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Breakthrough Institute Comment on 10 CFR Part 53: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (NRC–2019–0062)

February 28, 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.

This letter and its enclosures[1,2] provide the perspective of the Breakthrough Institute on the ongoing activities by the Nuclear Regulatory Commission (NRC) to develop a new technology-inclusive, risk-informed, and performance-based regulation, known as Part 53, under Title 10 of the Code of Federal Regulations. This correspondence is intended to engage with the NRC as a non-profit and independent stakeholder.

The Breakthrough Institute (BTI) is an independent 501(c)(3) global research center that identifies and promotes technological solutions to environmental and human development challenges. We advocate appropriate regulation and licensing of advanced nuclear reactors to enable the commercialization of innovative and economically viable emerging nuclear technologies, which we believe represent critical pathways to climate mitigation and deep decarbonization. The Breakthrough Institute does not receive funding from industry.

The timely completion of a risk-informed, performance-based and technology-inclusive licensing framework is important to the successful innovation and commercialization of advanced nuclear reactors in the United States. The effort by the NRC staff to write this draft regulation on the current timeline is to be commended. Adjustments are necessary to the draft rule to provide a licensing framework to meet this goal.

[1] See Enclosure 1. Historical Risk Metric Development

[2] See Enclosure 2. Implications for NRC Comprehensive Risk Standards in Part 53 Post Loper Bright Decision

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Introduction

In 2019, Congress passed the Nuclear Energy Innovation and Modernization Act (NEIMA), mandating the Nuclear Regulatory Commission (NRC) to establish a technology-inclusive licensing framework for advanced reactors.[3] In response, the NRC has been developing 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).

Background

The Breakthrough Institute has engaged significantly on development of the Part 53 rule. These engagements include but are not limited to:

- Multiple comments on the draft proposed rule
- Stakeholder consensus workshops and comment[4]
- Presentations [5]
- RIC panel on Perspectives on Risk-Informed Licensing of Advanced Reactors[6]
- Publications
- Letters[7,8]

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[3] Nuclear Energy Innovation and Modernization Act (NEIMA), Public Law 115-439 of 2019

[4] The Breakthrough Institute, *Stakeholder Consensus on Part 53 Major Topics*, November 2, 2023, https://thebreakthrough.imgix.net/pdfs/Stakeholder-Consensus-on-Part-53-Major-Topics-Final.pdf

[5] Dr. Adam Stein, The Breakthrough Institute, *10 Part 53 Perspective on Rule Development*, February 8, 2022 - NRC Public Meeting, https://www.nrc.gov/docs/ML2203/ML22038A171.pdf

[6] Dr. Adam Stein, The Breakthrough Institute, *W11 Perspectives on Risk-Informed Licensing of Advanced Reactors*, ML23069A275, Nuclear Regulatory Commission RIC 2023, https://www.nrc.gov/public-involve/conference-symposia/ric/past/2023/docs/abstracts/sessionabstract-14.html

[7] Dr. Adam Stein, The Breakthrough Institute, *"Draft for the NRC's Rulemaking on Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors" (RIN-3150-AK31; NRC-2019-0062)*, January 31, 2022, ML22038A112.

[8] Rani Franovich and Dr. Adam Stein, The Breakthrough Institute, *Comments on NRC's Staff's Preliminary Part 53 Rule Package and October 18-19 ACRS Sub-committee Meeting*, November 1, 2022, ML23006A081.

In addition to direct engagement, the Breakthrough Institute has coordinated multiple stakeholder consensus working groups to provide input on both the draft proposed rule and this proposed rule. There is broad stakeholder consensus on major topics that the NRC staff should consider when working on the development of the final Part 53 rule. The Breakthrough Institute directly signed on to and endorses the stakeholder consensus letter entitled, "Stakeholder Consensus on Proposed Part 53 Major Topics (NRC—2019—0062, RIN 3150—AK31)," submitted to the NRC on February 24th.[9] The consensus comment is a reflection of insights gained from extensive consultation with industry representatives, NGOs, public stakeholders, national laboratories, and reactor developers. The Breakthrough Institute also endorses a joint comment with other NGOs that provides high-level recommendations.[10] We also generally support comments from ClearPath.

These consensus comments address many of the specific requests for comment in the Federal Register Notice. In addition to these joint comments, we have chosen to expand on specific topics that are detailed in the following letter and enclosures.

General Comments

One of the core purposes of NEIMA was the creation of "a program to develop the expertise and regulatory processes necessary to allow innovation and the commercialization of advanced nuclear reactors."[11] The NEIMA prescribes a risk-informed and performance-based regulatory approach that is technology-inclusive. The proposed rule that is the subject of this comment is intended to meet that mandate.

Five basic tenets are needed:

1. Technology-inclusive — flexibility to be applied to a variety of technologies and operational strategies
2. Safety — No reduction in safety thresholds or increase beyond established thresholds from 10 CFR Part 50 & 52
3. Performance-based — Clear, objective, and measurable risk-informed performance criteria should be specified
4. Commercially viable — Regulation should be efficient, predictable, and not overly burdensome
5. Risk-informed — prioritize regulatory focus on systems with the highest safety significance to enhance decision-making

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[9] Stakeholder Consensus Working Group," Stakeholder Consensus on Proposed Part 53 Major Topics (NRC—2019—0062, RIN 3150—AK31)," https://www.nrc.gov/docs/ML2505/ML25056A010.pdf

[10] "Joint NGO Comments on NRC's Rulemaking on the Part 53, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)"

[11] Nuclear Energy Innovation and Modernization Act (NEIMA), Public Law 115-439 of 2019

This rulemaking is an effort to depart from the existing prescriptive model in 10 CFR Parts 50 and 52 to a risk-informed performance-based (RIPB) approach and to be technology inclusive. There are two themes in the comments already submitted to the NRC by other stakeholders: 1) that the rule needs to be very open to avoid unforeseen future limitations, or 2) that the rule should be more specific on performance requirements to reduce uncertainty of what will be acceptable and therefore streamline the regulatory process. It is noted that these opinions are roughly correlated to developers and industry groups for the former and license holders and utilities for the latter. This dichotomy of perspective is both important to understand and possible to satisfy in this rulemaking process.

Response to Specific Requests for Comments

The NRC is seeking advice and recommendations from the public on this proposed rule. This comment focuses on select aspects of the proposed Part 53 rule.

The following comments and recommendations align with the order of the "VI. Specific Requests for Comments" section in Part 53. BTI aims to answer the questions and provide insights that the NRC finds most useful and needed.

We are particularly interested in comments and supporting rationale from the public on the following:

1. Part 53 Overall Organization

Specific Request for Comment: The NRC is seeking comment on the proposed organization of the requirements in part 53 and possible improvements to how specific requirements (e.g., examples of which specific sections) could be consolidated or otherwise reorganized to make the rule clearer or more concise.

Specific Request for Comment: The NRC is seeking comment on whether such references to other regulations in various sections in the proposed part 53 provide benefits to applicants and licensees, or to other stakeholders seeking to understand the regulatory framework under part 53, or whether such references could be removed to reduce the length of part 53.

The Commission direction from the original rulemaking plan directs staff to "develop requirements at a high level and utilize guidance documents to address details and technology-specific considerations."[12] The Part 53 rulemaking should follow this direction to provide a flexible framework without unnecessary cross-references to existing regulations. However, the draft language initially referenced other parts of Title 10 extensively.

Crossreferencing was reduced in the second revision of some of the draft sections. We are in favor of avoiding unnecessary references when possible, particularly to the existing licensing pathways in Part 50 & 52. Including the text in Part 53 directly provides a clearer understanding of the requirements within the context of the entirety of Part 53, allows text to be modernized where appropriate, and decouples Part 53 from other regulations that may be updated in the future, thereby increasing the ability of those regulations to be modernized without impacting this rule. However, we do not feel that decoupling the Part 53 draft from prior licensing frameworks is sufficient reason in and of itself to increase safety or performance requirements, making a stricter regulation than is applied to the existing fleet.

While some references improve regulatory certainty and reduce burden—such as referencing Part 50 instead of creating a new paradigm—others impose unnecessary constraints that do not serve the statutory requirements of Part 53.

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[12] Nuclear Regulatory Commission, Rulemaking Plan on "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors, SRM-SECY-20-0032, October 2, 2020, ML20276A293.

The overall transferability of Parts 50 and 52 to Part 53 is critical for general usability for developers and applicants. For example, applicants must be able to use a Part 50 Construction Permit with a Part 53 Operating License, and a Part 52 Early Site Permit should be usable for a Part 53 Combined Operating License. The basis behind this ability to transition between frameworks, from existing to new, is that without it, the NRC would roadblock any developers currently in pre-application or any new developers. Within the current language, it is unsure how reactors licensed under Parts 50 and 52 can be transitioned to Part 53. This is true also in the regulatory guides and supporting guidance to Part 53.

Rule language should enable transfers between licensing frameworks except when there are specific reasons to avoid transfers without further evaluation. The NRC draft whitepaper "Development of New Reactor Application Standard Content to Support Timely, Efficient, and Effective Reviews of Subsequent Applications" (ML23296A032) identified that moving from a Part 50 pathway to a Part 52 pathway, even with the same technology, will face potential time delays and may not improve efficiency. Part 50 and 52 use a similar deterministic approach to licensing. The same challenges must be avoided in Part 53 that uses a performance-based approach, which if not addressed, could create further barriers to transitioning to this framework. The ADVANCE Act mandates looking for opportunities for licensing efficiency such as this recommendation, and provides incentives to encourage use of Part 53 once complete.

The existing quality assurance framework under Appendix B to Part 50 is well-established and effective for licensing under Parts 50 and 52. Since supply chain oversight applies across all regulatory frameworks, duplicating it in Part 53 is unnecessary. Industry stakeholders have recommended removing § 53.610 to improve supply chain efficiency. A flexible approach allowing for alternative quality assurance programs would promote international alignment while maintaining regulatory consistency and safety. Quality assurance requirements from Parts 50 and 52 should be transferable to Part 53.

Part 53 should efficiently handle a large volume of applications. There is concern within stakeholders that Part 53 would support and ensure scalability and efficiency. As directed by NEIMA, the NRC must "complete a rulemaking to establish a technology-inclusive, regulatory framework for optional use by commercial advanced nuclear reactor applicants for new reactor license applications" (NEIMA section 103(a)(4)). Adjacent to this technology-inclusive regulatory framework, NEIMA also calls for "predictable, efficient, and timely reviews" (103(a)(1)). Using both explicit text and overt intent from NEIMA, Part 53 is intended to and must meet these requirements to *efficiently* license new reactors.

The language in both the preamble and rule text must be aligned to ensure consistency and clarity. Part 53 should be revised to provide sufficient depth and breadth, promoting widespread adoption by developers and ensuring its effective implementation.

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Table 1. Recommendation – Part 53, Overall Organization

Affected Section	Recommendation
1. GENERAL	The NRC staff should follow the intent in SRM-SECY-20-0032 to "work prospectively with stakeholders to identify and develop necessary regulatory guidance and technical bases."
2. GENERAL	Below, we have listed sections that are recommended for removal. The basis is provided in other sections of this comment in addition to our specific recommendations to improve clarity in other sections as well. • Remove § 53.260 and § 53.270 to prevent redundancy. • Remove § 53.610 to prevent duplication and inefficiencies. • Remove § 53.620(d) to ensure technology-inclusivity.
3. GENERAL	Referencing EP requirements in Part 50 is intended to provide clarity on regulatory requirements. However, the NRC has already identified that more than one approach to EP is acceptable through the existence of multiple approaches in Part 50. Additionally, EP requirements in Part 50 and 52 are deterministically applied as the last layer of defense-in-depth. EP requirements may need to be different in a performance-based framework that uses an integrated approach to achieving or evaluating performance objectives. An integrated performance-based and risk-informed approach should consider EP protective actions relative to the spectrum of events to determine whether safety requirements are met. It should not prescriptively require the same specific approach used in a deterministic framework.

Affected Section	Recommendation
4. GENERAL	Indicate that finalized permits and licenses under other parts will be accepted for use under Part 53. Indicate that evaluations, such as SARs, EIS or EA, under a different Part are referenceable for a Part 53 review. Consider removing "under this part" throughout the Rule. **Part 50/52 to 53** At a minimum, remove "under this Part" from 53.1124(a) through (h), 53.1221, 53.1312, 53.1330(b), 53.1384(b), 53.1425, 53.1443(d), 53.1470, 53.1525, 53.1530. Alternatively add "or Part 50" or "or Part 52" following "under this Part" as appropriate. 53.1434 requires additional references to Part 50 and 52 LWA provisions. Conforming changes and updated references will be required. Guidance could provide additional clarity on limitations and any additional requirements as appropriate. The associated preamble language and some definitions in 53.020 would require conforming changes. **Part 53 to 50/52** Consider removing "under this part" from 53.1161, 53.1218, 53.1221, 53.1251, 52.1279, 53.1288(a)(3) to allow a Part 53 permit or approval to transition to a Part 52 or 50 application. 53.1300 should allow a transition from Part 53 to 50.
5. GENERAL	At a high level, the NRC staff should incorporate a new section within rule text that outlines pathways for efficient licensing. Basis is listed

Affected Section	Recommendation
	throughout this comment and its enclosures pointing to the statutory requirements and the NRC decisions that have led to this recommendation.
6. GENERAL	Aligned language between preamble and rule text. ● The NRC needs to define what "appropriate level of safety" means in the preamble (and 53.220 & 53.450): The applicant must propose the comprehensive risk metric or set of metrics and associated risk performance objectives, and the comprehensive risk metric or set of metrics and associated risk performance objectives must provide an **appropriate level of safety**. ● SRM-SECY-23-0021 directed the staff to not apply a PRA consensus standard as a strict checklist, but the preambles stated that these standards are retained because they have sufficient flexibility. ○ *SRM: The preamble should be revised to explain that the NRC's approval of the metric or set of metrics is not, by itself, an indicator of adequate protection. Rather, the metric (or set of metrics) is part of a suite of regulatory requirements that when considered holistically, form the basis for the NRC's decision making. This is analogous to the approach used for plants licensed under Part 50 and Part 52, where no single regulatory requirement governs whether a plant is "safe enough".*

2. 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?

Specific Request for Comment: If an applicant proposes a novel approach to comprehensive plant risk and the NRC approves the approach, should the resulting NRC-approved comprehensive plant risk metrics and associated risk performance objectives be codified or otherwise memorialized over time and, if so, how?

NRC approved risk metrics are quantitative measures developed over decades to assess the total, integrated risk from a nuclear facility. Initially, the NRC established broad Quantitative Health Objectives (QHOs) to articulate acceptable levels of individual and societal risk, but as technical analyses advanced, these broad objectives were refined into more specific surrogate metrics—such as Core Damage Frequency (CDF), Large Early Release Frequency (LERF), and Conditional Containment Failure Probability (CCFP). The evolution of risk metrics involved extensive technical research, iterative stakeholder engagement, and multiple layers of regulatory review, ultimately leading to a set of benchmarks that capture the complex, cumulative risks associated with both traditional Light Water Reactor (LWR) technology and newer advanced reactor designs.

Staff codified QHOs in the draft proposed rule.[13] The Commission removed QHOs in the SRM and replaced them with comprehensive risk metrics.[14] As currently framed in the proposed rule, applicant-defined comprehensive risk metrics (CRMs) and associated risk performance objectives in part 53 create regulatory uncertainty. It is a challenge for applicants to create and define their CRMs without proper guidance. Without an understanding of what the NRC would consider appropriate risk or other characteristics of such a metric. Existing metrics took significant time to develop and multiple layers of approval. Even with clear guidance, it is likely to create a barrier for applicants compared to existing licensing frameworks or force applicants to default to existing metrics.

There is a lack of clarity about what CRMs they are intended to be in relation to the proposed rule. CRMs were introduced to Part 53 only due to direction in the SRM. There was no public engagement between the SRM and the proposed rule. A workshop on risk metrics changed from

[13] Nuclear Regulatory Commission, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors, SECY-23-0021: Enclosure 1 - Proposed Rule Federal Register Notice, ML21162A102

[14] Nuclear Regulatory Commission, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors, SRM-SECY-23-0021: Enclosure 2 - Edited FRN, ML24064A050.

being related to Part 53 to excluding Part 53 at the last minute, catching all participants off-guard.[15] The staff is still thinking through the concept and how to most effectively apply it as was discussed in public meetings on Part 53 after the proposed rule was published.

The SRM that prescribed the comprehensive risk metrics indicated that further engagement with stakeholders is necessary to develop the metrics. We agree that is the case if comprehensive risk metrics are retained in the final rule.

There are challenges with the concept of comprehensive risk metrics that must be reconsidered.

Conflicting Terminology and Concepts of Risk

The proposed rule mixes regulatory terminology. Terms are used interchangeably in some instances, including "adequate protection", "appropriate level of safety", "acceptable" risk, "safe enough", "comprehensive risk", and "overall risk,", but in other instances it is stated that one does not constitute another. This creates more than regulatory uncertainty. The lack of clarity makes it difficult to even determine what is intended, and completely obscures what would be sufficient to meet the requirements in the rule. When discussing these terms in NRC public meetings, it quickly becomes clear that individuals start with their own mental model of the subject, usually anchored to a specific term that they are most familiar with. Gaining clarity would enable a more objective and efficient engagement on the proposed rule.

Comprehensive risk metrics are defined in the proposed rule as the "total, overall risk from the facility" and associated risk performance objectives are indicative values of the comprehensive risk metrics. However,the preamble later states that a "comprehensive risk metric or set of metrics with associated risk performance objectives is not, by itself, an indicator of adequate protection." and "this is analogous to the approach used for plants licensed under part 50 and part 52, where no single regulatory requirement governs whether a plant is "safe enough." However, the proposed rule states that the QHOs would be acceptable as a risk performance objective. Although the Safety Goals, including the QHOs, are not intended to serve as the sole basis of licensing decisions, they do provide a value for "acceptable risk" and "safe enough."

The proposed rule also suggests that comprehensive risk metrics and risk performance objectives are part of a holistic suite of regulatory requirements for decision making. We agree with that in part (see "Integrated approach to safety" below). However, it then states that is analogous to requirements in Part 50 or 52 where "no single regulatory requirement governs whether a plant is safe enough." It is true that those frameworks do not have a single requirement that defines "safe enough." However, the Part 50 and 52 licensing frameworks used an amalgamation of deterministic requirements and compared the outcomes to risk goals. Part 53 is significantly

[15] Part 53 was a topic under the meeting notice. See, https://www.nrc.gov/pmns/mtg?do=details&Code=20240889. However, the NRC presentation states that the meeting is not related to Part 53: ML24197A161.

different; risk is a core principle, and as drafted requires a comprehensive metric of "overall" risk. There is no comparable comprehensive metric in Part 50 or 52 that *could* define "safe enough."

It is counterintuitive and incongruent for the proposed rule to state that a comprehensive metric of overall risk that considers the effects of all regulatory requirements in the licensing framework and constitutes an appropriate level of safety represents something other than adequate protection. It is unclear under this proposed rule, what additional protection is required or necessary to determine that a plant is "safe enough" or provides "adequate protection" beyond a comprehensive evaluation of all requirements in the framework including a comprehensive risk metric and associated risk performance objectives for "overall risk" that the NRC determines indicate a level of "acceptable" or "appropriate" risk.

Challenges and functional barriers

There are significant challenges related to proposing new risk metrics. The evolution of existing metrics (Enclosure 1), conflicting terminology and definitions of risk in the proposed rule, Commission votes on the draft proposed rule, a recent workshop on risk metrics for advanced reactors, and elsewhere clearly indicate that there is a wide range of viewpoints on risk. Many of these perspectives and definitions conflict.

This not only presents a barrier to applicants defining their own metrics, it is central to the viability of the Part 53 framework as proposed.

As detailed in Enclosure 1, there are functional barriers to develop comprehensive risk metrics. These include historical timelines (discussed in depth in Enclosure 1), layers of approval necessary, and shifting application of existing NRC risk metrics. The lesson is that even when the NRC had internal mandates and timelines to develop a risk metric there were significant barriers. It is unrealistic to expect an applicant to effectively or efficiently define a new novel risk metric or set of metrics and receive NRC approval on a much shorter timeline as part of an application. Preapplication is not mandatory, nor are topical reports to retire regulatory risk before application. As a requirement in the proposed rule, it must be able to be reviewed and approved in the application scope and timeline. History indicates that review of a novel risk metric would not fit in the generic review schedules,[16] let alone meet the expectation in the ADVANCE Act to be more efficient in agency actions.

Given these challenges, the inevitable outcome will be a default to existing metrics, particularly the QHOs. However, the Commission disapproved of the QHOs for multiple reasons—beyond just their codification. While the QHOs were removed as a codified requirement, they remain embedded in the preamble. As a result, the QHOs are likely to become the functional default despite the Commission's decision to remove them. This outcome is contrary to Commission

[16] Nuclear Regulatory Commission, *Generic Milestone Schedules of Requested Activities of the Commission*, https://www.nrc.gov/about-nrc/generic-schedules.html

intent and underscores the challenge of defining a viable pathway for applicants to develop alternative risk metrics.

Defining Acceptable Comprehensive Risk

As explained in greater detail in Enclosure 2 to these comments, the proposed rule has the following policy and legal defects:

- Even though a foundational statutory mandate for the NRC is to assure that the utilization of nuclear material will provide "adequate protection to the health and safety of the public," the NRC historically—and here again in the proposed rule—refuses to specify a metric for "adequate protection" against which to evaluate applications. The proposed rule does not make clear what is "safe enough."
- The approach outlined in the proposed rule is therefore arbitrary and capricious. In a case-by-case review regime, an agency may require different applicants to take different *actions* based on each applicant's unique circumstances—e.g., the type of assurance required for a new AP1000 reactor is likely different from that required for a new microreactor—but an agency may not hold similarly situated applicants to different *standards*.
- The proposed approach also is inconsistent with Congressional intent, as made clear in the 1990 Clean Air Act Amendments, the NEIMA, and the ADVANCE Act. Even if the NRC's "historical practice" was once legally valid, it no longer enjoys that status.
- The Part 50 and 52 licensing frameworks used an amalgamation of deterministic requirements and compared the outcomes to risk goals. Part 53 is significantly different; risk is a core principle, both in terms of requirements and in the process of risk-informing evaluations. It is not a risk-based rule—a risk value is not the sole basis for decisions. Section 112 of the Clean Air Act does not require a risk-based approach and other regulations that follow the statute consider other factors between the "acceptable" and "ample margin" thresholds.

Integrated approach to safety

An integrated safety approach requires that a comprehensive safety metric should capture the cumulative effects of all regulatory requirements, rather than serving as an isolated indicator of risk. The proposed rule should, therefore, reflect that a comprehensive safety performance objective—when evaluated in the context of the entire regulatory framework—is sufficient to demonstrate that a plant is "safe enough." Please refer to the consensus comment. [17]

[17] Stakeholder Consensus Working Group. Stakeholder Consensus on Proposed Part 53 Major Topics (NRC—2019—0062, RIN 3150—AK31), https://www.nrc.gov/docs/ML2505/ML25056A010.pdf

The NRC's recent directive in SRM-SECY-23-0021 (2024) exemplifies this view by disapproving the codification of QHOs and directing applicants to propose a comprehensive plant risk metric that includes detailed methodologies and assumptions. This metric is not intended to stand alone as the sole basis for demonstrating adequate protection; instead, it should integrate with other regulatory measures to form a cohesive safety evaluation.

This is the only realistic approach to a comprehensive metric. To evaluate a comprehensive or overall risk or safety of a facility, the only realistic approach is to consider the effect of requirements such as quality control, reactor operator training, and emergency preparedness, as well as other requirements. Excluding these requirements would simply not provide a comprehensive or overall risk.

If this is conceptually approached from the opposite direction, the question could be framed as: *'If a comprehensive risk evaluation that does not consider all regulatory requirements in an integrated approach confirms that a facility has acceptable risk, are the other regulatory requirements necessary to protect the health and safety of the public?'* The answer may be yes for some regulations, such as decommissioning, which don't have any direct impact on operating safety. However, some other requirements may be more difficult to justify.

For the regulatory framework to be both effective and equitable, clear, consistent, and comprehensive guidance must be provided to applicants, so that they understand precisely what is expected and can reliably demonstrate compliance without having to reinvent a decades-long developmental process.

Table 2. Recommendation – Part 53, Subpart B—Comprehensive Risk Metrics

Affected Section	Recommendation
1. Subpart B—Comprehensive Risk Metrics	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.

Affected Section	Recommendation
	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 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.
2. Subpart B—Comprehensive Risk Metrics	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.
3. Subpart B—Comprehensive Risk Metrics	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.
4. Subpart B—Comprehensive Risk Metrics	Emphasize that the overall goal of CSM is to help ensure the outcome of "adequate protection of public health and safety" as the key figure of merit when evaluating existing or proposed metrics.
5. Subpart B—Comprehensive Risk Metrics	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 and evaluation

Affected Section	Recommendation
	methodologies that meet the overall intent of the CSM.
6. Subpart B—Comprehensive Risk Metrics	Remove explicit references to QHOs in the rule text to prevent QHOs from becoming a de facto regulatory requirement that requires applicant compliance
7. Subpart B—Comprehensive Risk Metrics	If comprehensive risk metrics are retained in the final rule, despite recommendations, further revision to the definition is required. The inconsistent use of terminology and concepts of risk must be addressed.
8. Subpart B—Comprehensive Risk Metrics	Comprehensive risk metrics and associated risk performance objectives must be consistent with Congressional direction on radiological risk standards in Section 112 of the Clean Air Act. If metrics are applicant-defined, the NRC must give clear direction in the preamble and separate guidance documentation that proposed metrics and objectives should be consistent with the level of risk established by Congress that define "acceptable risk" and "ample margin of safety to protect public health." If the NRC does not accept this comment, provide a detailed justification for the rejection, including a basis for why the comprehensive risk values in the Section 112 of the Clean Air Act do not form an appropriate comprehensive risk metric for this proposed rule. The NRC should also explain how this requirement, and metrics deemed acceptable in the preamble including the QHOs, do not require a level of protection of margin of safety that is more than what Congress determined is "ample".

3. Defense in Depth

Specific Request for Comment: The NRC is seeking comment on the inclusion of the proposed requirements to assess and provide defense in depth.

Specific Request for Comment: The NRC is also seeking comment on whether to include specific provisions in § 53.250 and subpart B to more explicitly address the possible role of inherent characteristics of some SSCs in preventing or mitigating unplanned events. How could possible inherent characteristics of SSCs be considered in the proposed requirements in § 53.250 or in any alternative requirements for defense in depth provided in response to this item?

Defense-in-depth is one "attribute that could assist in establishing the acceptability or license-ability of a proposed advanced reactor design" without requiring it in the rule.[18] Applicants should have the flexibility to identify safety functions, design criteria, and other characteristics that meet performance-based safety requirements.

As defined in the proposed rule text, defense-in-depth is not a performance-based requirement. 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.

This deterministic approach also creates challenges for anticipated event sequences that are not expected to result in the release of radioactive materials even if the event does occur. The definition of licensing basis events includes these anticipated event sequences. The draft text's prohibition on relying on a single barrier, regardless of its robustness, could apply the defense-in-depth philosophy more strictly than intended under existing Commission policies.

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." [19]

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[18] Nuclear Regulatory COmmission, *Policy Statement on the Regulation of Advanced Reactors*, October 14, 2008, https://www.federalregister.gov/documents/2008/10/14/E8-24268/policy-statement-on-the-regulation-of-advanced-reactors

[19] Nuclear Regulatory Commission, Application of the Single Failure Criterion to Nuscale Power LLC's Inadvertent Actuation Block Valves, SRM-SECY-19-0036, July 2, 2019, https://www.nrc.gov/docs/ML1918/ML19183A408.pdf

§ 53.250 should be as technology-inclusive as possible. The inherent characteristics of some SSCs can be stated as examples but not a comprehensive list of the proposed requirements. Defense-in-depth does not have to be in the rule to achieve reasonable assurance of adequate protection because addressing uncertainties is already required in existing Commission policy and guidance.

Table 3. Recommendation – Part 53, Subpart B—Defense in Depth

Affected Section	Recommendation
1. § 53.250 Defense in depth.	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 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.
2. § 53.250(b)	As stated above, we recommend retaining § 53.250(a) while removing (b) and (c) to maintain flexibility in how applicants address

Affected Section	Recommendation
	defense-in-depth. Rather than codifying specific provisions for inherent safety features in the rule, we propose that NRC acknowledge their role in guidance documents and SRPs (Standard Review Plans). This approach ensures that inherent safety features are recognized as valuable without being mandated in a way that could unintentionally limit flexibility. Additionally, the preamble should explicitly acknowledge that inherent safety features can play a role in meeting defense-in-depth objectives without dictating their use or precluding other approaches. This preserves a technology-inclusive framework while maintaining alignment with existing Commission policy and guidance on uncertainty management.

4. Probabilistic Risk Assessment

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.

Part 53 is mandated by NEIMA to be a risk-informed performance-based framework that is technology-inclusive. A systematic evaluation of risk is prudent and necessary. However, the proposed rule currently unnecessarily limits the options to evaluate risk by arbitrarily dictating applicants use PRA. A strict requirement for the use of PRA will also limit the transferability from existing frameworks to Part 53.

To be technology-inclusive, the framework must be flexible enough to efficiently 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. While PRA is a proven and valuable tool, mandating its use may preclude alternative, equally robust methods better suited to specific designs or scenarios. The rule should allow the use of PRA as one potential risk evaluation method, allowing applicants to use alternative methods that achieve equivalent

safety outcomes. The term "risk evaluation" was used to replace "PRA" in the Enclosure 2 to the SRM (ML2406A050)[20] and our recommendations below align with this change.

§ 53.450(b) 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.

§ 53.450(e) mandates comprehensive analyses, 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 such as over reliance on PRA, unnecessary regulatory burdens, and limiting the use of risk evaluation methodologies. It should allow more flexibility in the methodologies.

Consistent with the ADVANCE Act and Commission direction, alternative risk evaluations beyond PRA should be optionally usable in Part 53. ADVANCE Act Section 208(a)(1)(e) requires the NRC to develop strategies and guidance for "risk analysis methods, including alternatives to probabilistic risk assessments." The strict use of PRA in the proposed rule is limiting and explicitly contradicts the direction in the ADVANCE Act.

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.

A tangible example of the need for flexible risk evaluation approaches is the Kairos Power Hermes and Hermes 2 construction permit applications. Kairos did not use a strict PRA approach in these applications. The NRC approved and issued the construction permits for both facilities. It indicates that developers plan to use alternative approaches, and there is precedent that the NRC has already accepted alternative approaches. Limiting Part 53 to only a PRA methodology is arbitrary and does not align with past licensing decisions, the intent of NEIMA, the ADVANCE ACT, and the new mission statement of the NRC. It could also limit the transferability for applicants between licensing frameworks, limiting the potential for applicants to use Part 53 once finalized.

Instead of mandating specific methods, NRC should focus on defining clear performance outcomes, allowing applicants to choose the most appropriate risk evaluation approach.

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.

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[20] Nuclear Regulatory Commission, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors, SRM-SECY-23-0021: Enclosure 2 - Edited FRN, ML24064A050.

Additional clarity is needed on the definition of an "appropriate level of safety." This term is used differently in the proposed rule than existing rules and guidance. While NRC staff have indicated openness to proposals, a clearer definition of expectations—including clarity on ensuring safety "comparable to what has been licensed in the past"—should be explicitly addressed, either in the rule or accompanying guidance.

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 be developed as-needed to avoid inadvertently limiting innovation.

To align with risk-informed, performance-based, and technology-inclusive principles, the placement and control of risk evaluation-related information should prioritize:

a. Transparency and accessibility for safety evaluations.
b. Flexibility to integrate evolving risk insights.
c. 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.

Table 4. Recommendation – Part 53, Subpart C—Probabilistic Risk Assessment

Affected Section	Recommendation
1. § 53.450	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 technologically and actuarially plausible risk parameters and reasonable uncertainty margins. To do so, revise mentions of PRA to "risk evaluation." **Proposed Rule Text Revision — § 53.450:** ~~Requirement to have a probabilistic risk assessment (PRA). A PRA~~ *Risk Evaluation methods* of each commercial nuclear plant must be performed to identify potential failures, susceptibility to internal and external hazards,

Affected Section	Recommendation
	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. **Risk evaluation methods Definition:** 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 to change the PRA requirement to "risk evaluation,".
2. Subpart C—Probabilistic Risk Assessment	Guidance should be considered on the level of detail necessary depending 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)

Affected Section	Recommendation
	- 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 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.

5. Emergency Preparedness and Security Programs

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.

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 redeployable. It is unclear how emergency preparedness should be addressed for reactors that are on mobile platforms. One example is ships that use a reactor for propulsion and power. Ships that are powered by a reactor could visit many ports. The use of "initial" 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 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-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.

Table 5. Recommendation– Part 53, Subpart F—Emergency Preparedness and Security Programs

Affected Section	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	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. **Recommendations:**

Affected Section	Recommendation
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 establish a class of licensees that would not be required to protect against the design-basis threat (DBT) of radiological sabotage.	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 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 decisions 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.

Specific Request for Comment: The NRC is specifically seeking comment on possible challenges arising from the interactions between the proposed regulations and related assessments for grading the requirements for emergency planning and security.
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:
• 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 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. More clarity is also needed on how to consider uncertainty and cliff-edge effects.

Table 6. Recommendation– Part 53, Subpart F—Emergency Preparedness and Security Programs

Affected Section	Recommendation
1. 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,"	Additional guidance is needed to address graded approaches for emergency planning and security programs under the scenarios described for part 53 applicants and licensees. 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. 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.

6. Licenses To Construct and Operate Commercial Nuclear Plants of Identical Design at Multiple Sites

Specific Request for Comment: Given how the requirements in proposed § 53.1470 would be implemented as currently written, the NRC is seeking comment on whether there are opportunities to allow added flexibility for applicants under these provisions. This could include consideration of whether applications for which the "common design" is not completely identical could be evaluated under this provision and, if so, what the process would be for determining the appropriateness of a common review. In addition, the NRC is interested in feedback about the pros and cons of requiring that applications under these proposed provisions be submitted at the same time versus allowing them to be submitted on a staggered basis.

Providing flexibility in the review process for "common designs" that are not fully identical is necessary to support the efficient licensing and deployment of advanced reactors while maintaining safety and regulatory oversight and enabling innovation. Many design variations, such as site-specific adaptations or operational optimizations, do not fundamentally alter the risk or safety profile of a reactor. Allowing such applications to be evaluated under § 53.1470 would reduce unnecessary regulatory hurdles while ensuring appropriate scrutiny for changes that materially impact safety.

By incorporating performance-based thresholds, the NRC can establish clear criteria for what constitutes an acceptable deviation, preventing ambiguity and ensuring that flexibility does not come at the expense of safety. Careful wording of these provisions is essential to avoid confusion and ensure that the review process remains predictable and effective.

Allowing staggered submissions balances regulatory efficiency with industry flexibility. Requiring simultaneous submission could create unnecessary barriers for developers managing multiple projects with varying timelines. A staggered approach ensures that lessons learned from earlier reviews can be incorporated into subsequent applications, improving regulatory outcomes while reducing redundant NRC efforts. Additionally, enabling applicants to adjust timelines based on market conditions or project-specific developments provides a practical pathway for deployment without compromising safety or oversight.

Table 7. Recommendation – Part 53, Subpart H—Licenses To Construct and Operate Commercial Nuclear Plants of Identical Design at Multiple Sites

Affected Section	Recommendation
1. The proposed § 53.1470 provides optional requirements related to the submittal and NRC review of CP, OL, and COL applications to construct and operate commercial nuclear plants of identical design at multiple sites, similar to requirements found in appendix N in both 10 CFR parts 50 and 52. a. Proposed § 53.1470 would also require that each application list all the applications that are to be treated together to ensure that the NRC is clearly informed of the intentions of all applicants.	The NRC should revise § 53.1470 to allow applications for "common designs" that are not completely identical to be reviewed under this provision. This could include minor variations related to site-specific conditions or operational optimizations. **Proposed Revision to § 53.1470:** "Applications for commercial nuclear plants with a 'common design' that are not fully identical may be reviewed under this provision, provided the applicant demonstrates that deviations are minor, site-specific, or do not significantly

Affected Section	Recommendation
b. In addition, § 53.1470 would require the ACRS to report on each of the applications, as would be required by provisions in subpart H of part 53.	increase the risk or safety performance of the design, or reduce safety margins below accepted levels. The NRC shall evaluate such applications against performance-based thresholds specified in subpart [X]."
2. § 53.1470	Allow applicants to submit applications on a staggered basis while maintaining the option for simultaneous submissions. Include provisions to: 1. Require applicants, to the extent practical, to identify the staggered timeline upfront and describe how subsequent applications will incorporate NRC feedback from earlier reviews. 2. Provide flexibility for applicants to adjust staggered timelines based on market or project-specific developments. **Proposed Revision to § 53.1470:** *"Applicants may submit applications under this provision on a staggered basis. The applicant should list all intended applications in the initial submission and that the applicant provides a roadmap detailing the intended submission sequence and integration of NRC feedback from earlier reviews to the extent practical."*

7. Physical Security

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.

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 8. Recommendation – Part 73, Section 73.100—Physical Security

Affected Section	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."	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 *if* it is revised as recommended in our submitted comment:[21] • **Incompatibility with Part 53:** BTI acknowledges and supports the decision that the NRC is not currently proposing to add submittal requirements regarding physical security features or compensatory measures to standard design certification applications under 10 CFR Part 52, Subpart B. Should the NRC decide to take the opposite route, the inclusion of submittal requirements similar to those for emergency planning under § 52.17(b)(2) and (3) would cause unintended consequences for Part 53 if enacted too rigidly. In the near term, submittal requirements similar to existing regulatory frameworks

[21] Spencer Toohill, The Breakthrough Institute, *Comment on Alternative Physical Security Requirements for Advanced Reactors*, [Docket ID NRC-2017-0227], October 23, 2024. ML24312A335.

Affected Section	Recommendation
	would enable greater guidance specific to light-water technology. As this rulemaking is specifically addressing advanced reactors and the diverse technological qualities that come along with advanced reactors, it is essential for the NRC to not only consider but implement regulations that are technologically inclusive and flexible to adapt to forthcoming rulemaking and regulatory guidance. • **Clarify and harmonize security standards**: We advocate for ensuring consistency in terminology and definitions, such as replacing "high assurance" with "reasonable assurance," to align with the Atomic Energy Act and existing NRC regulations. This will reduce confusion and improve clarity for developers. • **Adopt a performance-based approach for security requirements**: Support a shift to performance-based standards for advanced reactors, aligning with the NRC's broader approach to risk-informed regulation. This should include harmonizing offsite dose limits across sections and preventing ambiguous interpretations of "significant release" language. • **Enhance flexibility for small entities and microreactors**: Reassess the use of a fixed 8 MWe threshold for defining small entities and instead adopt a more flexible, technology-inclusive definition that considers the diverse applications of advanced reactors, particularly in non-electric or small-scale use cases. Leave objectives and standards in implementing

Affected Section	Recommendation
	guidance. Make any necessary revisions to DG-5076 to ensure it applies to Part 53.

8. Recent Legislation

The Part 53 rulemaking must follow the intent and statutory requirements of NEIMA as well as adhere to ADVANCE Act provisions.

In 2019, Congress passed the Nuclear Energy Innovation and Modernization Act (NEIMA), mandating the Nuclear Regulatory Commission (NRC) to establish a technology-inclusive licensing framework for advanced reactors. The Part 53 rule needs to be developed to follow NEIMA's intent and published by 2027.

Numerous areas in the proposed rule fail to meet NEIMA's intent for the entirety of the rule to enable technology-inclusive licensing of diverse and innovative nuclear reactor designs and operational approaches. Various areas of the rule focus on prescriptive and defined technical specifications, limiting the applicability only to those designs that fit within those conditions. Throughout this consensus comment, we aim to point the NRC staff to those areas and propose performance based outcomes to better align with the intent and the stipulations of NEIMA.

These recommendations will:

- Align Part 53 with NEIMA's mandate to support innovation and commercialization.
- Reduce regulatory uncertainty for applicants by emphasizing predictable, objective criteria.
- Encourage broader participation in advanced nuclear projects by lowering barriers for smaller or first-of-a-kind reactor designs.
- Preserve safety and security by focusing on outcomes rather than prescriptive design features.

By integrating these provisions into Part 53, the NRC can more effectively support the development of a robust, diverse, and innovative advanced nuclear sector.

On July 9th, 2024, the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024 (ADVANCE Act), was signed into law. The ADVANCE Act of 2024 plays a crucial role in shaping Part 53 by reinforcing the need for a modernized, efficient, and technology-inclusive regulatory framework that supports the deployment of advanced nuclear reactors. The Act emphasizes streamlining licensing and siting, reducing unnecessary regulatory burdens, and

accelerating innovation, all of which align with the intent of NEIMA and the NRC's Part 53 rulemaking.

By integrating the flexibility and risk-informed approaches encouraged by the ADVANCE Act, the NRC can ensure that Part 53 supports, rather than hinders, the rapid and responsible deployment of advanced reactors needed for energy security, decarbonization, and economic growth.

Specific Request for Comment: The NRC is seeking comment on how Part 53 could be revised to better enable its potential use to implement the ADVANCE Act.

a) Section 203

The current definition is not technology-inclusive and is overly descriptive, limiting the flexibility needed to accommodate the diverse range of reactor technologies. It assumes a one-size-fits-all approach that doesn't account for the specific circumstances and characteristics of advanced reactors. Moreover, the assumption that population growth is inherently problematic overlooks the natural and expected trends of demographic shifts. Population growth tends to occur more in areas near existing plants due to factors like workforce commute, which is a common and predictable pattern.

Sections 53.530(a)(1) and (2) represent deterministic risk objectives, which fail to account for broader, population-related considerations. These objectives do not integrate the concept of defense-in-depth, particularly by not allowing for protective actions that are a critical part of emergency preparedness requirements. This narrow focus is inconsistent with a holistic, integrated approach to licensing, which should encompass the full spectrum of safety measures, including preparedness and protective actions, rather than focusing solely on fixed, prescriptive risk thresholds. The rule should be revised to align with a more flexible and inclusive framework that accounts for the unique safety features of advanced reactors and integrates the full range of protective measures.

b) Section 401

The NRC should address the provision of ADVANCE Act Section 401 in Part 53 rulemaking as possible to increase efficiency. However, Section 401 requires extensive external engagement that might not be complete in the available timeline.

c) Section 501

To align Part 53 with Section 501 of the ADVANCE Act and the newly enacted mission statement of the NRC, the NRC staff should explicitly incorporate principles of efficiency and societal benefit to

enable and advance nuclear technologies into the framework. It is clear that the NRC has the authority to consider the general welfare and benefits to society and is required to do so.[22]

These recommendations align with Section 501 by:

- Explicitly integrating efficiency and societal benefit considerations into Part 53.
- Ensuring that NRC staff and processes reflect the updated mission.
- Encouraging innovation and the timely deployment of advanced nuclear technologies.
- Balancing regulatory oversight with the broader policy goals of promoting nuclear energy as a societal good.

By incorporating these provisions into Part 53, the NRC can ensure that its mission and practices reflect the intent of the ADVANCE Act while maintaining the highest safety and security standards.

Specific Request for Comment: Specifically, Section 208 of the ADVANCE Act requires the NRC to develop and implement "risk- informed and performance-based strategies and guidance" in several areas for the licensing and regulation of micro-reactors, including with respect to "licensing mobile deployment." The ADVANCE Act requires the NRC to consider "the unique characteristics of micro-reactors," including physical size, design simplicity, and source term; opportunities to incorporate specific improvements related to streamlining the review process; and other policy and licensing issues. With regard to implementation, the ADVANCE Act provides the NRC with three options. The NRC may implement the developed strategies and guidance, as appropriate, via (1) the existing regulatory framework, (2) the Part 53 rulemaking, or (3) a pending or new rulemaking. Given the language included in Section 208, the NRC is seeking comment on how part 53 could be revised to better address the ADVANCE Act's requirements related to strategies and guidance for micro-reactors.

d) Section 208

To meet the requirements of Section 208 and facilitate the licensing and regulation of microreactors under Part 53, the NRC should focus on tailoring the framework to the unique characteristics of microreactors, streamlining review processes, and enabling innovative deployment strategies such as mobile deployment and pre-fueled transportation. We have listed specific proposed revisions, new provisions, and recommendations.

Ongoing efforts related to licensing microreactors in the form of public workshops, whitepapers, and policy option papers may provide more detailed and novel solutions.

The proposed revisions to Part 53 reflect the specific characteristics of microreactors and

[22] Dr. Adam Stein, The Breakthrough Institute, *Considering Nuclear Energy's Benefits to Society: Update to the Mission Statement of the Nuclear Regulatory Commission as Required by the ADVANCE Act*, November 25, 2024, https://www.nrc.gov/docs/ML2433/ML24337A023.pdf

opportunities for additional efficiencies. In general, these efficiency improvements could be achieved without specific rule text in an appropriately designed and implemented risk-informed performance-based rule. However, without specific statements that an efficient, risk-informed, and graded approach to application review should be used it is not clear that objective would occur.

Existing "covered sites" and operating production or utilization facilities may be located in areas that at one time were low population or remote but have developed over time. Existing rules and guidance limit or discourage development of new facilities at these sites.

Table 9. Recommendation – Recent Legislation

Affected Section	Recommendation
1. GENERAL — Part 53: Addressing NEIMA SEC. 103. ADVANCED NUCLEAR REACTOR PROGRAM. (a): (4) TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK.—Not later than December 31, 2027, the Commission shall complete a rulemaking to establish a technology-inclusive, regulatory framework for optional use by commercial advanced nuclear reactor applicants for new reactor license applications.	**Proposed Rule Text Revisions** 1. Definition of Technology-Inclusive Framework, Proposed § 53.2 (Definitions): Add a definition for "technology-inclusive framework": *"Technology-inclusive framework" means a regulatory approach that applies uniformly to all reactor designs by emphasizing performance-based and risk-informed safety objectives rather than design-specific prescriptive requirements, enabling the evaluation of a diverse range of advanced reactor technologies.* 2. Performance-Based Criteria for Safety Objectives, Proposed § 53.210 (Safety Criteria): Revise to explicitly state the technology-inclusive intent: *(a) Safety criteria must be established to ensure the safe operation of all commercial nuclear reactor technologies, regardless of design. These criteria shall be based on performance outcomes that align with risk-informed principles.* *(b) The criteria must:*

Affected Section	Recommendation
	(1) Address all potential radiological hazards without imposing design-specific technical solutions; *(2) Allow licensees to propose innovative approaches to meet safety performance standards; and* *(3) Be scalable to the size, complexity, and risk profile of the technology.* 3. Clarity on Applicability to Advanced Designs, Proposed § 53.300 (Application and Scope): Amend to clarify the inclusivity of various technologies: *(a) This part applies to all advanced reactor technologies, including, but not limited to, light-water, non-light-water, molten salt, fast neutron spectrum, and microreactor designs.* *(b) The Commission may issue supplemental guidance under this part to address technology-specific considerations, provided such guidance does not impose prescriptive requirements inconsistent with the objectives of § 53.210.* 4. Stakeholder Engagement and Pre-Application Process, Proposed § 53.500 (Pre-Application Engagement): Introduce a new provision to formalize pre-application processes: *(a) The Commission encourages early engagement with applicants to provide feedback on novel design approaches and clarify regulatory expectations.* *(b) Pre-application consultations may address:* *(1) Interpretation of performance-based safety objectives under § 53.210;* *(2) Identification of potential risks and mitigation strategies; and*

Affected Section	Recommendation
	(3) Review of technical and regulatory challenges unique to the applicant's design. 5. Other areas of the proposed rule that will subsequently need to be revised to align with the above provisions. **Guidance Enhancements** To support the implementation of these changes, the NRC should update its guidance documents (e.g., NUREG-series and Regulatory Guides): 1. Scalability Guidance: Include examples of how smaller reactors with lower risk profiles can meet performance-based objectives without unnecessary regulatory burden. 2. Technology Demonstrations: Allow for phased licensing or pilot programs to test new designs in a controlled manner while collecting operational data to inform full licensure. 3. Risk-Informed Review Examples: Provide hypothetical scenarios to illustrate how risk-informed principles apply to various advanced technologies, ensuring consistency in application.
2. SEC. 203. LICENSING CONSIDERATIONS RELATING TO USE OF NUCLEAR ENERGY FOR NONELECTRIC APPLICATIONS.	Revise 10 CFR 53.530(c) to "(c) ~~Reactor sites should be located away from very densely populated centers.~~ Areas of low-population density are, generally, preferred. However, in determining the acceptability of a particular site located away from a very densely populated center but not in an area of low-population density, consideration will be given to safety, environmental, economic, or other factors, which may result in the site being

Affected Section	Recommendation
	found acceptable." and put it in guidance so it is consistent with its counterpart in Part 50/52. A categorical exemption should be included for the existing sites, microreactors and coal to nuclear transitions. The definition of population center distance should be changed from the deterministic "25,000 residents" to a risk-informed performance-based objective, especially with the microreactors.
3. GENERAL — Part 53: Addressing ADVANCE Act Section 206. REGULATORY ISSUES FOR NUCLEAR FACILITIES AT BROWNFIELD SITES.	Create a categorical exemption of 53.530 for the existing sites defined as "covered sites" in the ADVANCE Act, including production facilities, utilizations facilities, brownfield sites, and microreactors. The definition of population center distance should be changed from a deterministic threshold of "25,000 residents" to a performance-based metric. Available information and data should be used to the extent possible. This may include site-specific geologic, seismic, weather, and other environmental data. The potential impacts to the environment from a new facility should consider improvements that may occur compared to the as-found condition of the site. The use of plant parameter envelopes and site parameter envelopes on a portion of a larger site without the need to segment the site parcel. The use of early site permits, with or without site parameter envelopes, to finalize site approval without the need to re-evaluate the site when evaluating a CP, OL, or COL. The ESP should remain valid until and unless significant changes in the

Affected Section	Recommendation
	site are identified. ESPs that are issued under Part 52 or 53 should be valid for any other licensing pathway.
3. GENERAL — Part 53: Addressing ADVANCE Act Section 208. REGULATORY REQUIREMENTS FOR MICRO-REACTORS.	**Proposed Preamble Language** *Section 208 of the ADVANCE Act emphasizes the need for risk-informed and performance-based strategies and guidance for licensing and regulating microreactors. This includes addressing unique features of microreactors such as physical size, design simplicity, and source term. In response, Part 53 revisions aim to ensure licensing flexibility, streamline the review process, and enable innovative deployment models such as mobile deployment and transportation of pre-fueled reactors. These revisions prioritize efficiency, regulatory clarity, and stakeholder confidence while maintaining safety, security, and environmental protection.* **Definitions** Mobile Microreactor: A mobile microreactor is a compact nuclear reactor system designed for operation at multiple locations without requiring permanent infrastructure at any single site. Mobile microreactors are intended for deployment and operation at multiple temporary or remote sites. It is not stationary and can also operate in motion. Transportable Microreactor: A transportable microreactor is a nuclear reactor system designed to be moved between locations in a fully assembled or partially modular state, specifically for deployment at a single, pre-approved or

Affected Section	Recommendation
	prepared site. It does not operate while moving. **Proposed Revisions and Additions to Part 53** 1. Microreactor-Specific Licensing Pathways, Proposed § 53.XXX (Microreactor Licensing Framework): Add a new section specific to microreactors: (a) This section provides a streamlined, risk-informed, and performance-based pathway for licensing microreactors, considering their unique characteristics. (b) Applicants seeking licenses for microreactors may: (1) Use pre-determined risk thresholds that reflect the simplified designs and lower source terms; (2) Submit consolidated applications that integrate multiple phases of the licensing review process; (3) Utilize performance-based alternatives to prescriptive requirements where feasible. (c) The Commission shall provide efficient licensing timelines and clear guidance for applicants pursuing mobile and pre-fueled reactor deployments. 2. Transportation of Fueled Microreactors, Proposed § 53.XXX (Transportation of Fueled Microreactors): Create a new section addressing transportation challenges: *(a) Applicants proposing to transport pre-fueled microreactors must provide:* *(1) A transportation safety analysis that accounts for unique design features;* *(2) A risk-informed plan for ensuring the*

Affected Section	Recommendation
	security of the reactor during transport; *(3) Emergency response plans tailored to the transportation route.* *(b) The Commission shall develop guidance to streamline approval of transport plans, leveraging experience from prior applications under Part 50 and Part 52.* 3. Siting and Deployment Flexibility, Proposed § 53.XXX (Siting and Mobile Deployment): Introduce provisions specific to siting and mobile deployment: *(a) The Commission shall allow for flexible siting criteria for microreactors, considering:* *(1) Reduced source terms;* *(2) Smaller physical footprints; and* *(3) Simplified designs that limit offsite consequences.* *(b) Applicants proposing mobile deployment must:* *(1) Demonstrate the ability to deploy and operate safely under varying site conditions;* *(2) Provide risk assessments for transitioning between sites; and* *(3) Establish performance-based criteria for environmental and operational compliance.* 4. Alternatives to PRA Part 53 must meet this provision in the ADVANCE Act and consider alternatives to PRA. Limiting the use of alternatives to PRA in a technology-specific way to microreactors would not comply with the intent of NEIMA to provide a technology-neutral, risk-informed, and performance-based licensing framework. Performance objectives should be

Affected Section	Recommendation
	defined for risk evaluations to determine acceptability. *Proposed Revision* § 53.450: *"~~Requirement to have a probabilistic risk assessment (PRA).~~ Risk Evaluation methods* of each commercial nuclear plant must be performed...
5. GENERAL — Part 53: Addressing ADVANCE Act Section 401. REPORT ON ADVANCED METHODS OF MANUFACTURING AND CONSTRUCTION FOR NUCLEAR ENERGY PROJECTS.	**Proposed Preamble Language** *Section 401 of the ADVANCE Act emphasizes the advanced methods of manufacturing and construction for nuclear energy projects. This includes addressing advanced manufacturing processes, advanced construction techniques and rapid improvement or iterative innovation processes. In response, Part 53 revisions aim to ensure any changes during construction still conform to the facility's licensed design and the NRC needs to determine when a license amendment is required. These revisions prioritize efficiency, regulatory clarity, and stakeholder confidence while maintaining safety, security, and environmental protection.* **Definitions:** **Rapid improvement:** The ability to implement improvements quickly to in-process or subsequent units. Changes may be applied to units that are in the production stage when necessary or optimal. **Iterative innovation processes:** A process that achieves innovation by optimizing a design or process across multiple units in a series. This process is characterized by refinement and improvement through updates to a design across

Affected Section	Recommendation
	multiple versions or generations. **Proposed Part 53 Rule Text for Section 401: Advanced Methods of Manufacturing and Construction** §53.XX Advanced Manufacturing and Construction for Nuclear Energy Projects (a) General Requirements for Advanced Manufacturing and Construction The Commission shall, in line with the provisions of the ADVANCE Act, adopt performance-based strategies to incorporate advanced manufacturing processes, construction techniques, and rapid iterative innovation methods into the licensing of nuclear energy projects. These methods should aim to enhance safety, reduce regulatory burden, and promote the efficient use of advanced technologies within the existing regulatory framework. The Commission will evaluate each advanced manufacturing and construction method based on its alignment with safety objectives, regulatory goals, and operational performance. **Guidance Development** To ensure that the use of advanced manufacturing and construction techniques is appropriately regulated, the staff must develop detailed guidance that expands on the general principles outlined in this rule. This guidance should address the following key areas: • Safety and Performance Standards: Specific criteria for evaluating the safety and performance of advanced manufacturing

Affected Section	Recommendation
	methods and construction techniques. ● Inspection and Oversight: Procedures for the inspection and oversight of facilities using advanced methods, ensuring compliance with applicable safety standards. ● Qualification of Materials and Components: Guidance on the qualification of new materials and components used in nuclear energy projects, including the need for compliance with existing codes and standards. ● Integration with Licensing Process: Clarification on how advanced manufacturing and construction methods can be integrated into the licensing process, including the development of standardized designs and the potential for expedited reviews. ● Transportation of Nuclear Reactor Components: Guidelines addressing the transportation of advanced nuclear reactor cores and components, including any specific requirements for handling and transport.
4. GENERAL — Part 53: Addressing ADVANCE Act Section 501. MISSION ALIGNMENT.	**Proposed Preamble Language** *Section 501 of the ADVANCE Act directs the NRC to update its mission statement to emphasize efficiency and societal benefits while maintaining safety, security, and environmental protection. To implement this, Part 53 will include provisions that balance robust regulatory oversight with streamlined processes, ensuring that the licensing and regulation of advanced nuclear technologies promote innovation, economic growth, and societal well-being. These changes aim to*

Affected Section	Recommendation
	eliminate unnecessary regulatory burdens and provide clear, predictable pathways for the civilian use of radioactive materials and nuclear energy. **Proposed Rule Text Revisions** 1. Statement of Purpose, Proposed § 53.1 (Purpose and Scope): Revise to include language reflecting Section 501's mandate: *(a) The purpose of this part is to establish a technology-inclusive, risk-informed, and performance-based regulatory framework for the licensing of advanced nuclear reactors.* *(b) The Commission shall administer this framework in a manner that:* *(1) Provides reasonable assurance of adequate protection of public health and safety;* *(2) Promotes the common defense and security;* *(3) Protects the environment;* *(4) Facilitates the efficient licensing and regulation of civilian uses of radioactive materials and nuclear energy; and* *(5) Supports the realization of societal benefits associated with nuclear energy and radioactive material technologies.* 2. Efficiency Requirements, Proposed § 53.450 (Regulatory Efficiency): Introduce a new provision to promote efficiency: *(a) The Commission shall ensure that the licensing process under this part minimizes unnecessary regulatory burden while maintaining safety, security, and environmental protection.* *(b) The Commission shall:*

Affected Section	Recommendation
	(1) Utilize performance-based and risk-informed approaches to reduce prescriptive requirements; *(2) Establish clear timelines and milestones for application reviews;* *(3) Provide applicants with timely feedback during the pre-application and review phases; and* *(4) Promote the use of standardized design reviews and pre-application consultations to streamline the licensing process.* 3. Promoting Societal Benefits, Proposed § 53.500 (Societal Impact Considerations): Include provisions to emphasize the societal benefits of nuclear energy: *(a) The Commission shall consider the potential societal benefits of advanced nuclear reactors and radioactive material technologies, including:* *(1) Contributions to economic development and job creation;* *(2) Environmental benefits, including reductions in greenhouse gas emissions;* *(3) National energy security; and* *(4) Public health improvements through reliable energy and medical isotope production.* *(b) The Commission shall develop guidance to assess and incorporate societal benefit considerations into regulatory decision-making.*
6. GENERAL — Part 53: Addressing ADVANCE Act Section 505. NUCLEAR LICENSING EFFICIENCY.	**Proposed Preamble Language** *Section 505 of the ADVANCE Act emphasizes the*

Affected Section	Recommendation
	importance of nuclear licensing efficiency. **Proposed Part 53 Rule Text for Section 505: Nuclear Licensing Efficiency** §53.XX Advanced Nuclear Licensing Efficiency The Part 53 pathway is designed to be more efficient. The NRC will give directions during the pre-application activities or during the application activities so that the licensing process will be smoothed out.

9. Codes and Standards

NEIMA demands the NRC to collaborate with standards-setting organizations to identify specific technical areas and incorporate the respective consensus-based codes and standards into the regulatory framework. The framing around where codes and standards are applicable should be clarified to be for safety components at least as applicable as the existing framework. The draft rule is unworkable without this change. Specifically, the rule should be modified to ensure that codes and standards for safety components are applied at least as stringently as they are in the current licensing frameworks, particularly for Part 50/52.

Table 10. Recommendations - Codes and Standards

Affected Section	Recommendation
1. § 53.440 (b) The design features required by § 53.400 must, wherever applicable, be designed using generally accepted consensus codes and standards that have been endorsed or otherwise found acceptable by the U.S. Nuclear Regulatory Commission (NRC).	**Rule Text Revision — § *section*:** **Proposed Revision:** "The design features ~~required by § 53.400~~ must, wherever applicable, be designed using generally accepted consensus codes and standards that are sufficient to meet the design criteria defined under 53.410, 53.420, 53.425, and 53.430 ~~have been~~

Affected Section	Recommendation
(c) The materials used for each SR and NSRSS SSC must be qualified for their service conditions over the design life of the SSC.	~~endorsed or otherwise found acceptable by the U.S. Nuclear Regulatory Commission (NRC).”~~ **Other Topics:** 1. Should just be for safety-related components ● Proposed Revision: (c) The materials used for each SR ~~and NSRSS SSC~~ must be qualified for their service conditions over the design life of the SSC. 2. The NRC should ensure that components are classified using performance-based approaches (including codes and standards) ● using language from NEIMA ○ *(B) options for licensing commercial advanced nuclear reactors under the regulations of the Commission contained in title 10, Code of Federal Regulations (as in effect on the date of enactment of this Act), including— (iv) the incorporation of consensus-based codes and standards developed under clause (iii) into the regulatory framework—* 3. The NRC should improve its existing process of reviewing/endorsing codes and standards ● It would benefit both the NRC and industry to build a list of C&S approved for certain NSRSS functions

Conclusion

In conclusion, it is crucial that the NRC)adopts a regulatory framework for advanced nuclear reactors that is risk-informed, performance-based and technology-inclusive, as directed by both intent and legal requirements of NEIMA and the ADVANCE Act. This feedback from BTI emphasizes the importance of clarity, consistency, and efficiency in the rule, ensuring that it supports innovation while maintaining safety. By considering and integrating our recommendations, the NRC can create a regulatory framework that fosters the safe and timely deployment of advanced reactors while balancing regulatory flexibility and certainty; ultimately

driving progress in the nuclear industry and advancing the broader goals of decarbonization and energy security through nuclear power.

1. **Clarity and Flexibility**: The NRC should clarify terminology, ensure consistent application of standards, and allow for flexible risk evaluation methods, including alternatives to PRA, which align with the goals of NEIMA and the ADVANCE Act.
2. **Enhanced Regulatory Efficiency**: Streamlining the rule language by removing redundant sections, such as § 53.610, and ensuring the transferability between the existing frameworks (Parts 50 and 52) and Part 53, which will enhance regulatory efficiency and reduce burdens on developers.
3. **Technology-Inclusivity**: The NRC should continue engaging with stakeholders and consider the unique characteristics of advanced reactors, especially SMRs and microreactors, ensuring that the rule remains adaptable to new technologies without imposing unnecessary constraints. This approach will promote both safety and innovation, making the regulatory framework more accessible for the deployment of advanced nuclear technologies that are vital for achieving deep decarbonization goals.

By adopting these recommendations, Part 53 can better support the commercialization of advanced reactors, ensuring both safety and flexibility while fostering technological advancements in nuclear energy.

Sincerely,

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Historical Risk Metric Development

The U.S. Nuclear Regulatory Commission's (NRC) prolonged process to develop and approve risk metrics has become a structural barrier for applicants required to incorporate these evolving standards. The NRC's history of risk quantification highlights the need for efficiency and responsiveness in future metrics development. As we enter an era of advanced reactors and innovative nuclear technologies with unique safety profiles, existing risk metrics may not be appropriate. The NRC has proposed requiring an applicant to define a comprehensive risk metric or set of metrics for licensing their technology. Historical experience shows that creating risk metrics for each technology or applicant in a timeline that enables innovation and commercialization of nuclear technology would be significantly challenging.

Background and Policy Development

The history of the NRC's risk metrics demonstrates the extensive time and technical resources required to develop metrics that align with safety goals. Before the NRC was created, nuclear regulation fell under the Atomic Energy Commission (AEC), established by Congress in the Atomic Energy Act of 1946 and updated in 1954 to allow commercial nuclear development. The AEC aimed to ensure "reasonable assurance" that the projected plant could be constructed and operated at the proposed site "without undue risk to the health and safety of the public."[1] Though, technical uncertainties and limited reactor experience made setting precise safety guidelines challenging. In the 1960s, the AEC faced criticism for its standards.[2] In 1974 Congress enacted The Energy Reorganization Act of 1974, replacing the AEC for the Nuclear Regulatory Commission,[3] which began operations in 1975.

Immediately after starting operation, the NRC began using new risk methodologies. The NRC started using probabilistic risk assessments (PRA) in 1975 to help predict and assess the

[1] Samuel J. Walker and Thomas R. Wellock, *A Short History of Nuclear Regulation, 1946—2009,* Office of the Secretary U.S. Nuclear Regulatory Commission, October 2010, Page 10. ML24211A051.

[2] Nuclear Regulatory Commission, *History*, https://www.nrc.gov/about-nrc/history.html

[3] Public Law 93—438, 88 Stat. 1233

likelihood of consequences of potential accidents.[4] The NRC published the first comprehensive PRA study, WASH-1400, in 1975, which analyzed the potential risks associated with nuclear power plants using statistical methods.[5] Despite being groundbreaking, the Rasmussen Report faced criticism for its potentially overly optimistic conclusions about the low risk of severe accidents. The majority of the NRC's early risk assessment efforts focused on the safety of nuclear power reactors, as public concern about potential accidents was high.

Following the 1979 Three Mile Island (TMI) accident, the NRC recognized the need for a formal safety goal policy. This process began in 1981 with preliminary evaluations and discussions, leading to a proposed safety goal statement in 1983 and a final policy in 1986.[6] Other work on risk occurred simultaneously with the development of the finalized Policy Statement on Safety Goals for the Operation of Nuclear Power Plants[7] (i.e., "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants" (1985)). All of which culminated in the Safety Goal Policy Statement which created a distinct starting point for both qualitative and quantitative health objectives and set standards for reactor safety, forming the foundation for future risk metrics.

The NRC's safety goal policy outlines Quantitative Health Objectives (QHOs)[8] to limit risks from nuclear plant operation. QHOs quantify that latent cancer risks to the public should not exceed one-tenth of one percent of all cancers. Derived QHOs further quantify this, setting limits for latent cancer at two in a million and prompt fatalities at five in ten million. To make these goals

[4] Nuclear Regulatory Commission, *Backgrounder on Probabilistic Risk Assessment*, https://www.nrc.gov/reading-rm/doc-collections/fact-sheets/probabilistic-risk-asses.html

[5] Nuclear Regulatory Commission, *Reactor Safety Study: An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants*, NUREG-75/014, October 1975, ML083570090.

[6] Nuclear Regulatory Commission, *1986 Policy Statement on Safety Goals for the Operation of Nuclear Power Plants*, 51 FR 30028, https://www.nrc.gov/reading-rm/doc-collections/commission/policy/51fr30028.pdf (hereinafter the Safety Goal Policy Statement)

[7] Safety Goal Policy Statement, Page 2.

[8] The QHOs are: (1) The risk to an average individual in the vicinity of a nuclear power plant of prompt fatalities that might result from reactor accidents should not exceed one-tenth of one percent of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. population are generally exposed, and (2) The risk to the population in the area near a nuclear power plant of cancer fatalities that might result from nuclear power plant operation should not exceed one-tenth of one percent of the sum of cancer fatality risks resulting from all other causes.

practical, the NRC also uses surrogate metrics like Core Damage Frequency (CDF) and Large Early Release Frequency (LERF) as indicators of meeting these health protection standards.

Driven by the Safety Goals Policy Statement, the NRC has slowly integrated these risk metrics into practice to ensure public safety and to answer "how safe is safe enough." Over years of regulatory development, the NRC set and updated core benchmarks, established numerous precedents, and continued to alter and adapt risk metrics. Risk metrics evolved over *decades*, often requiring extensive research and stakeholder consultation. Through internal and public deliberation, risk objectives and quantitative limits were gradually refined, though this extended the timeline for final approvals and raised numerous questions and uncertainties for new developers and new technologies.

Timelines

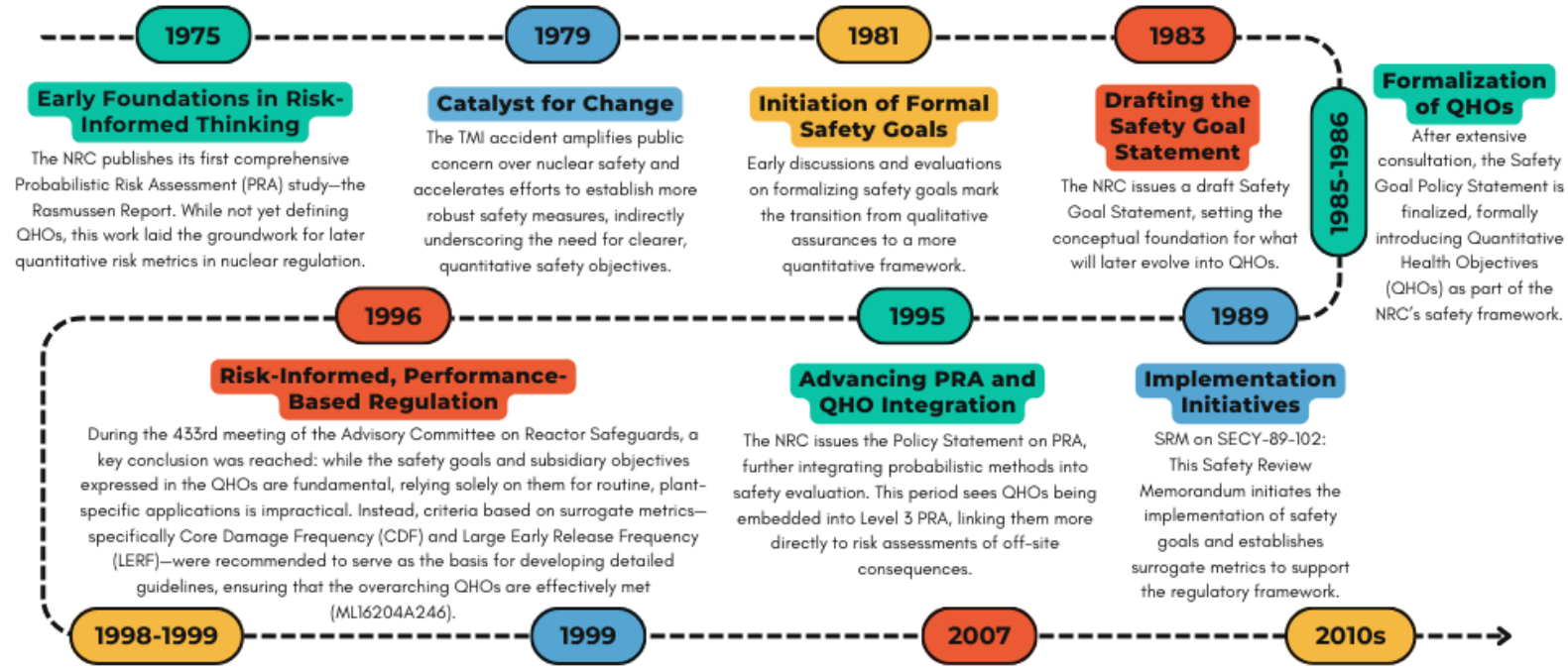
It is informative to consider the timelines of major NRC risk metrics. The timelines chronicle the decades-long evolution of key risk metrics and associated regulatory guidance that underpin today's comprehensive risk metrics used by the NRC. They highlight why expecting an applicant to develop an entirely new, comprehensive set of risk metrics is not only impractical but also excessively burdensome. Historical evidence demonstrates that the development of such metrics—from the initial establishment of Quantitative Health Objectives (QHOs) and Derived QHOs to surrogate metrics—has been a complex, iterative process requiring extensive research, stakeholder engagement, and regulatory deliberation.

BTI has compiled these historical timelines to showcase the major milestones and documentation that contributed to the evolution of six risk metrics: QHOs, Derived QHOs, Large Release Frequency (LRF), Large Early Release Frequency (LERF), Core Damage Frequency (CDF), and Conditional Containment Failure Probability (CCFP). It is important to note that these timelines capture only the primary milestones; many additional documents, regulatory decisions, revisions, and guidance have also influenced the evolution of these metrics but have been omitted for clarity. This collection illustrates that the current risk metrics are the result of decades of incremental improvements and policy refinements, and in some cases major policy shifts on how metrics are used. The purpose of these timelines is to provide context for the challenges faced in creating and updating risk metrics, reinforcing the argument that expecting

new applicants to independently develop comparable comprehensive metrics is unrealistic given the historical precedent.

See the following:

Timeline: Evolution of Quantitative Health Objectives (QHOs) and Related Documentation



Timeline: Evolution of Derived QHOs

1982

Initial Release of NUREG-0880

The NRC releases NUREG-0880 as a discussion paper that establishes safety goals for nuclear power plant operation. This document outlines acceptable occupational exposures, offsite releases in effluents, and specifies that the incremental risk to the average individual within 10 miles of the plant site boundary should be no more than 2 x [unit specification pending further details].

1983 - *March*

SECY-82-1B

On March 24, 1983, the NRC issues SECY-82-1B, which presents a Proposed Commission Policy Statement on Severe Accidents and Related Views on Nuclear Reactor Regulation. This document broadens the regulatory approach to severe accidents and lays additional groundwork for translating broad safety goals into specific numerical (derived) objectives.

1983 - *May*

NUREG-0880, Revision 1

In May 1983, NUREG-0880, Rev. 1 is published. This revision refines the initial safety goals and incorporates feedback from stakeholders, further shaping the framework for quantifying risk metrics.

1986

Finalization of the Safety Goal Policy Statement

The NRC finalizes its Safety Goal Policy Statement, setting broad safety targets to guide reactor operations. This document lays the groundwork for later developing more precise numerical measures—what we now refer to as Derived QHOs.

1989-1990s

Formal Development of Derived QHOs

Building on the foundations established by NUREG-0880 and SECY-82-1B, regulatory analysts begin the process of translating the NRC's broad safety goals into specific, quantifiable measures—what we now refer to as Derived QHOs. These numerical targets provide clearer benchmarks for evaluating risk in nuclear power plant operations.

2007

NUREG-1860 – Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure

In December 2007, NUREG-1860 is published, exploring a risk-informed and performance-based regulatory structure for future plant licensing. Although its primary focus is on licensing, the study influences discussions on updating safety metrics and informs the context in which Derived QHOs are applied.

2012

SOARCA Report (NUREG-1935)

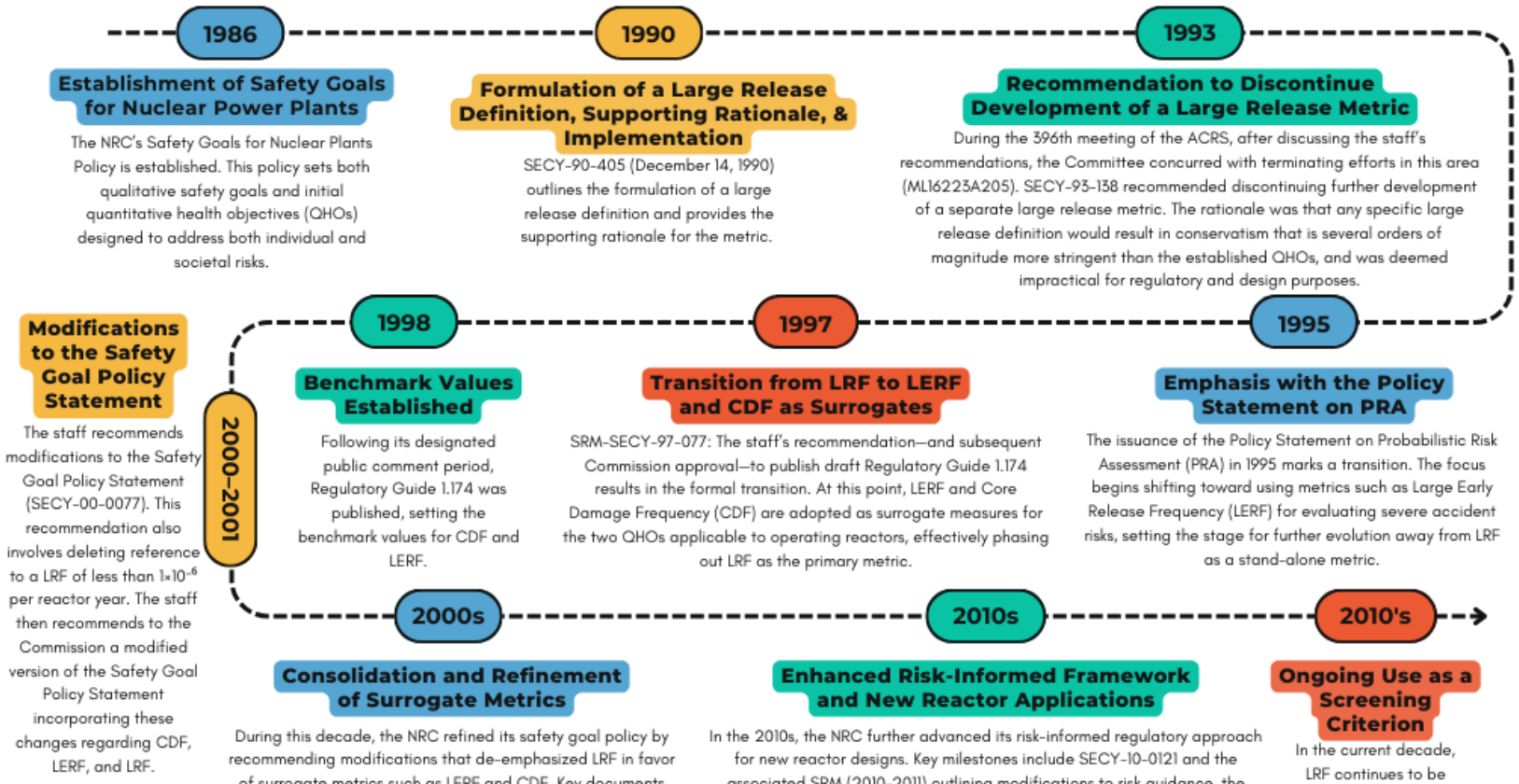
The SOARCA Report, published as NUREG-1935 in November 2012, offers updated insights into reactor consequences. This state-of-the-art analysis informs ongoing refinements of risk metrics, including the evaluation and potential adjustment of Derived QHOs to better reflect current understanding and technology.

2010s-2020s

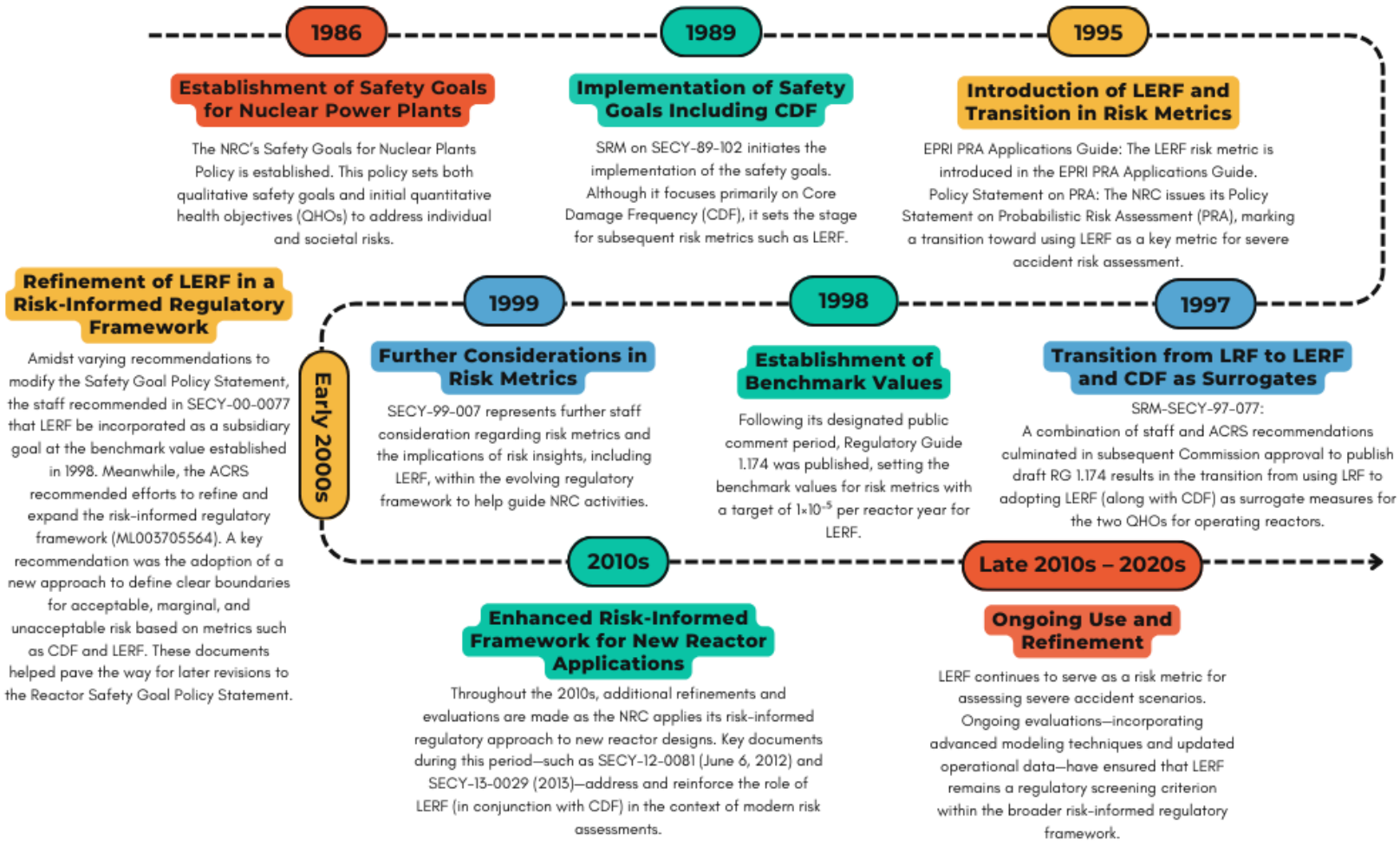
Enhanced Stakeholder Engagement on Risk Metrics

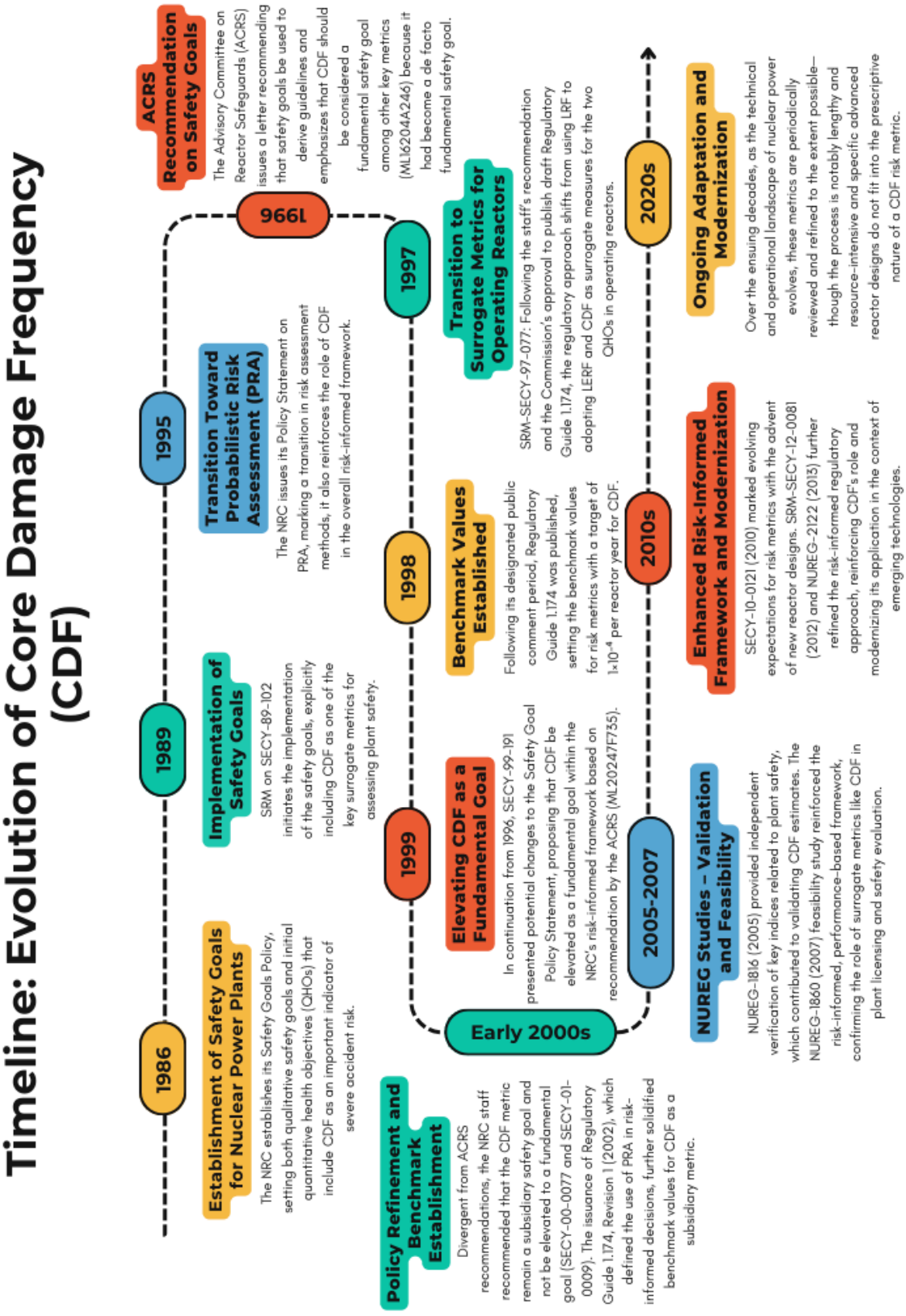
Around 2018 and extending into the early 2020s, the NRC hosted a series of stakeholder workshops and technical review sessions aimed at revisiting and refining its risk metrics—including Derived QHOs—in light of new operational experience and evolving analytical techniques. This renewed emphasis reflects ongoing efforts to update and refine safety metrics based on contemporary safety data and advanced modeling techniques.

Timeline: Evolution of Large Release Frequency (LRF)

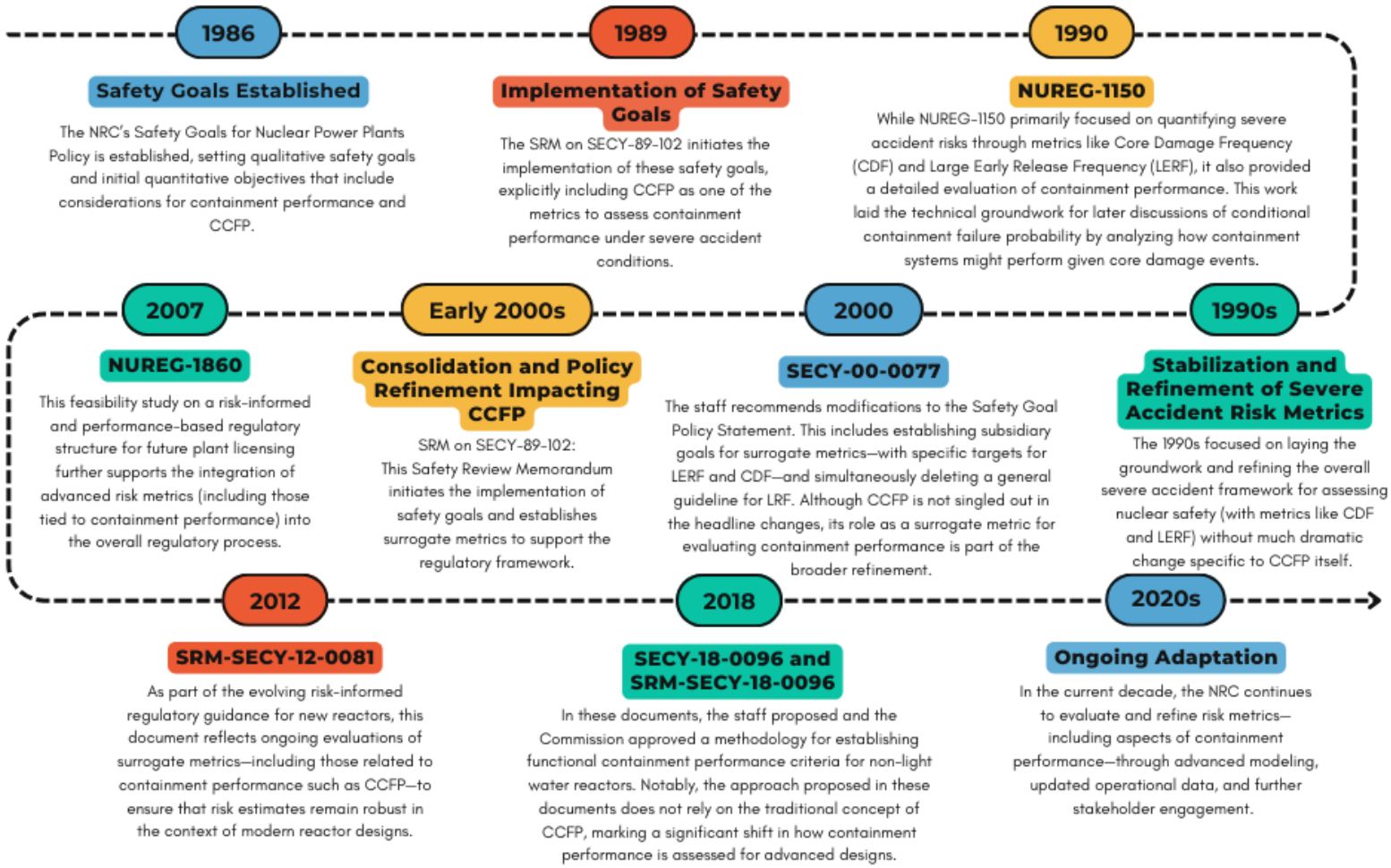


Timeline: Evolution of Large Early Release Frequency (LERF)




Timeline: Evolution of Core Damage Frequency (CDF)
1986
Establishment of Safety Goals for Nuclear Power Plants
The NRC establishes its Safety Goals Policy, setting both qualitative safety goals and initial quantitative health objectives (QHOs) that include CDF as an important indicator of severe accident risk.
1989
Implementation of Safety Goals
SRM on SECY-89-102 initiates the implementation of the safety goals, explicitly including CDF as one of the key surrogate metrics for assessing plant safety.
1995
Transition Toward Probabilistic Risk Assessment (PRA)
The NRC issues its Policy Statement on PRA, marking a transition in risk assessment methods, it also reinforces the role of CDF in the overall risk-informed framework.
1996
ACRS Recommendation on Safety Goals
The Advisory Committee on Reactor Safeguards (ACRS) issues a letter recommending that safety goals be used to derive guidelines and emphasizes that CDF should be considered a fundamental safety goal among other key metrics (ML16204A246) because it had become a de facto fundamental safety goal.
1997
Transition to Surrogate Metrics for Operating Reactors
SRM-SECY-97-077: Following the staff's recommendation and the Commission's approval to publish draft Regulatory Guide 1.174, the regulatory approach shifts from using LRF to adopting LERF and CDF as surrogate measures for the two QHOs in operating reactors.
1998
Benchmark Values Established
Following its designated public comment period, Regulatory Guide 1.174 was published, setting the benchmark values for risk metrics with a target of 1×10^{-4} per reactor year for CDF.
1999
Elevating CDF as a Fundamental Goal
In continuation from 1996, SECY-99-191 presented potential changes to the Safety Goal Policy Statement, proposing that CDF be elevated as a fundamental goal within the NRC's risk-informed framework based on recommendation by the ACRS (ML20247F735).
Early 2000s
Policy Refinement and Benchmark Establishment
Divergent from ACRS recommendations, the NRC staff recommended that the CDF metric remain a subsidiary safety goal and not be elevated to a fundamental goal (SECY-00-0077 and SECY-01-0009). The issuance of Regulatory Guide 1.174, Revision 1 (2002), which defined the use of PRA in risk-informed decisions, further solidified benchmark values for CDF as a subsidiary metric.
2005-2007
NUREG Studies – Validation and Feasibility
NUREG-1816 (2005) provided independent verification of key indices related to plant safety, which contributed to validating CDF estimates. The NUREG-1860 (2007) feasibility study reinforced the risk-informed, performance-based framework, confirming the role of surrogate metrics like CDF in plant licensing and safety evaluation.
2010s
Enhanced Risk-Informed Framework and Modernization
SECY-10-0121 (2010) marked evolving expectations for risk metrics with the advent of new reactor designs. SRM-SECY-12-0081 (2012) and NUREG-2122 (2013) further refined the risk-informed regulatory approach, reinforcing CDF's role and modernizing its application in the context of emerging technologies.
2020s
Ongoing Adaptation and Modernization
Over the ensuing decades, as the technical and operational landscape of nuclear power evolves, these metrics are periodically reviewed and refined to the extent possible—though the process is notably lengthy and resource-intensive and specific advanced reactor designs do not fit into the prescriptive nature of a CDF risk metric.

Timeline: Evolution of Conditional Containment Failure Probability (CCFP)



Assessment: Part 53

Given the decades-long evolution of risk metrics, requiring applicants to propose entirely new, comprehensive risk metrics within a single licensing application is unrealistic. Historical evidence shows that developing these metrics has involved extensive research, multiple layers of approval, and significant stakeholder engagement over many years. This historical lens on the issue underscores that a streamlined or adaptive approach is needed if advanced nuclear applicants are to meet safety requirements efficiently.

The proposed Part 53 rule is mandated to establish a more flexible, technology inclusive, risk-informed, performance-based regulatory framework for licensing both LWRs and non-LWR advanced reactors to enable innovation and commercialization. The proposed rule seeks to do that through a probabilistic risk assessment (PRA)-led approach aligned with fundamental U.S. safety goals. As currently framed, the expectation is that applicants define their own comprehensive risk metric(s).

As indicated by this comment, and many others, this stipulation in the proposed rule introduces significant regulatory uncertainty. It is counterintuitive and incongruent for the proposed rule to state that a comprehensive metric of overall risk that considers the effects of all regulatory requirements in the licensing framework and constitutes an appropriate level of safety represents something other than adequate protection. It is unclear what additional protection is required outside a comprehensive evaluation of all requirements in the framework. Without clear guidance on what constitutes an acceptable risk metric, applicants face an unpredictable and burdensome process that diverts critical resources from the core work of licensing advanced designs.

Without an understanding of what the NRC would consider appropriate risk or other characteristics of such a metric. Existing metrics took significant time to develop and multiple layers of approval. Even with clear guidance, it is likely to create a functional barrier for applicants compared to existing licensing frameworks. The likely outcome will be for applicants to default to existing metrics.

In support of this position, the NRC's recent SRM-SECY-23-0021 further clarifies that the Commission disapproved codifying QHOs within Part 53. Instead, it directs applicants to propose a comprehensive plant risk metric, including detailed methodologies and assumptions. The functional barrier to introducing new, rather than existing, risk metrics in an application indirectly reverts back to use of the QHOs as a default, albeit without direct codification. The proposed rule even endorses the QHOs specifically as an acceptable metric.

Importantly, while these comprehensive metrics are required, they are not stand-alone indicators of safety; rather, they are intended to be one component of a broader risk-informed regulatory framework that also considers other regulatory requirements and defense-in-depth measures. The NRC emphasizes the need for additional stakeholder engagement to refine these risk metrics, address limitations in post-approval changes, and gather public feedback as experience with new reactor designs grows.

Given the lengthy process the NRC has historically undertaken to define and validate risk metrics, it is clear that requiring applicants to propose and gain approval for entirely new risk metrics within a single application is unrealistic, even if streamlined. Current surrogate metrics, originally developed for light-water reactor (LWR) technology and validated retrospectively for existing plants, were not designed to be created anew for each applicant. For example, CDF and LERF are based on assumptions specific to LWR designs, making them less directly applicable to advanced reactor technologies. Moreover, the process of refining and validating these metrics historically has required iterative revisions, as seen in milestones such as SECY-00-0077 and SECY-01-0009, and the subsequent issuance of Regulatory Guide 1.174, Revision 1. Further, this approach is inconsistent with requirements in the ADVANCE Act for the NRC to be more efficient and predictable in licensing of new reactors.

Together, this historical context and recent regulatory direction support the call for clear, predefined metrics or adaptable frameworks that enable innovative reactor designs to meet safety compliance benchmarks without imposing an unrealistic burden on applicants.

Conclusion

In summary, the historical evolution of risk metrics—from QHOs to surrogate measures like CDF, LERF, and CCFP—demonstrates that developing a comprehensive risk metric to support decision-making in a risk-informed regulatory framework is a decades-long, iterative process that involves extensive technical analysis, stakeholder engagement, and multiple rounds of regulatory review. This presents a practical and functional barrier to implementing the requirements in the proposed Part 53 rule.

The proposed Part 53 rule, as currently framed, introduces terms and requirements that are inconsistent with this established process, placing an undue burden on applicants by expecting them to independently develop and validate comprehensive risk metrics. For a regulatory system to be both effective and fair, a clear understanding of expectations is essential. This includes detailed guidance that defines acceptable risk metrics and delineates how they integrate with the broader regulatory framework. Such clarity would not only facilitate more efficient licensing of advanced reactor designs but also ensure that both applicants and NRC staff operate under well-defined, achievable benchmarks for safety compliance.

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Implications for NRC Comprehensive Risk Standards in Part 53 Post Loper Bright Decision

By Adam Stein and Kyle Danish

Introduction and Summary

At the direction of Congress, the Nuclear Regulatory Commission (NRC) has proposed a rule for public comment (10 CFR Part 53) that would establish new licensing and regulatory standards for nuclear power plants. However, in its current form, the proposal does not comply with the NRC's statutory directives. Instead of following its mandate to set risk standards for nuclear plants that "provide reasonable assurance of adequate protection to public health and safety," the NRC has doubled down on an approach that is both arbitrary and excessively conservative. The NRC may be under the impression that it can continue to rely on a deferential judiciary to support its work. However, in a post-Chevron world, courts will not simply defer to an agency's judgments on questions of statutory interpretation. The courts will do their own work. To evaluate what Congress intended for reactor risk standards, a reviewing court will take note of the numerical cancer risk standard that Congress codified in the Clean Air Act—and which Congress made clear should be the benchmark that applies to nuclear power plants. The reviewing court will also give weight to the unmistakable message that Congress has sent through recent legislation that the licensing framework for reactors should be risk-informed and should enable the public to obtain the benefits of safe nuclear power. To ensure legal durability in a post-Chevron world, the NRC should revisit its proposal to ensure that it has established a metric for protection of health and safety that is consistent with the long-established standard codified by Congress.

The NRC's Proposed Part 53 Rule

In recent years, Congress has passed new laws that are significantly prescriptive about how the NRC should implement its role as the nation's nuclear regulator. With overwhelming, bipartisan majority votes, Congress sent an unmistakable message in the 2019 "Nuclear Energy Innovation and Modernization Act" (NEIMA)[1] and the 2024 "Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act" (ADVANCE Act)[2] that it expects the NRC to overhaul its licensing framework—and that it should be establishing a significantly more risk-informed and efficient licensing and regulatory environment for nuclear reactors. The NRC has commenced that process in its current Part 53 rulemaking.[3] In the ADVANCE Act, Congress went as far as mandating that the NRC revise its mission statement to ensure that it "does not unnecessarily limit (1) the civilian use of radioactive materials and deployment of nuclear energy; or (2) the benefits of civilian use of radioactive materials and nuclear energy technology to society."[4] The NRC responded to that mandate in January 2025.[5]

Long-standing laws require the NRC to limit the risks from reactor operations to the public, including the risks from emissions of radionuclides, which are a known carcinogen at certain levels. The foundational Congressional directive to the NRC on risk regulation is stated in Section 182 of the Atomic Energy Act (AEA):

> In connection with applications for licenses to operate production or utilization facilities, the applicant shall state such . . . information as the Commission may, by rule or regulation, deem necessary in order to enable

[1] P. L. No. 115-439 (Jan. 14., 2019) (the NEIMA).
[2] P. L. No. 118-67 (July 9, 2024) (the ADVANCE Act).
[3] NRC, Risk-Informed, Technology-Inclusive Framework for Advanced Reactors, 89 Fed. Reg. 86,918 (Oct. 31, 2024) (Part 53 Proposed Rule). Part 53 refers to the section of the Code of Federal Regulation in which the new rule would be codified.
[4] ADVANCE Act, Sec. 501.
[5] NRC, NRC Approves Updated Mission Statement (Jan. 24, 2025), available at https://www.nrc.gov/cdn/doc-collection-news/2025/25-005.pdf.

> it to find that the utilization or production of special nuclear material will be in accord with the common defense and security and will provide adequate protection to the health and safety of the public.[6]

Under this structure, the objective is "adequate protection to the health and safety of the public." The statute then affords the NRC a degree of discretion in determining what "information" the Commission needs from applicants to determine whether a proposed reactor will meet this objective. Inherent in this ends-means structure is the initial establishment of a consistent metric for "adequate protection" even if the "information" needed to make an "adequate protection" finding may vary for different plants in different settings.

However, the NRC has not implemented its authority this way. Historically, the NRC has expressly avoided establishing a regulatory definition of "adequate protection." Instead, the NRC has prescribed a host of performance requirements, design objectives, and other criteria. Then, the NRC has declared that compliance with this assemblage of requirements provides reasonable assurances of "adequate protection."

In its Part 53 rulemaking, the NRC proposes to continue this approach:

> Consistent with historical practice, Sections 182 and 161of the Act are cited as authorizing legislation within the proposed rule. However, specific language from the Act would not be incorporated into the safety objectives or safety criteria in part 53. This is because, again consistent with historical practice, the NRC would not be defining "adequate protection" through the individual safety requirements in part 53. Rather, part 53 would enable the NRC to make its required findings under the Act by providing sufficient performance standards, safety criteria, and related requirements on how

[6] Atomic Energy Act of 1954, as Amended Through P.L. 118—67, Enacted July 9, 2024 (Atomic Energy Act), Sec. 182.

applicants must demonstrate compliance with Subpart B and other subparts.[7]

There are several problems with this approach. First, it is arbitrary and capricious.[8] The NRC insists that its job is to ensure that each applicant provides "reasonable assurance" of "adequate protection." Yet, the NRC reasons it need not define the "adequate protection" end-point for these assurances. In particular, in the case of cancer risk from radionuclides, the NRC has failed to specify a numerical exposure level that all applicants must meet, even though measuring radiation is necessarily a numerical exercise. As a result, it is impossible to identify the standard of "adequate protection" that applies to all applicants and impossible to evaluate whether the "assurance" demanded from any particular applicant is "reasonable." That is not a valid approach under administrative law. In a case-by-case review regime, an agency may require different applicants to take different *actions* based on each applicant's unique circumstances—e.g., the type of assurance required for a new AP1000 reactor is likely different from that required for a new microreactor—but an agency may not hold similarly situated applicants to different *standards*.

Absent a cognizable standard for "adequate protection," the level of protection imposed by the NRC's suite of requirements could be well less or far more than what is adequate. The NRC's implicit answer to this question is: "trust us." Yet, without a discernable stopping point for what constitutes "adequate protection," the NRC can—and typically does—ask for endless mitigation and assurances from applicants. For example, the NRC proposes to continue under Part 53 a requirement that applicants keep radionuclide doses to the public "as low as reasonably achievable" (the so-called ALARA requirement). The proposed rule points to an ALARA "goal" of keeping doses to the public from routine plant effluents below 10 millirem per year, but the NRC cautions that this metric "should

[7] Part 53 Proposed Rule at p. 86,925.

[8] 5 U.S.C. Sec. 706(2)(A) (requiring a court reviewing an agency action to hold the action unlawful if it is arbitrary and capricious).

not be construed as a radiation protection standard."[9] Radiation protection standards are in Part 20 and other regulations, and ALARA requires the licensee to identify further protections with a goal of at least an order of magnitude reduction or until cost prohibitive. In other words, there is no defined floor to what the NRC can request of an applicant. If the Commission determines more protection from a particular applicant is "achievable," it considers itself authorized to demand it, whether or not the added protection achieves significant public health benefits. "Achievable" reductions are not the same as what may be "necessary" to achieve adequate protection. As a result, every application is its own, standard-less adventure. Under the NRC's interpretation of the statute, its discretion is unbounded. However, in general, reviewing courts must be able to ascertain the agency's rationale so as to evaluate whether the agency's action can be shown to be understandable, adequately explained, and rational.[10]

Congress' Unambiguous Statement about Preferred Metrics for Limiting Cancer Risk from Operation of Nuclear Reactors.

The other flaw in the NRC's interpretation is that it implies that Congress had no intention for what constitutes "adequate protection to the health and safety of the public" in the context of radionuclide emissions—leaving the Commission to fill that void with its collection of criteria, guidance, and generalized objectives. However, this is

[9] Part 53 Proposed Rule at p. 87.052 (proposed sec. 53.425).

[10] *Motor Vehicle Mfrs. Ass'n v. State Farm Auto. Ins. Co.,* 463 U.S. 29, 43 (1984) ("Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. The reviewing court should not attempt itself to make up for such deficiencies; we may not supply a reasoned basis for the agency's action that the agency itself has not given. *SEC v. Chenery Corp.,* 332 U. S. 194, 332 U. S. 196 (1947)."); *see also Airmark Corp. v. FAA,* 758 F.2d 685, 691 (D.C. Cir. 1985) ("Deference to agency authority or expertise . . . is not a license to treat like cases differently") (quoting *U.S. v. Diapulse Corp. of America*, 748 F.2d 56, 59 (9th Cir. 1984)).

inaccurate. Congress has spoken directly to this question, albeit in another law: the Clean Air Act.[11]

In Section 112 of the Clean Air Act, Congress gave the EPA and the NRC overlapping authority to set cancer risk limits for nuclear reactors.[12] Congress vested this authority in the EPA as part of EPA's Clean Air Act Section 112 authorities to set risk standards for carcinogenic and other hazardous air pollutants from industrial facilities—a category that includes nuclear reactors.

In the original, 1970s version of Section 112, Congress directed the EPA to limit carcinogenic pollutants to levels that would ensure "an ample margin of safety to protect public health"—a narrative mandate that is noticeably similar to the NRC's "adequate protection" narrative mandate. If anything, the requirement for an "ample margin" suggests a safety metric even more restrictive and conservative than "adequate protection."

As we explained in an article published last year in the Environmental Law Reporter, Congress then took important steps to set the boundaries of this "ample margin of safety" mandate as part of its amendments to the Clean Air Act in 1990.[13] Prior to 1990, the EPA had promulgated Section 112 hazardous air pollutant standards for several types of regulated facilities. In the process, the EPA formulated a methodology with quantitative metrics for maximum lifetime cancer risk, which the EPA applied to all of the regulated facilities.

The EPA "residual risk" methodology generally provides that the "ample margin of safety" standard is met using a two-step process.[14] First, determining "acceptable risk" includes a

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[11] 42 U.S.C. §§ 7401 *et seq.*

[12] *Id.* § 7412.

[13] K. Danish, A. Stein, and P. Libus, "Will Risk Aversion at the NRC Avert the Energy Transition?", 54 Envtl. L. Rep. 10,241 (Mar. 2024), available at https://www.vnf.com/webfiles/WillRiskAversionAtTheNRCAvertTheEnergyTransition.pdf.

[14] *Id.* 10,249.

presumptive limit on the maximum individual lifetime cancer risk (MIR) for as many people as possible, which is no greater than one in one million.[15] Second, the methodology allows no person to face an MIR greater than 100 in one million. The second metric addresses what is sometimes called the "Maximum Exposed Individual" (MEI).[16] It constrains the lifetime risk of contracting cancer that a person living near a regulated source of carcinogenic emissions—typically within 50 kilometers—would have if the individual were exposed to the maximum pollutant concentrations 24 hours per day for 70 years.[17]

In its 1990 amendments to the Clean Air Act, Congress explicitly codified this quantitative methodology as a valid interpretation of "ample margin of safety."[18] In other words, Congress adopted specific numerical metrics for what is an "ample margin of safety" for cancer risk. Notably, Congress did not require or authorize different levels of cancer deaths from different types of facilities. Rather, as drafted, this quantified "ample margin of safety" standard applies to all facilities subject to Section 112—expressly including nuclear reactors.[19]

In the same set of amendments, Congress addressed the overlapping EPA-NRC regulatory authority over carcinogenic emissions from nuclear reactors. Congress allowed the EPA to cede regulation to the NRC—but only if the EPA determines that the NRC's regulations meet the "ample margin of safety" standard.[20]

Accordingly, through the 1990 amendments, Congress established that its now-quantified "ample margin of safety" metric would be the yardstick for measuring the health-protectiveness of the NRC's regulations.

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[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] Clean Air Act Section 112(f)(2)(B).
[19] *Id.* Section 112(d)(9).
[20] *D.*

In the mid-1990s, the EPA undertook this comparative analysis.[21] The methodology that the EPA used for this analysis is worth noting. The agency converted its Congressionally codified cancer risk metric into an annual maximum radiation dose level, which it calculated to be ten millirems per year. The EPA then found that the maximum permissible dose from an NRC-regulated nuclear reactor during routine operations was one millirem per year—at least an order of magnitude below the ten millirem maximum that provides an "ample margin of safety."[22]

In other words, Congress has spoken clearly about what it considers to be the appropriate metric for health protection from nuclear power plants. Yet, the NRC has proposed to continue to regulate at a level far more stringent than what Congress intended. The NRC's approach is not only arbitrary and capricious; it also is inconsistent with its statutory authority and Congressional intent.

Loper Bright and the End of Deferential Judicial Review

Given these flaws, the legal durability of not only the proposed part 53 rule but even the NRC's longer-standing regulations is in question. Yet, the NRC may be under the impression that it can continue to rely on what has historically been a deferential standard of review from the federal judiciary. This would be a mistake.

In June of 2024, the U.S. Supreme Court issued a series of decisions that will have far-reaching impacts on judicial review of actions by administrative agencies. The headliner of these decisions was *Loper Bright*[23], which overruled the Court's 1984 decision in *Chevron*[24]. The latter case had established what has been known as the "*Chevron* doctrine."

[21] National Emission Standards for Radionuclide Emissions From Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities Not Covered by Subpart H, 60 Fed. Reg. 46206 (Sept. 5, 1995).
[22] *Id.* at 46208
[23] *Loper Bright Enterprises v. Raimondo,* 603 U.S. 369 (2024) (*Loper Bright*).
[24] *Chevron U.S.A. v. Natural Resources Defense Council*, Inc., 467 U.S. 837 (1984) (*Chevron*).

To understand the impact of *Loper Bright*, it is important to understand what it overturned. The now-defunct *Chevron* doctrine, presumed that if Congress did not directly address the precise question at issue in an agency's governing statute, the question for the reviewing court is whether the agency's rule-based interpretation is based on a permissible reading of the governing statute. Therefore, under *Chevron*, if a statute is "silent or ambiguous" on a particular matter, a reviewing court should uphold an agency's interpretation so long that it is a "reasonable interpretation" of the underlying law.[25]

In *Loper Bright*, the Supreme Court rejected this highly deferential approach. Importantly, the decision emphasizes that it is the *duty of the courts* to exercise their independent judgment in deciding whether an agency has acted within its statutory authority. *Loper Bright* holds that even when a "statute [is] ambiguous, there is a best reading all the same," and the reviewing court is required to adopt the one that "after applying all relevant interpretive tools, [the court] concludes is best."[26]

To be clear, *Loper Bright* acknowledges that courts should consider the expertise of the relevant agency. However, that guidance should be weighted based solely on its "power to persuade"; the agency guidance is not controlling.[27]

The *Loper Bright* majority also recognized some instances in which the meaning of the statute is that Congress intended to delegate "a degree" of discretion to the implementing agency.[28] The decision cites the example of the Atomic Energy Act requirement that the owner of a nuclear facility notify the NRC when the facility "contains a defect which could create a substantial safety hazard, *as defined by regulations which the [NRC] shall promulgate*."[emphasis added][29] As noted above, Section 182 includes an element of this

[25] *Id.* at 844.
[26] *Loper Bright,* at slip op. at 23.
[27] *Id.* at 25 (quotation omitted).
[28] *Id.* at 17.
[29] *Id.* at 17 fn. 5 (emphasis in the original).

kind of delegation. It allows the NRC to define the "information" that the Commission "may . . . deem necessary" for its safety review. However, Section 182 does *not* include language delegating to the NRC the underlying determination of what constitutes "adequate protection" for nuclear plants. Again, Section 182 distinguishes ends from means. Congress acknowledged the expertise of the NRC in identifying the specific information needed for a safety determination; however, it did not expressly delegate to the NRC a determination of how safe nuclear power should be.

Even in explicit or implicit delegation situations, however, *Loper Bright* makes clear that the reviewing court may not simply defer to any "reasonable" interpretation of the agency. Rather, the court must independently interpret the statute and "effectuate the will of Congress"[30]; the court must "fix the boundaries" of the delegation.[31]

The last qualification is particularly important as the NRC (and its predecessor agency, the Atomic Energy Commission) has enjoyed a long history of wide deference from the courts, including pre-*Chevron*.[32] Some observers believe these decisions generally insulate the NRC's interpretations of its governing statutes (the AEA) from the impacts of *Loper Bright*. Moreover, the NRC itself appears to believe it may be insulated from the impacts of *Loper Bright*.[33]

However, this view disregards the plain instructions from the *Loper Bright* decision directing reviewing courts that they may no longer simply defer to any "reasonable" interpretation of an agency and must instead independently interpret the statute and

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[30] *Id.* at 18.

[31] *Id.*

[32] *See, e.g.,* Baltimore Gas & Elec. Co. v. Natural Res. Def. Council, Inc., ("*BG&E v. NRDC*") (noting that "a reviewing court must remember that the Commission is making predictions, within its area of special expertise, at the frontiers of science. When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.") ; *Power Reactor Dev. Corp. v. Int'l Union of Electrical, Radio and Machine Workers, AFL-CIO*, 367 U.S. 396 (1961),

[33] Letter to the Honorable Eric S. Schmitt, et al., from NRC Chair Hanson, responding to letter regarding the Supreme Court decision in Loper Bright Enterprises v. Raimondo (dated Sept. 26, 2024).

"effectuate the will of Congress." The presumption that other, non-*Chevron* cases (especially ones articulating similar standards of review) will enable courts to circumvent the impacts of the *Loper Bright* decision fails to recognize not only the broad reach of the decision, but also the new mandates from Congress after those earlier decisions. These changes include the 1990 Clean Air Act amendments, which established a clear Congressional benchmark for radionuclide emissions from nuclear plants. It also includes the recent Congressional laws that include detailed mandates for the NRC on a host of matters. As noted above, the NEIMA explicitly directs the NRC to establish a new "technology-inclusive, regulatory framework" for licensing commercial advanced nuclear reactors. The NEIMA also specifically requires the NRC to account for the relative safety advances of such reactors in its licensing framework; it directs the Commission to report to Congress on "the unique aspects of commercial advanced nuclear reactor licensing, including the use of alternative coolants, operation at or near atmospheric pressure, and the use of passive safety strategies." In short, in the NEIMA, Congress made clear its view that advanced reactors were a new, safer type of reactor, deserving of their own licensing framework with appropriately tailored standards.

The ADVANCE Act goes even further. It doubles down on mandates to the NRC to make licensing for *all* reactors more timely, predictable, and efficient. In addition, as noted above, the ADVANCE Act commanded the NRC to change its mission to ensure that it is not unnecessarily depriving the public of the benefits of nuclear energy technology—a mandate in the AEA that the agency has not fulfilled.[34]

These Congressional directives, combined with the evolution of case law over the years—especially the recent decisions coming down from the Supreme Court—mean that the NRC is no longer subject to such extremely deferential judicial review, especially when it comes to interpreting Congressional intent. It is far less likely that a reviewing court will place substantial weight on the NRC's body of past experience or judgments with respect

[34] Adam Stein, Considering Nuclear Energy's Benefit to Society, The Breakthrough Institute (Nov. 26, 2024), available at https://thebreakthrough.org/issues/energy/considering-nuclear-energys-benefit-to-society.

to its licensing framework. In the wake of the *Loper Bright* decision and the recent enactment of the NEIMA and the ADVANCE Act, reviewing courts will no longer simply accede to the Commission's judgments about what Congress has told it to do.

For these reasons, any court reviewing the NRC's interpretation of "adequate protection of public health and safety" will not simply interpret the silence in the AEA as a delegation to the NRC to come up with its own approach. Rather, the court will engage in a search for any statement by Congress about what it intends to be the yardstick for protection of public health from radionuclide emissions from nuclear plants. That searching look necessarily will lead to the 1990 Clean Air Act amendments and the numerical "ample margin of safety" standard codified by Congress and established as the benchmark for nuclear plants. The court will also take into account the recent directives in the NEIMA and the ADVANCE Act.

Implications for the Proposed Part 53 Licensing Framework

What does this demonstrated Congressional intent mean for the NRC's promulgation of a cumulative risk-informed standard in the Part 53 rulemaking? One way to visualize this issue is to examine its implications for the Licensing Modernization Project (LMP).[35] The LMP was an industry initiative to formulate a risk-informed standard that the NRC could use for licensing advanced reactors, which the NRC endorsed.[36] The industry proponents derived the standard from the Commission's prior risk determinations for light-water

[35] Nuclear Energy Institute, Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Based Development (Report Revision 1) (August 2019), available at https://www.nrc.gov/docs/ML1924/ML19241A472.pdf.

[36] NRC, Guidance for a Technology-Inclusive, Rick-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for License, Certifications, and Approvals for Non-Light-Water Reactors, Regulatory Guide 1.233, Revision 0 (June 2000), available at https://www.nrc.gov/docs/ML2009/ML20091L698.pdf.

reactors.[37] In its March 2023 draft of Part 53, the NRC staff proposed to adopt 'Framework A' based on the LMP and to codify the QHOs as the cumulative risk standard. In the draft, the staff again avoided using the cumulative risk metrics (i.e., the QHOs) to define "adequate protection" and reiterated that the NRC can "make its required findings under the AEA" by "providing sufficient performance standards, safety criteria, and related requirements on how applicants must demonstrate compliance."[38] In short, the NRC requires further regulation beyond the cumulative risk metrics.

As noted above, the Commission voted to avoid codification of the QHOs in Part 53. Instead, the staff was directed to "specify that applicants must propose a comprehensive plant risk metric (or set of metrics)" and associated methods for calculating the metrics.[39] The Commission defined the term "cumulative" or "comprehensive" to mean "that the risk metric(s) should approximate the total overall risk from the facility (i.e., all modes, all hazards) to the extent practicable." The proposed rule indicates that the individual cancer risks in the NRC Safety Goals and the QHOs would be acceptable to meet this requirement.[40] Yet, despite encompassing overall risk, the Commission emphasized that "approval of the metric or set of metrics is not, by itself, an indicator of adequate protection"—a position that is more conservative still (i.e., requires still lower risk).

The LMP methodology, endorsed by the NRC as an acceptable approach for Part 53, includes consideration of "risk significant" events below the limit. These events are considered to account for uncertainty and edge effects. However, the EPA MIR standard is clear that both the acceptable risk and ample margin of safety values are inclusive of

[37] Idaho National Laboratory, Modernization of Technical Requirements for Licensing of Advanced Non-Light Water Reactors: Selection and Evaluation of Licensing Basis Events (March 2020), available at https://inldigitallibrary.inl.gov/sites/sti/sti/Sort_27107.pdf.
[38] SECY-23-0021: Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (March 2023), available at https://www.nrc.gov/reactors/new-reactors/advanced/modernizing/rulemaking/part-53.html.
[39] Memorandum to Raymond Furstenau, Acting Executive Director for Operations, from Carrie M. Safford, Secretary, SECY-23-0021, available at https://www.nrc.gov/docs/ML2406/ML24064A039.pdf.
[40] Part 53 Proposed Rule at p.87926

uncertainty, not requiring further margin below those levels. The graph below depicts the LMP standard alongside the EPA's ample margin of safety metrics at different frequencies and doses.

Comparison of NRC-endorsed risk metrics with the Clean Air Act

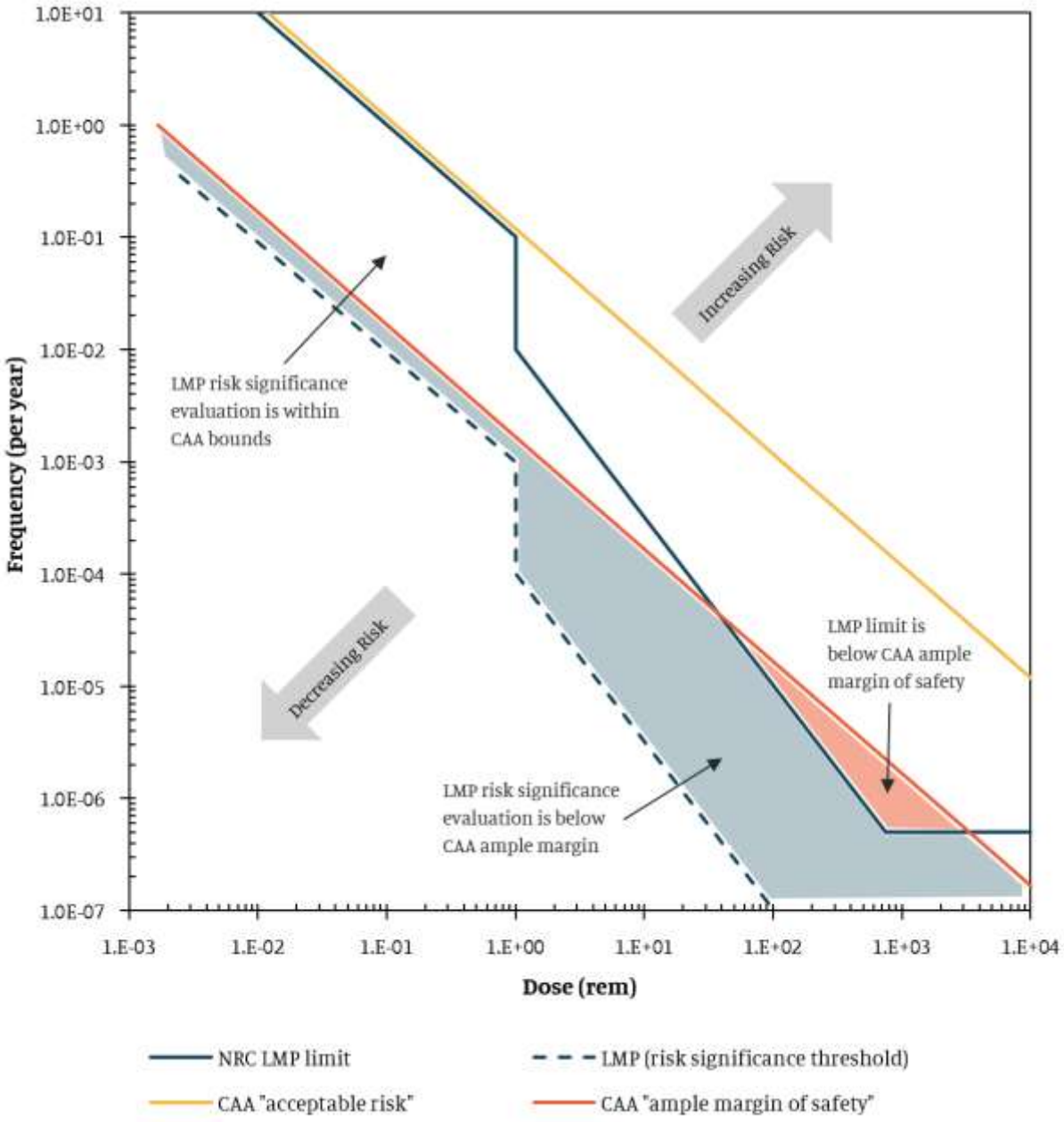

Figure 1: Comparison of NRC-endorsed risk thresholds for licensing and acceptable risk metrics defined in the Clean Air Act. The NRC-endorsed risk limit never exceeds the CAA maximum limit. The NRC risk limit and region that is considered "risk significant" is more conservative (lower risk) than the CAA minimum "ample margin of safety" in some areas. The CAA relative dose values are calculated using the ISCORS conversion factors.

The graph makes clear that the LMP more or less tracks the "ample margin" standard codified by Congress in its 1990 amendments to the Clean Air Act, falling below the EPA's "acceptable risk" standard and at or above the EPA's "ample margin of safety" standard for standard operations and accidents. For very low frequency, high dose events, however, the LMP cumulative dose standard is far stricter than the "ample margin of safety" metric; it is an order of magnitude or greater more restrictive.

Therefore, if the NRC were to adopt the LMP-based standard as proposed in 2023 in the final Part 53 rule, or require equivalent risk performance objectives, it would exceed the authority granted to the Commission by Congress. Put another way, once a licensee has established that its design meets the "ample margin of safety" level, the NRC lacks the legal authority to require additional demonstrations from the licensee, much less additional mitigation. Yet, in the case of the proposed Part 53 rule, the NRC requires further demonstration even beyond the satisfaction of these risk metrics, including compliance with other regulations and guidance, deterministic criteria, methodologies to evaluate margin and uncertainty, required defense-in-depth, and prescriptively assuming that only some systems are available to mitigate postulated accident sequences.

This standard is not only inconsistent with the "ample margin of safety" standard, but it would also obviate current practice at the NRC, whereby any event within two further orders of magnitude of the LMP dose/frequency standard is deemed risk significant, requiring further information, analysis, or mitigation against uncertainty. The congressionally codified "ample margin of safety" standard already anticipates uncertainty in exposure to ionizing radiation associated with the operation of commercial nuclear energy facilities. The Section 112 standard is what Congress

concluded not only provides adequate protection but also provides an *ample margin* of safety. Therefore, the Section 112 standard already accounts for these additional factors.

The existence of a threshold for an ample margin of safety does not strictly prescribe the use of risk-based regulation where all decisions rely on meeting a specific risk value. Nor would it undermine the use of a suite of regulatory requirements to protect the public and environment, such as financial qualifications, operator licensing, or quality control.

Insisting on further demonstration of safety beyond the already conservative "ample margin of safety" standard goes far beyond the authority to protect public safety delegated to the NRC by Congress, essentially insisting, uniquely for nuclear energy, on additional layers and margin of safety on top of the ample margin of safety already established through the EPA's MIR standard. Yet, there is no evidence of any Congressional intent to hold nuclear energy to a standard distinct from other known risky industrial activities.

For these reasons, if the NRC seeks to establish a new comprehensive risk standard and associated overall risk objective or requires applicants to define such standards with NRC approval, it will need to make modifications to the proposed rule to avoid exceeding its congressionally granted authority. The additional layer of requirements for analysis and mitigation associated with dose/frequency events below the EPA standard would have to be abandoned or considered as part of the "comprehensive" risk standard. Moreover, any alternative approach to regulating cumulative risk will need to avoid promulgating rules, practices, or standards that functionally require license applicants to demonstrate safety beyond dose and frequency consistent with the EPA's MIR standard.

The Commission must make it clear that more restrictive comprehensive risk metrics developed by applicants, as required in the Commission vote on Part 53 and included in the proposed rule, do not need to be more restrictive than those prescribed by the Clean Air Act to be deemed acceptable.

Potential Implications for Licensing of Light-water Reactors

To be sure, the implications of *Loper Bright* should be top of mind for the NRC in its Part 53 rulemaking as it works to meet the mandates from Congress to establish a new licensing framework tailored to advanced reactors.

However, the analysis outlined above raises an additional question: Could an applicant for a license, or a license renewal, for a light-water reactor challenge a restrictive NRC rule—whether specific to the application or generally applicable—that is predicated on the existing latent cancer risk standard, i.e., by asserting that the underlying standard is inconsistent with Congressional intent and has been since at least 1990?

Until this year, such a legal challenge to an agency's long-standing regulation might have been considered to be time-barred. By way of background, in some respects, federal law provides that the deadline to bring a lawsuit against an agency (known as the "statute of limitations") is six years after the cause of action "first accrues." [41] Until this year, courts were divided about how to apply the statute of limitations for challenges to a general agency regulation. Does the cause "accrue" when the plaintiff was injured by the application of that regulation? Or does it "accrue" when the regulation was first published? United States Courts of Appeal have held that the latter interpretation applies. This interpretation has foreclosed challenges to the validity of agency regulations that have already been "on the books" for many years.

However, the Supreme Court overturned this precedent in its blockbuster set of June 2024 decisions. In *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the Supreme Court held that the statute of limitations to challenge an agency enforcement action based on a previously promulgated regulation begins to run when the plaintiff suffers an injury from the enforcement action, not when the agency published the underlying rule.

It may take some time to assess the full implications of *Corner Post* for NRC orders, at least outside the context of enforcement proceedings. However, one potential implication is

[41] In the specific case of the NRC, whose rules are subject to review under the "Hobbs Act," such review must be sought within 60 days of promulgation. 28 U.S.C. 2344.

that *Corner Post* opens the door to a lawsuit challenging the latent cancer risk standards anytime they are used as the basis for a new order—whether a case-specific order or an order of general application. This could mean that an unfavorable order on a license for a new light-water reactor or a license renewal for an existing reactor could attract a challenge claiming that the NRC predicated the order on invalid standards.

Were such a challenge to go forward, the reviewing court could very likely evaluate whether the highly restrictive existing standard is consistent with Congressional intent as stated in Section 112 of the Clean Air Act and in the recent ADVANCE Act directive for the NRC to modify its mission to more fully take into account the benefits to the public of nuclear power.