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Comment On: NRC-2019-0062-0012
Preliminary Proposed Rule Language: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors

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Comment (080) from Patrick White on FR Doc # 2020-24387

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General Comment

See attached.

Attachments

NIA_Comment_Rethinking_Part_53

NUCLEAR INNOVATION ALLIANCE

November 5th, 2021
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Subject: Nuclear Innovation Alliance Comments on Preliminary Proposed Rule Language, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors" [Regulation Identifier Number RIN-3150-AK31; Docket ID NRC-2019-0062]

Dear U.S. Nuclear Regulatory Commission Staff:

The Nuclear Regulatory Commission (NRC) is currently working to develop a risk-informed, performance-based, and technology-inclusive regulatory framework in 10 CFR Part 53 ("Part 53") to support the regulation and deployment of advanced reactors. We thank the NRC staff for their on-going work to facilitate stakeholder discussion and feedback on draft rule text.

Our comment provides the Nuclear Innovation Alliance's perspective on the Part 53 rulemaking and is based on our focus for the need to develop and deploy advanced nuclear reactors to support public clean energy needs. Development of an effective risk-informed, performance-based, and technology-inclusive regulatory framework is critical to the deployment of advanced nuclear reactors at a scale needed to make a meaningful contribution to our clean energy goals.

This comment focuses on the need to rethink the Part 53 regulatory framework to increase regulatory flexibility and implement a more performance-based and technology-inclusive rule. We believe that a Part 53 regulatory framework could be designed in a manner that maximizes the regulatory flexibility for advanced reactor developers while also providing optional pathways that increase predictability through prescription use of specific regulatory methods and programs. This approach minimizes the need for exemptions throughout the regulatory process and results in a more complete technology-inclusive regulatory framework that facilitates use of performance-based and risk-informed regulatory requirements and methods.

We again thank NRC staff and management for their continued work to make Part 53 an effective framework to support the safe development and deployment of advanced reactors. If you have any questions, please contact me at pwhite@nuclearinnovationalliance.org.

Sincerely,

Patrick White
Project Manager
Nuclear Innovation Alliance

NIA Public Comment: Rethinking Part 53
November 5th, 2021

The current Nuclear Regulatory Commission (NRC) staff discussion text for 10 CFR Part 53[1] reflects the inherent challenge in creating a regulatory framework based on the direction and vision of the Nuclear Energy Innovation and Modernization Act (NEIMA). NEIMA instructed the NRC to create a technology-inclusive regulatory framework that would facilitate use of performance-based and risk-informed requirements and methods[2]. To satisfy NEMIA's requirement to be technology-inclusive, the regulatory framework must be flexible enough to accommodate a variety of advanced reactor technologies regardless of coolant, fuel, size, application, safety case, licensing approach, and other attributes.

At early public meetings, NRC staff and management received a wide array of stakeholder feedback based on different stakeholder needs. Specifically, stakeholders requested that the NRC create a rule that could simultaneously:

- reduce regulatory burden associated with application preparation and review
- acknowledge the overall increase in safety of advanced nuclear reactor technology
- reduce prescriptive analytic and programmatic requirements to facilitate regulatory flexibility and use of design-specific licensing methods
- increase regulatory process predictability and review duration certainty
- provide flexibility in the use of risk information required to establish design requirements
- increase use of risk information permitted to justify regulatory decision making

Several of these requests are in tension. For example, some stakeholders may be concerned that reducing the number of prescriptive regulatory requirements and increasing regulatory flexibility could reduce both regulatory process predictability and review duration certainty. Similarly, risk insights are essential for the design of nuclear systems, but the desired use and scope of risk information required for advanced reactor applications might differ by applicant. To date, the NRC continues to evaluate these divergent stakeholder positions as part of their rulemaking activities in its efforts to develop an appropriate advanced reactor regulatory framework consistent with Congressional intent.

The discussion text for Part 53 released by the NRC staff through October 2021[3] has tried to reconcile these requests by developing a rule that attempts to balance flexibility and predictability through a mix of prescriptive and performance based regulatory requirements. The current staff discussion text seeks to develop a technology-neutral regulatory framework through the elimination of technology-specific design criteria and addition of performance-based regulatory requirements. These changes could enable application of the rule to any advanced reactor technology but it is currently uncertain if it the rule could be effectively applied to all technologies. The additional regulatory flexibility provided by performance-based regulatory requirements could create uncertainty if applicants are unsure how to demonstrate compliance

[1] NRC Accession Number ML20289A534
[2] Nuclear Energy Innovation and Modernization Act (NEIMA), Public Law No. 115-439, 132 Stat. 5565 (2019).
[3] NRC Accession Number ML20289A534

with the performance-based requirements. Some industry stakeholders have expressed concern that an overly flexible regulatory framework would lack predictability and could be unusable by some applicants.

Predictability was introduced into the staff discussion text for the regulatory framework through the addition of prescriptive analytic and programmatic requirements for advanced reactors. Many of the prescriptive requirements were based on the industry-led Licensing Modernization Project (LMP). The LMP requirements (originally developed as an optional set of methods to support risk-informed advanced reactor license applications under 10 CFR Part 50 and Part 52) have already been reviewed and approved by NRC staff in Regulatory Guide 1.233. It is important to note that while the LMP process has been extensively reviewed by industry and NRC staff, the process has never been tested by an applicant or even fully demonstrated in a tabletop licensing exercises that covered all aspects of facility design, licensing, and operations.[4]

Addition of these prescriptive requirements helped create a more predictable regulatory framework that facilitated the regulation of any reactor technology. One challenge of these prescriptive requirements, however, is that LMP heavily relies on the use of probabilistic risk assessment (PRA) methods to support design and operation decisions for nuclear facilities. Inclusive of LMP-based requirements effectively prescribed significant use of PRA in licensing activities. While the use of LMP-based prescriptive analytic and programmatic requirements did not fully align with all advanced reactor stakeholders, it initially appeared that the process was supported by industry and aligned with NRC priorities and plans to increase use of risk information in regulatory activities. However, subsequent feedback from industry stakeholders during public meetings on the Part 53 discussion text suggested that the alignment may not have been as strong as initially perceived. The inclusion of LMP methods (initially developed as optional guidance) as mandatory requirements in the Part 53 discussion text raised concern among industry stakeholders and advanced reactor developers who were not involved with the initial LMP development process.

The current staff discussion text of the rule attempts to balance flexibility and predictability by utilizing technology-neutral, performance-based safety limits but requiring that applicants use prescribed methods and organizational programs to demonstrate compliance with the safety limits. This regulatory approach, while effective for some advanced reactors, is only partly performance based and is not technology inclusive. While the safety limits are performance-based, the methods for demonstrating compliance are not. The prescriptive methods for demonstrating compliance with safety limits may preclude effective regulation for some advanced reactor technologies. Specifically, it may not be technically necessary or economically feasible for some advanced reactor designs, particularly reactors with low thermal power or inherent safety, to demonstrate compliance with the safety limits by using the prescribed methods. Alternative analysis methods and organizational programs could, instead, be used to demonstrate facility and design compliance with safety limits more effectively. These prescriptive requirements in the current staff discussion text of the rule could effectively exclude some advanced reactor technologies by imposing requirements that are technically unnecessary and economically infeasible. While NRC staff has recently released additional draft text for that provides an alternative deterministic analysis pathway for Part 53, the initial draft text appears to simply provide a second set of prescriptive methodology requirements.[5] Thus, the NRC's current approach to balancing flexibility and predictability ultimately results in a process that does not fully meet the goal of producing a technology-inclusive regulatory framework for advanced reactors.

[4] Modernization of Technical Requirements for Licensing of Advanced Non-Light Water Reactors, INL/EXT-20-60393-Rev000

[5] NRC Accession Number ML20289A534

The challenge associated with satisfying the conflicting stakeholder requirements is highlighted by industry reactions to the current staff discussion text of the rule. A 2021 survey by the U.S. Nuclear Industry Council[6] found that while 74% of advanced reactor developers believe that Part 53 is important or essential to the U.S. advanced reactor industry, 59% of developers are dissatisfied, very dissatisfied, or believe that the draft Part 53 is not helpful at all. The current NRC staff's approach to balance flexibility and predictability was based on programs that were seemingly supported by industry (i.e., LMP), but it now appears that industry support for LMP as an *optional* approach under Part 50 or 52 does not carry over to support for a *mandatory* LMP approach under Part 53. This confusion has led to a draft rule that may not meet the initial intent of NEIMA: enabling safe and effective licensing of advanced reactor technologies through a technology-inclusive regulatory framework that facilitates use of performance-based and risk-informed requirements and methods.

The seemingly conflicting stakeholder needs could be met, however, by implementing a more performance-based regulatory framework that enables advanced reactor developers to justify their own safety case that satisfies a set of common, standard safety limits. This framework would maximize flexibility for developers interested in licensing advanced reactor technologies that utilize innovative design, evaluation, or programmatic methods to demonstrate compliance with safety limits. The overall regulatory framework could also include a second *optional* regulatory pathway that provides more prescriptive regulatory methods and approved programs that an applicant could utilize to demonstrate compliance with regulatory requirements. This second, more prescriptive pathway could be similar in structure to major sections of the current staff discussion text of the rule, would leverage existing work on the draft Part 53 rule text, and leverage the existing work used to develop LMP regulations. Further iteration of the draft Part 53 rule text in this second optional pathway would likely be require to ensure that it is a viable, optional prescriptive pathway for the licensing of advanced reactors.

This dual regulatory pathway would provide the needed flexibility for advanced reactor developers who believe that a unique approach to regulatory methods and programs for their design could reduce their regulatory burden while still demonstrating compliance with standard safety limits. Advanced reactor developers who utilize this pathway could leverage inherently or passively safe designs that enable use of simpler licensing analyses, eliminating the need for the reduced conservatisms associated with resource intensive PRA-heavy evaluations. The dual pathway could also provide the desired predictability for advanced reactor developers who would like to utilize an LMP-like process for licensing evaluations within Part 53. The dual regulatory pathway is possible because the full performance-based regulatory pathway fully encompasses the optional regulatory pathway with more specific regulatory methods and requirements. Thus, a single consistent set of regulatory requirements would be present in the rule to ensure a consistent regulatory basis for all licensees, but the specification of acceptable regulatory methods and programs would reduce the uncertainty associated with licensing activities.

This comment outlines a new proposed structure of a Part 53 regulatory framework and provides example regulatory text for key sections. The goal of this comment is to highlight how a Part 53 regulatory framework could be designed in a manner that maximizes the regulatory flexibility for advanced reactor developers while still providing pathways with increased predictability by prescribing use of specific regulatory methods and programs. This approach minimizes the need for exemptions throughout the regulatory process and results in a more complete technology-inclusive regulatory framework that facilitates use of performance-based and risk-informed regulatory requirements and methods.

[6] https://www.usnic.org/news/usnic-announces-results-of-2021-advanced-nuclear-survey

The following attachments provide more detailed information on a revised Part 53 structure:

- Attachment 1 provides overall discussion and a high-level outline for the draft rule with titles of major subparts and sections.
- Attachment 2 provides example rule text for a Part 53 Purpose Statement
- Attachment 3 provides example rule text for Part 53 Subpart B (Safety Basis for Nuclear Utilization Facilities)
- Attachment 4 provides example rule text for portions of Part 53 Subpart D (General Safety Case for Nuclear Utilization Facilities), specifically for Facility Design Evaluations

These attachments provide insight as to how NRC can build on the work it has completed thus far, account for stakeholder input, and develop a Part 53 regulatory framework that facilitates the effective regulation of all advanced reactor technologies and provides varying levels of flexibility and predictability to advanced reactor developers.

Attachment 1: High-level outline of proposed revised rule

This attachment provides a high-level outline of a revised Part 53 rule structure that facilitates technology-inclusive regulation of advanced reactors. NIA's proposed revised rule structure divides the regulatory framework into eight major subparts:

- Purpose and Principles Statement
- Subpart A: General Provisions
- Subpart B: Safety Basis for Nuclear Utilization Facilities
- Subpart C: Licenses, Certifications, and Approvals
- Subpart D: General Safety Case Format for Nuclear Utilization Facilities
- Subpart E: Pre-approved Safety Case Formats for Nuclear Utilization Facilities
- Subpart F: Enforcement
- Subpart G: Other Administrative Topics

More detailed discussion for each of the proposed major subparts is provided below. Table 1 lists the major subparts and expected top level subsections.

Setting standards

NIA's proposed revised rule structure first develops a clear basis for the technology-inclusive and performance-based regulation of advanced reactors. The "Purpose and Principle Statement", Subpart A ("General Provisions"), and Subpart B ("Safety Basis for Nuclear Utilization Facilities") clearly define the goal of the Part 53 regulatory framework, the performance-based fundamental safety limits for nuclear utilization facilities:

- The "Purpose and Principle Statement" provides a clear description of the Part 53 rule goals and can help to guide applicants, staff, and others on meeting both the language and intent of the Part 53 rules.
- The "General Provisions" provides the general administrative regulatory text needed to support a new regulatory framework and would adopt similar text from existing rules with modification.
- The "Safety Basis for Nuclear Utilization Facilities" provides performance-based, fundamental safety limits for all nuclear facilities. These limits are the basis for all regulatory decisions and represent the minimum expected safety characteristics of nuclear utilization facilities regulated by the NRC.

These initial positions of the revised Part 53 rule create both the philosophical and performance-based safety bases for a nuclear utilization facility. All facilities are required to satisfy these common requirements regardless of the license, certification, approval type, or licensing methods or controls utilized in design-specific or facility-specific safety cases.

Subpart B ("Safety Basis for Nuclear Utilization Facilities") is the underlying technical basis of all regulatory activities. Satisfactory demonstration of compliance with the regulatory limits in Subpart B is the regulatory foundation for licensing under a revised Part 53 regulatory framework. Some regulatory limits could cross reference existing regulation (e.g., worker dose requirements or environmental emission release limits) while other regulatory limits would need to be developed specifically for Part 53. Other regulatory limits would likely leverage existing regulatory guidance or on-going risk-informed rulemaking processes (e.g., public dose limits or performance-based security objective requirements). Two unique provisions added as part of this revised rule structure are the definition of risk-informed performance requirements and the definition of alternative requirements.

NIA's proposed revised rule is focused on development of a technology-inclusive, performance-based, and risk-informed regulatory framework. Specifically, definition of risk-related performance requirements helps place a quantitative limit on risk for activities where inherent hazards (e.g., potential release of radioactive fission products) cannot be fully eliminated by design. The regulatory principle of "reasonable assurance of adequate protection" is commonly used a qualitative standard for assessing the minimum level of safety required by regulators. The challenge with this qualitative standard is that it is, by its very nature, qualitative and subjective. Different reasonable interpretations of this standard may apply, so quantitative definitions of safety performance and operations are desirable to increase the regulatory certainty associated with the application and review process.

Prescriptive requirements and regulatory limits directly related to risk quantification (such as quantitative health objectives [QHOs]), while risk-informed and performance-based, are technology-neutral but not necessarily technology-inclusive. NIA's proposed revised rule, instead, focuses on applicant definition and demonstration of compliance with a risk-informed quantitative performance metric. This applicant-defined metric facilitates assessment of compliance with the qualitative regulatory principle of achieving "reasonable assurance of adequate protection."

The risk-informed, performance-based qualitative metric selected by applicants may include QHOs (as proposed in the current staff discussion text), historic plant safety surrogates (such as core damage frequency, large release frequency, large early release frequency), or another technical surrogate defined by the applicant that helps quantify or bound the frequency and consequence of plant incidents. Under this proposal, NRC staff review will need to find that demonstration of compliance with the defined technical surrogate metric would satisfy the regulatory intent of providing "reasonable assurance of adequate protection." This review, however, foreshadows the tradeoff between flexibility and predictability inherent in NIA's proposed revised rule framework. Use of previously accepted methods and technical surrogates discussed in advance with regulators can be leveraged to increase regulatory process predictability.

Applicant definition of this metric provides the flexibility for selection and use of risk-informed and performance-based limits that are most appropriate for a specific project and technology. This technology-inclusive approach to defining regulatory limits can, in principle, be extended to any performance-based regulatory limit. NIA's proposed revised rule framework explicitly provides for the definition and use of alternative regulatory limits (without need for exemptions) if it is shown that the surrogate regulatory limit is analytically and practicably consistent with the existing regulatory limits. Explicit acceptance of alternative performance-based metrics facilitates a more inclusive and performance-based regulatory framework for advanced reactors.

Defining regulatory mechanisms

Under NIA's proposed revised rule framework, the applicant has flexibility to determine the evaluations, analyses, and programs that they believe are appropriate to demonstrate compliance with regulatory limits. The NRC staff is then responsible for an independent review of the applicant's safety case and assessing whether the facility safety case is reasonable, has acceptable detail to facilitate independent evaluation, and appropriately demonstrates compliance with the performance-based regulatory requirements in Subpart B. The number of prescriptive regulatory requirements outside of those specified in Subpart B are minimized. This development of appropriate performance-based regulatory requirements in Subpart B facilitates the creation of a technology-inclusive regulatory framework for advanced reactors.

NIA's proposed revised rule structure next outlines the licenses, certifications, and approvals that are available as regulatory mechanisms within the Part 53 regulatory framework in Subpart C ("Licenses, Certifications, and Approvals"). This section provides the scope of each regulatory mechanism and

relationship to other mechanisms and regulations, information on general administrative topics for the regulatory mechanisms (e.g., renewal process), and the expected contents of the application for the regulatory mechanism. The final section (content of the application) is based on what stages of the facility lifecycle (e.g., design, siting, operations, decommissioning, etc.) are relevant to the specific regulatory mechanism. These licenses, certifications, and approvals are intended to implement the regulatory tools currently available under the Part 50 and Part 52 regulatory frameworks.

The specific portions and scope of Subpart D ("General Safety Case Format for Nuclear Utilization Facilities") are detailed for each regulatory mechanism. This helps provide clarity about the scope of information needed for each regulatory tool to enable NRC staff evaluation and assess demonstration of compliance with the regulatory safety limits. Completed portions for all sections of Subpart D would not be necessary or required for all regulatory mechanisms.

For example, approval of construction permit (CP) application would require completion of major parts of project organization, design, siting, and site-specific safety case and minor parts of other portions of Subpart D to facilitate staff assessment of whether the proposed nuclear utilization facility could be constructed and operated safely. The approval of the operating license (OL) application, in contrast, would require that nearly all portions of the Subpart D would be complete to justify the safe operation of a nuclear utilization facility throughout the facility life cycle. Depending on NRC policy, some portions of Subpart D related to the plant end of life (e.g., facility shutdown and transition, and decommissioning) could be left incomplete with the requirement that the portions would be completed during the operational lifetime of the plant. Parts of these portions of Subpart D would need to be completed to provide NRC staff confidence that the facility could be safely and effectively decommissioned.

The process of specifying the necessary lifecycle information needed to support regulatory decision making would be repeated for all regulatory mechanisms specified in Subpart C. Referencing appropriate portions of Subpart D for each regulatory tool prevents the repetition of identical regulatory language (as contrasted with significant sections of repeated text currently present in Subpart A through Subpart F of 10 CFR Part 52).

Developing a regulatory safety case

NIA's proposed revised rule structure next provides details on the information that NRC staff would expect license applicants to provide to demonstrate compliance with the regulatory limits in Subpart B ("Safety Basis for Nuclear Utilization Facilities"). Subpart D ("General Safety Case Format for Nuclear Utilization Facilities") is explicitly organized around the expected facility lifecycle stages and provides guidance on information that should be submitted to the regulator as part of a facility application.

Subpart D ("General Safety Case Format for Nuclear Utilization Facilities") defines the set of facility- or design-specific information that would be submitted to the regulator to demonstrate regulatory compliance as the project safety case. It is important to distinguish the evaluations, analyses, and programs included in the project safety case from those that may be performed by an applicant as part of design activities. The project safety case should be the minimum set of information that facilitates demonstration of regulatory compliance and should not include all design, risk, and performance evaluations that were used to support development activities. Some of this additional information may be necessary for NRC audits but should not de facto be considered as part of the licensing basis. This clarification is necessary because it helps minimize extraneous information submitted to the regulator for review and can ensure that NRC staff are focused on the specific technical information and level of detail that is needed for them to support their evaluation of applicant demonstration of compliance with the regulatory limits in Subpart B.

The structure of NIA's proposed Subpart D is based on developing a project safety case in stages based around the lifecycle of a nuclear utilization facility. There are nine stages highlighted in the draft subpart from project organization through decommissioning. For each stage, a high-level description of expected information that could be submitted to demonstrate compliance with regulatory limits is provided. A minimum set of guiding descriptions are included in the NIA's proposed revised Part 53 regulatory framework as "should" statements to emphasize how the safety case for a facility could be made and not require how a safety case must be made. The regulatory limits in Subpart B are the foundational basis for NIA's proposed revised Part 53 regulatory framework; the prescriptive requirements on the contents of the safety case should be minimized to ensure that the Part 53 maximizes applicant flexibility as a technology-inclusive and performance-based regulatory framework. Additional regulatory guidance to applicants should be developed and released to supplement the rule text.

The use of a fully applicant-defined project safety case to demonstrate compliance with performance-based regulatory requirements maximizes applicant flexibility to utilize methods that they believe are best suited for their specific facility application. The inherent drawback of this flexibility, however, is a lack of predictability related to the review and approval of applications. The NRC's traditional standard of "adequate assurance of reasonable protection" is inherently subjective when used to evaluate demonstration of compliance with performance-based safety limits. As a result, this process is subject to uncertainty related to the level of detail, assumptions, and scope of information needed to support regulatory decision making. It's important to note that this uncertainty is still present in other regulatory reviews and remains an on-going challenge for all regulatory activities.

Under NIA's proposed revised Part 53 regulatory framework, both applicant and NRC staff activities can contribute to increased predictability within a flexible process. Applicants could engage with NRC staff during pre-application interactions to discuss (and receive feedback on) their planned safety case strategy and work to utilize industry codes, standards, best practices, and regulatory precedent to provide context for the proposed safety case. NRC staff could work to provide non-binding guidance for the regulatory text that provides additional information on how applicants may (but are not required to) demonstrate compliance with regulatory limits. This guidance must be carefully crafted and utilized so that it does not become de-facto regulatory text and reduce applicant flexibility in demonstrating compliance with regulatory limits. The NRC staff must also be open to evaluating new safety case methodologies and clearly communicate observed deficiencies in applicant safety cases in a manner that facilitates applicant correction without requiring use of prescriptive methods if the case otherwise demonstrates compliance with the performance-based fundamental safety limits.

Utilizing prescribed regulatory safety case methods

NIA's proposed revised rule structure also provides a second optional regulatory pathway that provides increased predictability (but reduced regulatory flexibility) by prescribing many of the regulatory methods that are used to demonstrate compliance with the performance-based regulatory limits. Subpart E ("Pre-approved Safety Case Formats for Nuclear Utilization Facilities") outlines how specific prescribed regulatory methods, analyses, organizations, and programs could be used to effectively demonstrate compliance with the regulatory limits in Subpart B.

The text of Subpart E could be similar in structure and format to the currently proposed staff discussion text of the Part 53 rule, adapted to the general safety case structure described in Subpart D. This allows the staff to leverage existing discussion text developed as part of the Part 53 rule development process, regulatory reviews completed as part of the LMP, and self-consistent integration of these methods into a larger and more flexible regulatory framework. The existing staff discussion text incorporated into this new

Subpart E would need additional revision to address the on-going discussions between NRC staff and stakeholders as part of the Part 53 rulemaking process.

A technology-inclusive and performance-based approach to Part 53 will facilitate the use of any applicable regulatory methods. The general safety case structure described in Subpart D is fully inclusive of an LMP-based regulatory methods and those methods could be utilized without a specific prescriptive subsection. Inclusion of an optional method based on existing staff discussion text of the Part 53 rule (subject to further iterations between NRC staff and stakeholders) is intended to provide a regulatory pathway with increased predictability by prescribing regulatory methods that can be used to demonstrate compliance with regulatory limits. This rule structure enables self-consistency within the regulatory framework and could meet the needs of applicants seeking both flexibility and predictability in the regulatory process. Additional rulemaking to specify approved regulatory methods or applicant use of regulatory tools to clarify approved regulatory methods could be used to further increase process predictability. The regulatory impacts of adding additional rule text should be considered to ensure that the process does not add unnecessary complexity to the Part 53 regulatory framework.

Administrative regulatory details

The final subparts of NIA's proposed revised rule focus on providing the additional administrative language needed to support a new regulatory framework. These subparts would be written to facilitate technology-inclusive, risk-informed, and performance-based regulation of advanced reactors. Much of the regulatory language could be adapted from existing regulation in 10 CFR Part 50 and 10 CFR Part 52 except where minor changes are needed to adapt prescriptive requirements to performance-based requirements. As an example, Subpart F ("Enforcement") is explicitly included in the outline for NIA's proposed revised rule but other administrative details would likely be included in subparts past Subpart G for different administrative topics.

Table 1: Proposed Part 53 rewrite draft outline

Subpart	*Section*
Purpose and Principles Statement	53.000. Purpose and principles statement
Subpart A: General Provisions	53.001 - 53.00*x*. General discussion and scope
	53.00*y*. Description of licensing classes
Subpart B: Safety Basis for Nuclear Utilization Facilities	53.100. Subpart scope
	53.101. Safety basis requirement compliance
	53.102. Public dose requirements
	53.103. Worker dose requirements
	53.104. Environmental emission release requirements
	53.105. Security objective requirements
	53.106. Risk-informed performance requirements
	53.107. Alternative regulatory requirements
Subpart C: Licenses, Certifications, and Approvals	53.200. Subpart scope
	53.201. Standard design approval
	53.202. Standard design certification
	53.203. Early site permit
	53.204. Construction permit and operating license
	53.205. Combined license
	53.206. Manufacturing license
	53.207. Limited work authorization approval
Subpart D: General Safety Case Format for Nuclear Utilization Facilities	53.300. Subpart Scope
	53.301. Project organization
	53.302. Facility design evaluation
	53.303. Site evaluation
	53.304. Project-specific safety case
	53.305. Manufacturing and construction
	53.306. Facility commissioning & transition to operations
	53.307. Facility operations
	53.308. Facility shut down & transition to decommissioning
	53.309. Decommissioning
Subpart E: Pre-approved Safety Case Formats for Nuclear Utilization Facilities	53.400: Subpart scope
	53.401. Project organization
	53.402. Facility design evaluation
	53.403. Site evaluation
	53.404. Project specific safety case
	53.405. Manufacturing and construction
	53.406. Commissioning and transition to operations
	53.407. Operations
	53.408. End of operations and transition to decommissioning
	53.409. Decommissioning
Subpart F: Enforcement	53.500. Subpart scope
	53.501. Standard discussion
	53.502 - 53.50*x*. Other sections (as needed)
Subpart G: Other Administrative Topics	53.600. Subpart scope
	53.601. Standard discussion
	53.602 - 53.60*x*. Other sections (as needed)

Attachment 2: Example draft rule text for Part 53 Purpose and Principles Statement

This attachment provides example draft rule text for a Part 53 Purpose and Principles Statement. The goal of this statement is to provide a clear description of the Part 53 principles and to guide applicants, staff, and other stakeholders on meeting both the language and intent of the Part 53 rule.

53.000. Purpose and Principle Statement

The purpose of the licensing rules within this Part is to provide a pathway for the effective regulation of advanced reactors. The regulatory basis for this rule is performance-based, risk-informed, and technology-inclusive, and is based on the following principles:

- The rule is technology-inclusive: it is applicable to any nuclear energy technology and provides a practical pathway to safe construction, operation, and decommissioning.
- The rule is performance-based: regulatory decisions are based on applicant demonstration of compliance with regulatory requirements and applicants can select the methods used to demonstrate compliance.
- The rule is risk-informed: risk information is included as one factor but not the only factor to support design, operation, and regulatory compliance decision making.
- This rule is inclusive of designs, technologies, and business models: the use of regulatory exemptions should be minimal or not be required to facilitate licensing decisions.
- This rule facilitates the effective regulation of fission reactors: rules, reviews, and interactions should all be conducted with goal of facilitating safe utilization of nuclear technology

These regulatory principles underpin both the text and interpretation of this rule for the performance-based, risk-informed, and technology-inclusive regulation of fission reactor technology. The regulatory processes within this Part must provide reasonable assurance of adequate protection of public health and safety and to promote the common defense and security and to protect the environment.

Attachment 3: Example draft rule text for Part 53 Subpart B (Safety Basis for Nuclear Utilization Facilities)

This attachment provides example draft rule text for Part 53 Subpart B (Safety Basis for Nuclear Utilization Facilities). This Subpart is the underlying technical basis of all regulatory activities in the revised Part 53 text. Satisfactory demonstration of compliance with the regulatory limits in Subpart B is the regulatory foundation for demonstrating reasonable assurance of adequate protection as required by the Atomic Energy Act using the Part 53 regulatory framework.

Subpart B: Safety Basis for Nuclear Utilization Facilities

53.100. Subpart Scope

Each advanced nuclear plant must be designed, constructed, operated, and decommissioned to prevent or mitigate the unplanned release of radionuclides that would be inimical to the common defense and security or to the reasonable assurance of adequate protection of public health and safety. In addition, each advanced nuclear plant must take such additional measures as may be appropriate when considering potential risks to public health and safety. These safety basis limits shall be carried out by meeting the performance-based safety criteria identified in this subpart.

53.101. Safety basis requirement compliance

The safety basis requirements in this Subpart should not be considered target limits but rather maximum acceptable limits. There is no expectation that all possible radiation releases or hazardous exposures will be reduced to zero by design or operation.

53.102. Public dose requirements

The dose requirements for members of the public are defined for acute exposures and chronic exposures.

53.102(a). Acute public dose requirements

The acute public dose requirements are defined based on the once-in-a-lifetime accidental or emergency dose of 25 rem (250 mSv).

53.102(a)(1) Exclusion area boundary acute dose requirement

An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of any release of radionuclides would not receive a radiation dose in excess of 25 rem (250 mSv) total effective dose equivalent.

53.102(a)(2) Low population zone boundary acute dose requirement

An individual located at any point on the outer boundary of the low population zone who is exposed to the radioactive cloud resulting from any release of radionuclides (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (250 mSv) total effective dose equivalent.

53.102(b). Chronic public dose requirements

The contribution to the total effective dose equivalent to individual members of the public from normal plant operation does not exceed the public dose limits provided in Subpart D of 10 CFR Part 20.

53.103. Worker dose requirements

The dose limits for workers are defined based on the occupational dose limits in Subpart C of 10 CFR Part 20.

53.104. Environmental emission release limits

The environmental emission release limits for facilities are defined based on the emission release limits in Appendix B of 10 CFR Part 20.

53.105. Security objective requirements

The security objective requirements for facilities are defined based on the security requirements in 10 CFR Part 73. Advanced reactors are expected to provide enhanced margins of safety and/or use simplified, inherent, passive, or other innovative means to accomplish their safety and security functions. Alternative performance-based security requirements from 10 CFR Part 73 may be applicable if one of the following conditions applies:[7]

- The radiological consequences from a hypothetical, unmitigated event involving the loss of engineered systems result in offsite doses below the reference values defined in 53.102(a);
- The plant features necessary to mitigate an event and maintain offsite doses below the reference values in 53.102(a) of this chapter cannot reasonably be compromised by an adversary;
- Plant features include inherent reactor characteristics combined with engineered safety and security features that allow for facility recovery and mitigation strategy implementation if a target set is compromised, destroyed, or rendered nonfunctional, such that offsite radiological consequences are maintained below the reference values defined in 53.102(a)

Performance-based security requirements should be utilized by facilities when possible to ensure that security requirements are appropriate.

53.106. Risk-informed quantitative performance requirements

The risk-informed performance requirements for facilities shall be self-defined on a project-specific basis to facilitate assessment of compliance with the qualitative regulatory principle of achieving “reasonable assurance of adequate protection.” Facilities shall define or develop project-specific performance-based quantitative surrogate metrics that facilitate demonstration of compliance with the qualitative regulatory requirements.

53.107. Alternative regulatory requirements

Applicants and licensees shall be permitted to develop, define, and demonstrate compliance with alternative regulatory requirements for any safety basis requirement in this Subpart. Satisfactory demonstration of compliance with alternative regulatory requirements shall be considered equivalent to demonstration of compliance with the equivalent safety basis requirement in this Subpart. Alternative regulatory requirements shall be analytically and practicably self-consistent with existing safety basis limits in this section. Demonstrated compliance with alternative regulatory requirements shall result in an equivalent to or greater level of safety for workers, the public, and the environment.

[7] These security objective requirements are intended to follow the on-going criteria developed as part of the alternative physical security requirements rulemaking process.

Attachment 4: Example draft rule text for Part 53 Subpart D (General Safety Case for Nuclear Utilization Facilities)

This attachment provides example draft rule text for Part 53 Subpart D (General Safety Case for Nuclear Utilization Facilities). This Subpart outlines the expected stages of the facility lifecycle and provides guidance on information that should be submitted to the regulator as part of a facility application. The use of a fully applicant-defined safety case to demonstrate compliance with performance-based regulatory safety maximizes applicant flexibility to utilize methods that they believe are best suited for their specific facility application. Specific example text is provided for Facility Design Evaluations to demonstrate the use of flexible and performance-based requirements within the Part 53 regulatory framework. The Facility Design Evaluation is similar to the Final Safety Analysis Report and is intended to demonstrate compliance with the safety basis requirements.

53.302. Facility design evaluation

The facility design evaluation portion of the project safety case shall demonstrate that the facility design complies with the safety basis requirements described in Subpart B for a specific set of boundary conditions and assumptions. This evaluation is subject to explicit boundary conditions and assumptions that must be considered when assessing the applicability of evaluation conclusions to other licensing activities.

This section provides the expected sections that may be included in a facility design evaluation. The specific sections used by applicants to demonstrate facility compliance with the safety basis requirements may vary by facility.

53.302(a). General description

The facility design evaluation shall provide a general description of the facility and the concept of operations. This application should include a general summary description of the major facility systems, structures, and components, the practices and safety concepts, and a comparison of the facility's design and construction with prevailing modern standards and international practices. The description should provide an overall understanding of the facility, without the need to refer to other sections in the license documentation.[8]

53.302(b). Design philosophy and facility and design safety principles

The facility design evaluation should describe the design philosophy and safety principles of the facility. This section should include a general description of unique physical, chemical, and radiological hazards present in the facility (e.g., hazards not present in a standard industrial facility). The general approach and methods used to eliminate, reduce, mitigate, or control each hazard should be discussed and justified.

"The [evaluation] should describe the design principles and requirements that cover the processes for the overall design of the facility, and the operation and interaction of all of the systems, structures, and components (SSCs) to be addressed. To ensure that the facility will be reliable, robust and maintainable, the applicant should ensure that the design:

- conforms to high quality levels commensurate with its importance to safety
- is informed by recent developments in knowledge and technology
- is resistant to the effects of common-cause events and, to the extent practicable, to severe accidents

[8] Draft text adapted from Canadian Nuclear Safety Commission (CNSC) (2020), *Licence Application Guide: Guide to Construct A Reactor Facility*, REGDOC-1.1.2, Rev. 2, Sec. 3.2.2.

When aspects of the design are based on conservative deterministic principles, such as those outlined in international codes and standards or in regulatory documents, the application should describe the use of such principles. If the design of the reactor facility partially but does not fully comply with a specific deterministic principle in a regulatory document or best practice, the applicant should demonstrate that the overall level of safety is not impaired and that the underlying design principle is still applicable.

The application should describe the decision-making methodology (for example, cost/benefit, best available technology, and so on) that was used to select the design option."[9]

53.302(c). Detailed description

"The applicant should provide a detailed description of the facility to facilitate independent assessment of plant systems, structures, and components (SSCs) and operations that are important to meeting Subpart B safety basis limits. The application should describe in detail the characteristics, major components and design basis requirements (such as the functional and performance requirements associated with the definition of design basis). The level of detail provided for each SSC should vary based on the importance of the SSC to meeting the safety basis requirements. Information needed to facilitate independent assessment of demonstrated compliance with regulatory requirements should also be provided by the applicant.

53.302(d). Facility safety limits

The applicant shall define facility-specific safety limits. The facility-specific safety limits must be consistent with the Subpart B regulatory limits. The safety limits may be taken directly from Subpart B or may be developed specifically for the facility using additional technical or regulatory justification. These surrogate facility safety limits may be defined to reduce the regulatory burden associated with analyses while still demonstrating overall compliance with the Subpart B regulatory limits.

The facility-specific safety limits may be prescriptive, or performance based but demonstration of compliance with facility specific safety limits must simultaneously result in demonstration of compliance with all Subpart B regulatory limits. These facility specific safety limits shall be used as the basis for the facility design evaluation portion of the safety case.

53.302(e). Specific safety case organization and processes

The applicant shall describe the organization of the facility-specific safety case and the processes used to demonstrate compliance with the facility-specific safety limits. The maturity, detail, and finality of the safety case and processes shall be commensurate with or greater than the finality of the specific licensing activity.

The facility-specific safety case shall include a safety analysis report (SAR). The applicant shall define the contents of the facility SAR and provide justification supporting the adequacy of these evaluations to enable demonstration of compliance with the facility-specific safety limits. The SAR may include a safety analyses that employs deterministic evaluations, risk-informed evaluations, analyses that employ a combination of both deterministic and risk information, a hazards analysis, or other safety evaluations as defined by the applicant.

The applicant should describe the facility-specific safety case development process and methodology. Processes for incorporation of insights from the facility specific safety case into the design should be outlined. The applicant should also describe the programs and oversight in place

[9] Draft text adapted from CNSC (2017), *Licence Application Guide: Licence to operate a Nuclear Power Plant*, REGDOC-1.1.3, Sec. 4.5.3.

to ensure that the safety analysis is carried out by technically qualified and appropriately trained staff, and is in accordance with the management system program supporting safety analysis.

53.302(f). Facility safety case boundary conditions and assumptions

The applicant shall define and justify the boundary conditions and assumptions for the facility safety case. These boundary interfaces shall characterize the applicability of the facility safety case for demonstrating compliance with the facility safety limits. These boundary conditions and assumptions should include the physical boundary conditions of the safety case (e.g., systems, structures, and components explicitly evaluated within the safety case versus assumed external behavior), the operational boundary conditions (e.g., internal and external limiting conditions that bound safety case evaluations), and any other bounding assumptions or limits on the applicability of facility safety case.

53.302(f)(1). Assumptions

The facility safety case shall explicitly characterize any major assumptions used in the evaluations to demonstrate compliance with the facility safety limits. The basis for these assumptions and the implications on the applicability of the facility safety should be explicitly stated.

53.302(f)(2). Boundary conditions and limiting cases

The facility safety case shall explicitly characterize limiting conditions used in the evaluations to demonstrate compliance with the facility safety limits. The basis for these limiting conditions and the implications on the applicability of the facility safety should be explicitly stated. These boundary conditions and limiting cases may include factors such as specific bounding internal and external hazards, or description of bounding system conditions such as assumed operational lifetime.

53.302(f)(3). Maintenance of safety case conditions

The facility safety case shall identify any other operational, organizational, or performance-based requirements that are assumed as part of the facility safety case. This may include surveillance, maintenance and inspection program requirements.

53.302(g). Facility-specific safety case

The applicant shall develop a safety case for the facility. The facility-specific safety case shall provide sufficiently detailed information, evaluations, and analysis to facilitate demonstration of compliance with the facility-specific safety limit. The safety case shall:

- identify the facility's hazards by a thorough and systematic process;
- identify the failure modes of the plant or equipment by a thorough and systematic fault and fault sequence identification process;
- demonstrate that the facility conforms to relevant good engineering practice and sound safety principles.
- provide sufficient information to demonstrate that engineering rules have been applied in an appropriate manner;
- identify areas of optimism and uncertainty, together with their significance, in addition to strengths and any claimed conservatism. Handing of these uncertainties and their implications on the facility specific safety case should be analyzed.[10]

[10] Draft text adapted from UK Office for Nuclear Regulation (2020), 2014 Safety Assessment Principles for Nuclear Facilities, 2014 edition, Rev. 1, p. 29, para. 102, SC.5.

Whenever operator action is taken into account [as a safety assumption in the SAR], the applicant shall demonstrate that the operators will have reliable information, sufficient time to perform the required actions, documented procedures to follow, and adequate training.

53.302(g)(1). Major principles and portions

[More detailed guidance on major principles and expected portions for a technology independent review could be provided here. Could be adapted from ONR SAPS 2014 Paragraphs 145-189 in this Subpart or placed in guidance]

53.302(h). Demonstration of facility regulatory compliance

The applicant shall demonstrate that their facility complies with the facility-specific safety limits and, by extension, the Subpart B regulatory limits. Compliance with all facility specific safety limits shall be demonstrated. A standard of reasonable assurance of adequate protection shall be used when evaluating demonstrated compliance with the facility specific safety limits.

The engineering detail in the facility-specific safety case evaluations shall be commensurate with or greater the analysis conservatism, uncertainties, margin, and the regulatory significance of the conclusions supported by the facility safety case evaluations.

If the facility-specific safety case cannot be used to demonstrate compliance with the facility specific safety limits, the facility specific safety case or safety limits must be modified. Exemptions to demonstration of compliance with facility specific regulatory limits are not permitted.

53.302(i). Facility safety case applicability

The applicant shall describe the applicability of the facility safety case to support different licensing evaluations The scope of the safety case, engineering principles and standards, level of engineering detail and evaluation finality, assumptions, and uncertainties may all affect the applicability of the facility safety case to assist in demonstrating compliance with regulatory requirements. The applicant should characterize the conclusions from the facility safety case and describe the intended use of the facility safety case to support licensing evaluations.