From: Afzali, Amir
To: Shams, Mohamed
Cc: Reckley, William; Cubbage, Amy; Segala, John
Subject: [External_Sender] FW: Part 53 Position Letter
Date: Monday, May 24, 2021 12:17:40 PM
Attachments: 10CFR53-Letter-5-21-2021.pdf

Greetings,
FYI. We cannot lose this historic opportunity for developing a transformational, holistic, and integrated RIPB technology inclusive regulatory framework.
Best regards,

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Licensing and Policy Director- Next Generation Reactors
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From: Afzali, Amir
Sent: Monday, May 24, 2021 9:54 AM
To: John.Tappert@NRC.gov; Scott.Moore@nrc.gov
Cc: Cullen, Gregory V. <GVCULLEN@energy-northwest.com>; Nolan, Chris <Chris.Nolan@duke-energy.com>
Subject: Part 53 Position Letter

Dear Mr. Tappert and Moore,
Please find attached a signed position letter, addressed to Mr. Tappert, on the following aspects of the currently proposed Part 53 language:

- Explicitly including performance objectives of the regulation in the rule (e.g., frequency and consequence values for events from which Design Basis Accidents are selected and quantitative health objectives).
- Enabling the development and deployment of owner-controlled programs for managing the reasonable assurance constituent of the regulatory mission (programmatic requirements, regulatory oversight programs, etc.) while enabling an effective and efficient regulatory inspection and enforcement framework.

We would also like to request that this letter to be shared with the
Advisory Committee on Reactor Safeguards (ACRS), Future Plant Designs Subcommittee's members.
Best regards,
Amir

Amir Afzali

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May 21, 2021

Mr. John Tappert
Director, Division of Rulemaking, Environmental, and Financial Support
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Technology-Inclusive, Risk-Informed and Performance-Based Regulatory Framework for Advanced Reactors

Dear Mr. Tappert,

This letter and its enclosure provide the signatories' perspectives on the ongoing activities by the Nuclear Regulatory Commission to develop new a regulation, Part 53, under Title 10 of the Code of Federal Regulations. We support the following specific aspects of the proposed content of the draft Technology Inclusive, Risk-Informed and Performance-Based (RIPB) Part 53, subparts B, C, and F (the publicly available revisions as of April 8, 2021), and we believe the rule can be (and should be) finalized by October of 2024:

- Explicitly including performance objectives of the regulation in the rule (e.g., frequency and consequence values for events from which Design Basis Accidents are selected and quantitative health objectives)

- Enabling the development and deployment of owner-controlled programs for managing the reasonable assurance constituent of the regulatory mission (programmatic requirements, regulatory oversight programs, etc.) while enabling an effective and efficient regulatory inspection and enforcement framework

Our perspectives are derived from and fully consistent with decades of licensed operation of nuclear power facilities.

In the enclosure, which is provided for your information, we outline options that were considered in reaching our conclusions regarding the approach and content that are most appropriate for a Part 53 regulation. Also provided are several questions and observations that we have encountered in discussions among the nuclear industry regarding the proposed Part 53. The responses are also offered as our perspectives on these questions and observations.

We recognize the need for extensive and constructive engagement with the Staff as the draft of all the subparts are formulated and matured, and we look forward to continuing to work closely with NRC in its development of Part 53.

Yours truly,

A. Afzali

Amir Afzali
Next Generation Licensing and Policy Director
Southern Company Services

Greg Cullen
Vice President, Energy Services and Development
Energy Northwest

Chris Nolan
Vice President of Regulatory Affairs, Policy, and Emergency Preparedness
Duke Energy

Enclosure: Owner/Operator Perspectives on Subparts B, C and F, including the overall approach and content of proposed Part 53

1. Introduction

In response to the Nuclear Energy Innovation and Modernization Act (NEIMA), the NRC Staff is developing Part 53, which is a risk-informed and performance-based (RIPB) rule. Based on the congressional request and the Commission's direction, the rule finalization date has been expediated from 2027 to October 2024. This enclosure provides topics for discussion regarding the timing, content, and direction of the proposed rule.

Conclusions are provided regarding the timing, the specific contents of Subpart B, "Technology-Inclusive Safety Requirements," and Subpart C, "Requirements for Design and Analysis," and the overall direction in finalizing this rule. The purpose of these conclusions is to provide the necessary flexibility to licensees in the development of the safety case while effectively and efficiently employing the principles of an RIPB-based regulatory framework identified in Subpart F, "Requirements for Operations." The signatories to this letter believe that, although there is room for improvement, the current draft Part 53 for these subparts, including the necessary PRA requirements, provide an adequate platform for the formulation of an agile, predictable, and resilient regulatory framework for licensing, inspection, and oversight during design, construction, and operations. The context and bases for these recommendations are provided below.

2. Current Part 53 Status and Key Subparts

The Part 53 rule covers the life cycle of a nuclear plant (licensing, siting, construction, operation, and decommissioning) and is a foundation upon which the entire regulatory framework (licensing, inspection, and enforcement) is to be established. Figure 1, which is reproduced from an NRC presentation, illustrates this point.

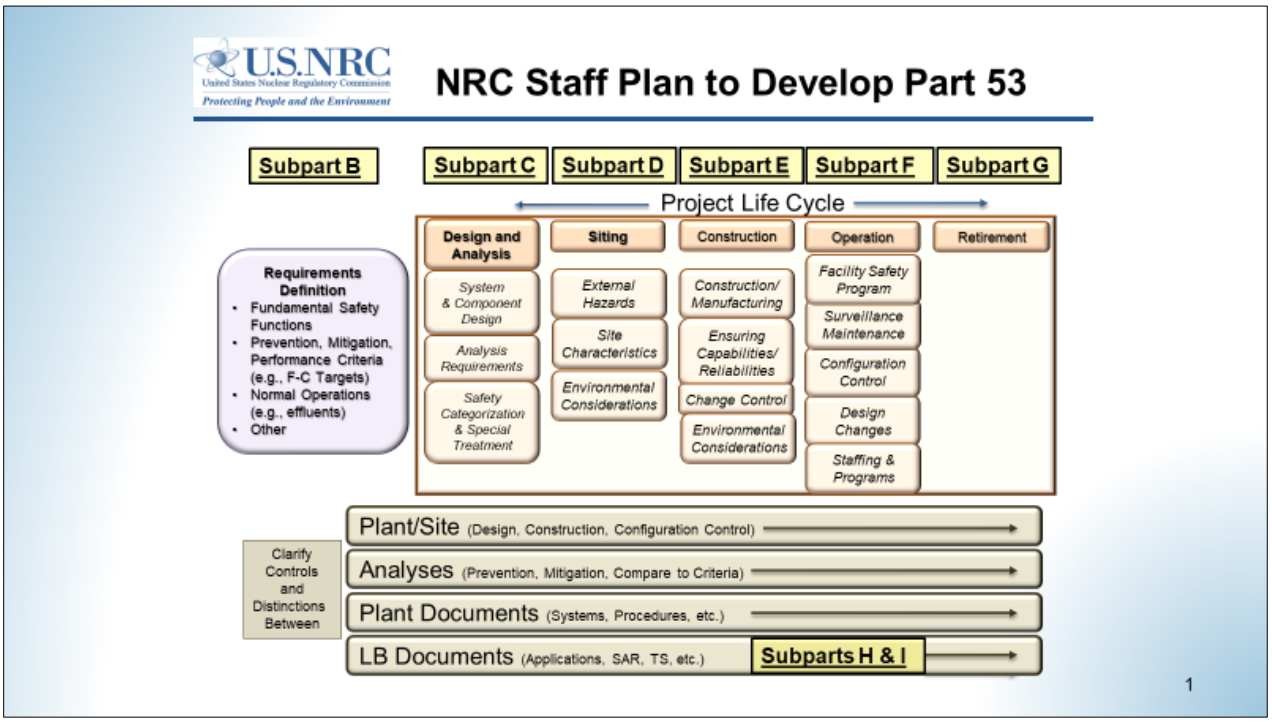

Figure 1. Part 53 Overview

The rule includes many subparts which build upon each other. Two key subparts, Subparts B and C, provide direction for establishing the requirements for the safety case, which is used to construct the

requirements in the later subparts. The draft language in Subparts B and C, which are the focus of these recommendations, needs to be largely settled as soon as possible to help formulate the other subparts.

3. Regulatory Framework Options

At a high level, the potential options for the regulatory framework construct are:

- Option 1: Unstructured Construct—This is the construct wherein very high-level performance objectives are included in the rule (similar to the United Kingdom's Safety Assessment Principles and to the original Part 50 regulatory framework). Such a construct is characterized by maximum flexibility with minimum predictability. History tells us that, based on utilities' feedback, this is a less desirable approach due to the considerable lack of predictability (time, cost, and technical content).
- Option 2: Structured Construct—Two alternatives have been identified (currently offered via Parts 50 and 52 and in NRC's draft Part 53):
    - Alternative 2a: RIPB Construct—This would be based on a quantitative RIPB methodology. In such a construct, Part 53 would be formulated such that the high-level performance objectives of the regulations are explicitly included in the rule language, and guidance is provided on how to comply with the rule language and how to deal with changes (state of knowledge changes or unexpected performance-based changes). This is consistent with all RIPB programs such as 10 CFR 50.69, risk-informed surveillance frequency programs, and the Canadian Nuclear Safety Commission approach when a guidance document is provided on how to meet the expectations. This is reasonably predictable and flexible (agile) and is resilient in that it allows for changes in the state of knowledge.
    - Alternative 2b: Compliance Construct (detailed prescriptive rules)—Similar to the current Part 50 and Part 52, these are highly predictable but restrictive (against innovation) and time-consuming to develop and administer. Departures, deviations, or exemptions require extensive justification for alternative or non-applicable requirements for designs different from the compliance basis. For Part 53 to be a foundation of such a framework, it must provide a platform for creating technology-specific (and most probably design-specific) design criteria (most likely based on the different Advanced Reactor Design Criteria) and use rule-based approaches (single failure criteria, prescriptive siting requirements, etc.) to deal with reliability, availability, completeness, or performance uncertainty elements of the safety case.

We believe that Alternative 2a provides the maximum predictable flexibility and resilience and that Part 53, as a foundation of such a framework, can be deployed by the 2024 deadline. Specifically, we believe that Part 53 should form the foundation for a regulatory framework for licensing, inspection, and enforcement that:

- Facilitates an integrated and holistic technology inclusive, RIPB modernization of the regulatory framework such that it is *agile, predictable, and resilient*.
- Includes performance objectives of the regulation in the rule language.

4. Bases for this Position

We conclude that Option 2a should be made available to owners/operators because we are committed to deploying advanced reactors in a commercially viable manner as part of our energy generation

portfolios to meet environmental responsibilities (such as net-zero goals). To increase the likelihood that these technology/design options will be available and to facilitate owners/operators in making the best technological choices for their business needs (which will result in successful long-term deployments), we would like to have a regulatory framework that:

- Enables commercial viability while increasing social acceptability and license-ability while meeting the reasonable assurance of adequate protection standards.
- Facilitates right-sizing of the requirements (technical and programmatic for licensing—including siting, oversight, and enforcement) throughout the life cycle of a nuclear energy system based on its safety case.
- Provides a platform for establishing equitable requirements for different designs and technologies based on their safety cases (allowing owners/operators to make the best choices for their needs rather than choosing a design based on its previously negotiated licensing requirements).

Part 53 should be in place as soon as possible because:

- The modernized framework is needed by 2024 to provide efficient oversight and enforcement of the ARDP awardees (during construction and operation). [Note: Although the two ARDP awardees are planning to submit their applications prior to 2024 using Part 50 or 52 rules, both are using the LMP methodology for developing their safety cases and would benefit from the future application of the Part 53 licensing infrastructure.]
- Other designers are making design choices now, and having an RIPB-based optional rule will enable them to make the best choices for their designs.
- The industry and NRC have been working on the bases of an RIPB rule for over 30 years. This body of work includes the following:
    - Modular High Temperature Gas-cooled Reactor licensing activities, some of which are documented in NUREG-1338, published in 1995.
    - Exelon's licensing activities and conclusions for the Pebble Bed Modular Reactor. For example, the proposal that Exelon documented in its letter to the NRC on January 31, 2002, includes the following excerpt: "Certain regulatory objectives are not amenable to probabilistic treatment in the present regulatory environment. These include occupational exposure minimization, environmental impacts other than radiological, and security and safeguards. These objectives will be met in the conventional manner as consistent with existing practice. For the remaining objectives (limiting public exposures during normal operation, and preventing and mitigating accidents), Exelon has developed a risk informed licensing approach as described in this paper."
    - Another related activity is "Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing," Volumes 1 and 2 (NUREG-1860), published December 2007.
    - Next Generation Nuclear Plant (NGNP) licensing activities (e.g., NGNP Licensing Plan, published in 2009). This was a collaborative/cooperative effort between NRC and DOE with support from INL and private industry.

- NEI 18-04 methodology (a product of the LMP), which was endorsed in RG 1.233 in 2019, and the ongoing Technology Inclusive Content of Application Project, a component of the NRC Advanced Reactors Content of Application Project.
- Over thirty years of experience with RIPB programs, including:
  - Regulatory inspection and enforcement programs such as the Reactor Oversight Program (including the significance determination program), risk-informed NOED, risk-informed Accident Sequence Precursor, and generic safety issue resolution, to name only a few. It should be noted that all of these programs are currently available for advanced LWR-based designs but have to be developed for non-LWRs.
  - Voluntary programs, such as RIPB Inservice Inspection, Risk-Informed Flexible Allowed Outage Time (piloted for the NRC by Southern Company), 10 CFR 50.69, RIPB Structures, Systems, and Components Classification (piloted for NRC by Southern Company), and an RIPB fire protection program (i.e., NFPA 805).
- There is a PRA standard for non-LWRs, ASME/ANS RA-S-1.4-2021, and a PRA Peer Review Process Guidance, NEI 20-09 Rev 1, already in place with plans underway for NRC endorsements.
- Reliability Integrity Management Program (ASME Section XI Division 2).
- ANS 53.1 (for HTGRs), the only NRC-endorsed design standard, is RIPB.
- The NRC Staff has not identified any challenges to developing the rule that they cannot overcome.

5. Conclusions

Owners/operators hold the operating licenses and are accountable for protecting the safety of the public and the environment. Incorporating the lessons that the owners/operators have learned is necessary to gain the confidence of prospective owners/operators in that there is a modernized regulatory framework within which commercially viable advanced nuclear energy systems can be designed, constructed, and operated.

Additionally, owners/operators are technology agnostic and favor designs that best serve their needs, which includes enhanced safety. When these needs are met, deployment past the first-of-a-kind demonstration projects becomes feasible, resulting in the realization of possibilities that are fueling considerable private and public investments. Thus, they prefer a modernized regulatory framework that both accommodates and treats equitably the entire range of advanced nuclear energy technologies and design concepts. Such a framework will focus on the fundamental safety concepts as well as maintenance, oversight, and enforcement of those safety concepts throughout the lifetime of the licensed facility.

We believe that in achieving a truly RIPB rule (which would be an alternative to the current Part 50 and Part 52 language), the NRC-proposed approach for Subpart B and C is on target. There are a number of reasons for this position, including the following:

- Both historical and contemporary evidence shows the importance of using RIPB approaches (PRA plus deterministic), not only to right-size the requirements and eliminate unnecessary burden, but also to identify events before events find us and result in the erosion of public confidence and the addition of siloed conservative requirements.

- We believe there is a need for this rule to include the performance objectives of the regulations and policies to create a transformative, integrated, and holistic RIPB regulatory framework that sets transparent and equitable technical requirements (SSCs and programmatic features), as well as regulatory oversight and inspection programs.

6. Frequent Questions/Comments, Observations, and Responses

Question/Comment 1: Is drafting of Part 53 occurring at a pace that does not provide sufficient opportunity for a full hearing and resolution by all important stakeholders?
Response 1: Although communication among parties needs to improve, the pace is not the issue. The industry and NRC have been working on the bases of an RIPB rule for over 30 years. This body of work in this area is described in Section 4.
Additionally, the aggressive pace is not too fast, and it is actually needed. For example, the current awardees of DOE's Advanced Reactor Demonstration Project are expected to finalize the design, licensing, and construction of their advanced reactors in five to seven years. Although these awardees may not fully benefit from a finalized RIPB regulatory framework before they submit their applications, they will benefit from other regulatory framework modernizations that will use Part 53 as their foundations (e.g., RIPB Reactor Oversight Program). Furthermore, public and private sectors are making significant investments in ensuring advanced reactors (particularly the non-LWRs) are available as an option to provide affordable, reliable, and clean energy. It is critical to provide a modernized regulatory framework as soon as possible for ensuring these designs can be efficiently designed, constructed, and operated.
Question/Comment 2: The level of regulation appears to be increasing rather than simplifying and providing flexibility in licensing (e.g., Subpart F).
Response 2: We believe that the Staff's stated objective for the additional requirements included in the draft Subpart F is consistent with establishing an effective and resilient regulation. For example, if our understanding of the Staff's statement is correct that the addition of the "facilitate safety program" in Subpart F will result in the NRC's "Safety Issue Program" (Management Directive 6.4, Generic Issues Program) transitioning from a *performance* role to an *oversight and enforcement only* role, then there will be significant improvements in the efficiency of dealing with new potential issues and in the NRC resource costs. For example, "Audit of NRC's Screening and Assessment of Proposed Generic Issues," (OIG-19-A-07, January 23, 2019) found that "the Program's screening stage can be strengthened through improved timeliness of initial screening and posting of documentation on the program website. Additionally, overall program management could be improved through better monitoring of labor resources used for Generic Issues."
Question/Comment 3: The rule language should be flexible to provide optionality for those that wish not to use PRA.
Response 3: Optionality is very important. Therefore, we believe that the current proposed language is creating the desired *optionality* because Parts 50 and 52 do not explicitly include the performance objectives of the regulation. By reverting to the Part 50 and 52 vague language, we would actually be obstructing optionality versus creating optionality.
Additionally, we advocate for a Part 50/52 affirmative safety case option for those that do not wish to use a risk-informed approach. In such an option, when it is demonstrated that the performance objectives of the regulation are met, the need for exemptions is either eliminated or significantly reduced (through generic exemptions). Such an option will also be helpful to ARDP applicants that are using LMP and Part 50/52 processes.
Finally, we recognize the need for this option while not giving in on the principles of creating an RIPB regulatory framework or on the timeline; as the lessons learned from the termination of the

Technology-Inclusive RIPB activities (which was initiated as a result of the 2005 energy act) indicate, abandoning either the RIPB approach or the aggressive timeline will result in neither the regulator nor the industry being adequately ready for timely and efficient deployment of commercially-viable advanced reactors.

Question/Comment 4: Including the performance objectives of the regulations in the rule creates additional burden compared with Part 50 and Part 52 by (1) requiring PRA to meet the rule language and (2) providing an opportunity for the interveners to challenge that the rule is met.

Response 4: It should be noted that Part 52 requires PRA. Also, the current Part 50/52 alignment update, as well as the evidence from the historical post-TMI licensing activities, indicate that PRA will be required from Part 50 and 52 applicants.

Furthermore, the 10 CFR 50.69 rule requires PRA, and the risk-informed criteria for categorization include PRA-based targets. Therefore, although this concern is valid and should be addressed, the evidence shows that the inclusion of the performance objectives in the rule, while creating clarity, does not result in additional burden.

Question/Comment 5: The use of PRA for licensing of the advanced non-LWR-based designs could be problematic due to the lack of operating experience and the management of uncertainties.

Response 5: The risk-informed related history of LWRs (e.g., WASH-1400, which provided many insights with minimal operating experience), as well as of non-LWRs (e.g., Non-LWR PRA Standard development), have shown that the development and use of PRA are not only practical, it is also a highly reliable approach for developing the safety case. Also, the following should be noted about the non-LWR PRA standard (ANSI/ASME/ANS RA-S-1.4-2021, "Probabilistic Risk Assessment Standard for Advanced Non-Light Water Reactor Nuclear Power Plants,") one of the few non-LWR-based industry standards ready for usage:

- The standard benefitted from extensive pilot PRAs that were done using the trial use version, including three pebble bed HTGRs, one prismatic HTGR, three sodium-cooled fast reactor designs, a fluoride salt high-temperature reactor, a heat-pipe micro-reactor, and a molten salt reactor.
- It was the first PRA standard that was unanimously approved by the ASME/ANS JCNRM, as well as the ASME, ANS, and ANSI standard boards.
- The non-LWR PRA project team resolved more than 500 comments from NRC Staff, NEI, industry, and consultants, and it was noted by all commenters that their concerns were successfully addressed, leading to the unanimous approval.
- The 80% of the technical requirements that are common to LWRs are in complete alignment with the next edition of the LWR Level 1/LERF PRA standard that is currently in the late stages of approval.
- The standard is specifically structured to support LMP applications, including selection of LBEs, safety classification of SSCs, selection of reliability and capability targets and performance requirements, and evaluation of defense-in-depth using both absolute and relative risk-significance criteria.
- The standard includes technical requirements to address uncertainties due to the lack of design details for PRAs in various design stages and those due to the relative lack of service experience.
- The state of knowledge for the development of PRA data for non-LWR PRAs varies among the different technologies but is more advanced than that which was available to support the first LWR PRAs analyzed in the Rasmussen study.

Question/Comment 6: The NRC's requirements for the inclusion of quantitative health objectives could be problematic.

Response 6: The Safety Goal Policy Statement details the acceptable level of radiological risk from nuclear power plant operation and includes the following two quantitative objectives in determining the achievement of the safety goals:

- 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 (0.1 percent) of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. population are generally exposed.
- 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 (0.1 percent) of the sum of cancer fatality risks resulting from all other causes.

Although the policy statement is not a regulation, it has influenced various regulatory actions, primarily the development of the Regulatory Analysis Guidelines used in backfit analyses and the guidance developed for risk-informing reactor regulatory activities.

As stated SECY-13-0029:

> "As part of NRC and industry initiatives to expand the use of probabilistic risk assessment (PRA) for operating reactors, the NRC provided draft Regulatory Guide (RG) 1.174 for Commission review in 1997. Since then, for operating reactors, a LERF guideline of 10^{-5} per reactor year has been used as a surrogate for the prompt fatality QHO and a core damage frequency (CDF) guideline of 10^{-4} per reactor year has been used as a surrogate for the cancer fatality QHO. The staff has shown through calculations the appropriateness of these surrogates, and the Commission has continued to approve their use. These metrics have been applied to various aspects of reactor operation."

Also, as recognized in the same SECY, "the NRC did not define which releases would be considered 'large,'" i.e., no dose limit was defined.

Therefore, the inclusion of the QHOs is not only practical, but it is also actually needed to:

- Enable commercial viability while increasing social acceptability and license-ability and meeting the reasonable assurance of adequate protection standards.
- Facilitate right-sizing of the requirements (technical and programmatic for licensing—including siting, oversight, and enforcement) throughout the life cycle of a nuclear energy system based on its safety case.
- Provide a platform for establishing equitable requirements for different designs and technologies based on their safety cases (allowing owners/operators to make the best choices from the safety point of view and for their commercial viability needs rather than choosing a design based on its negotiated licensing requirements).