorily demonstrates compliance with TI-RIPB safety requirements. This insight provides the basis for how the NRC Commission can resolve many of the differences between NRC staff and external stakeholders on Part 53.

[NIA believes that restructuring the proposed draft Part 53 rule](#) to focus on demonstrating compliance with TI-RIPB safety requirements will create a truly flexible regulatory framework for advanced reactors. Applicants would be required prepare and submit a “safety case” to the regulator that provides the design features, safety analyses, and operational programs that together demonstrate the applicant’s compliance with TI-RIPB safety requirements in Part 53. The applicant would have complete flexibility to select the features, analyses, and programs needed to demonstrate compliance, and the NRC would evaluate and validate the applicant’s safety case. This would enable a truly technology-inclusive advanced reactor regulatory framework in which applicants have the flexibility to tailor the safety case to their design’s hazards, operational characteristics, and business model. It would also enable regulatory innovation, with NRC and license applicants learning from one another and incorporating lessons learned into an evolving regulatory framework.

One challenge of this approach to restructuring, however, is that it eliminates the prescriptive design requirements, safety analysis requirements, and operational program requirements that have historically provided regulatory predictability. Applicants would need to work with NRC to ensure that the plan their safety case was acceptable and NRC staff validation of the safety case may require changes to the application or additional regulatory analyses. The opportunity for additional analyses or delays added during review limits the predictability of the regulatory framework. This weakness can be overcome by leveraging existing NRC staff efforts to create Framework A and Framework B in the current draft proposed rule. The existing safety analysis requirements and operational program requirements in these frameworks could be moved to NRC regulatory guidance or non-mandatory appendices of the rule text as

optional methods for applicants to use when developing their safety case. [In NIA's recommended restructured rule](#), an applicant can choose a highly flexible system in which they define their own safety case or choose a more predictable system where they follow optional methods or programs already approved by NRC staff. This optional regulatory guidance or non-mandatory appendices of the rule text for Part 53 could also evolve and grow as advanced reactor developers and the NRC staff gain experience licensing advanced reactors and reach consensus on the use of new safety cases. This solution represents a bridge from the current proposed draft Part 53 rule to a regulatory framework that resolves major differences between NRC staff and external stakeholders.

Next Steps on Creating a Usable 10 CFR Part 53

The NRC Commission is in the best position to redirect the Part 53 rulemaking process and realign NRC staff and external stakeholders. The NRC staff is expected to submit the proposed draft Part 53 rule package to the NRC Commission for their review and approval in February 2023. The Commission can decide to change the structure of the rule to better align with the TI-RIPB safety requirement framework described above and work with NRC staff to convert existing proposed safety analysis requirements and operational program requirements into optional regulatory guidance or non-mandatory appendices of the rule text for applicants. Transformation of the Part 53 rule into a true TI-RIPB regulatory framework for advanced reactors by leveraging existing staff work can help solve the incredible regulatory challenge of creating a comprehensive advanced reactor regulatory framework in less than 5 years. A path forward that directs NRC staff towards a TI-RIPB safety requirement framework is the only effective pathway to create a usable Part 53 rule that meets the both the intent and legal requirements of NEIMA.

The NRC Commission must take the lead and provide guidance to NRC staff to restructure the draft proposed rule based on TI-RIPB safety requirements with optional analytic methods and operational programs. With the right Commission direction, the capable NRC staff can create a Part 53 that provides both flexibility and predictability for advanced reactors and enables the commercialization and deployment of advanced nuclear energy.