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NUCLEAR ENERGY INSTITUTE

December 23, 2020

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

Subject: NEI Input on the NRC's Rulemaking on, *Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)*

Project Number: 689

Dear Mr. Tappert:

The Nuclear Energy Institute (NEI)[1] and its members appreciate the Nuclear Regulatory Commission's (NRC) efforts to establish a technology-inclusive, risk-informed, and performance-based regulatory framework for advanced reactors, commonly referred to as the Part 53 rulemaking. We are pleased to see the staff's November 2, 2020 response to SRM-SECY-20-0032 providing a milestone schedule and key uncertainties for the Part 53 rulemaking, and the supplemental details in the staff's presentation at the November 18, 2020 public meeting. We also appreciate the NRC's November 16, 2020 letter indicating general agreement with the input we provided by letter dated October 21, 2020. While there is still much work ahead to achieve a technology-inclusive, risk-informed and performance-based Part 53 rule that is transformational and meets the needs of future new reactor designers, owners and operators, we believe that the NRC's approach is headed in the right direction.

The purpose of this letter is to provide additional input on the Part 53 rulemaking to inform the NRC's efforts. While the NRC public meetings are effective in soliciting stakeholder input, we plan to supplement this input through periodic letters. Specifically, this letter addresses the following topics:

[1] The Nuclear Energy Institute (NEI) is responsible for establishing unified policy on behalf of its members relating to matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect and engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations involved in the nuclear energy industry.

1. Success criteria for the final rule (a.k.a., project requirements), including requirements and constraints (e.g., Atomic Energy Act) for the final rule, and key decisions that must be addressed in the rulemaking,
2. Risk-informed performance-based safety criteria that defines adequate protection in terms of radiological impacts to the public, and
3. Feedback on input provided by the Advisory Committee on Reactor Safeguards (ACRS)

Success Criteria (a.k.a, Project Requirements)

In our October 21st letter, we recommended a five-step process for the Part 53 rulemaking process, with the first step being to "Frame the Part 53 Rulemaking Effort" by November 30, 2020. Step 1 was further divided into three activities, and in our letter, we provided input on the first activity to "establish a vision and goals for the final rule and the process steps for the rulemaking". The second and third activities were to "identify requirements and constraints (e.g., Atomic Energy Act) for final rule" and "establish the success criteria for the final rule (a.k.a., project requirements) and key decisions that must be addressed in the rulemaking".

In Attachment 1, we provide input on the success criteria for the Part 53 final rule (a.k.a. project requirements), based in part on a review of requirements from the Atomic Energy Act. The purpose of these success criteria is to define what functionality needs to be provided in the final Part 53 rule, and will be a guide for the Part 53 development, and future discussions to be held between the NRC staff and industry to ensure that the final rule meets the pre-defined success criteria. These success criteria define what Part 53 must accomplish (e.g., establish safety requirements), not how to do it (e.g., specifying the dose limits for members of the public) nor the process by which to develop the new rule. We note that the inclusion of some success criteria will depend on the final scope of the Part 53 rule, for example whether decommissioning will be included. These success criteria align with the direction in the Nuclear Energy Innovation and Modernization Act, and the vision and goals that we proposed in our October 21st letter. While these success criteria are intended to be exhaustive, there could be additional criteria identified over the course of the rulemaking.

We encourage the NRC to use the list of success criteria in Attachment 1 to plan topics for discussion at future NRC public meetings.

Safety Criteria

During the NRC's public meeting on November 18, 2020, the NRC discussed draft proposed rule text for Part 53 Subpart B "Technology-Inclusive Safety Requirements". We offer the following feedback on the NRC's

draft proposed rule text. This feedback is the basis for the alternative draft rule text in Attachment 2. This text is intended to replace the draft rule text proposed by the NRC in its entirety.

Safety Objectives and Two-Tier Criteria – The NRC proposes a new approach in Part 53 in terms of defining the safety objectives. Consistent with 10 CFR Parts 50 and 52, NRC's draft section 53.20 requires advanced nuclear plants to provide reasonable assurance of adequate protection of the public health and safety and the common defense and security. However, the NRC further requires such plants to "take such *additional* measures to protect public health and minimize danger to life or property as may be reasonable when considering technology changes, economic costs, operating experience, or other factors." In its November 2020 "Discussion Table," the NRC staff ascribes these two requirements to Atomic Energy Act (AEA) Section 182 ("License Applications") and Section 161 ("General Duties of the Commission"), respectively. In draft sections 53.22 and 53.23, the NRC staff proposes two tiers of safety criteria that apparently are intended to coincide with the two safety objectives.

The NRC's draft rule text is confusing and does not lend itself to easy implementation. As a threshold matter, we are concerned about the manner in which the staff distinguishes between "adequate protection" and "minimize danger" as two different safety objectives or standards to be applied in the initial licensing of an advanced reactor. As the NRC's Director of the Office of New Reactors noted in an August 29, 2018 memorandum (ML18240A410) prepared in consultation with OGC, "[t]he legal standard for [NRC] licensing decisions is that [the agency] have reasonable assurance of adequate protection – not the elimination of all risk." We agree that "reasonable assurance of adequate protection" is the operative standard for purposes of new reactor licensing, but believe that any "additional measures to protect public health and minimize danger to life" would be above and beyond what is "adequate." This principle is discussed in the D.C. Circuit decision cited by the staff in its Discussion Table. *See Union of Concerned Scientists v. NRC,* 824 F.2d 108, 118 (D.C. Cir. 1987) ("Under section 161 of the Act, the Commission may order plants to provide "extra-adequate" protection; in deciding whether to establish or enforce such requirements, the Commission may take into account economic costs."). Importantly, as reflected in its backfitting regulations, the NRC has required such "extra-adequate" protection measures only when they have demonstrable safety benefits that are justified in light of their economic costs.

Accordingly, in Attachment 2, we propose structural changes to the draft rule text to more closely tie the safety objectives to the safety criteria, essentially establishing two sets of requirements: (1) those that are necessary to establish reasonable assurance of adequate protection without regard to economic costs, and (2) those which provide substantial, additional protection (i.e., extra-adequate protection) that is justified on the basis of costs/benefits. We further propose that the NRC provide greater clarity regarding the application of the "adequate protection" standard to reduce uncertainty and unintended regulatory expansion during application reviews. In particular, we suggest that the staff consider the guidance on adequate protection provided in the aforementioned August 29, 2018 NRO memorandum, and in the January 15, 2019 memorandum (ML19015A290) issued by the Director of the Office of Nuclear Material Safety and Safeguards (NMSS). Finally, insofar as the staff opts to retain use of the "minimize danger"

language in its draft regulations (which NEI does not believe is necessary), it should make clear that any associated requirements are intended to provide cost-justified extra-adequate protection.

Overall Safety Construct – The NRC's safety criteria include many elements that we view as part of the overall safety construct (e.g., safety functions, licensing basis events, and defense in depth). While these elements of the safety requirements may ultimately be located in the NRC's proposed Subpart B, we are not proposing alternative draft rule text in Attachment 2, because we expect these to be developed after establishing the safety criteria. It is important to develop the safety criteria first, because they are the limits that define adequate protection and extra-adequate protection. Requirements related to licensing basis events, safety functions, and defense in depth are elements that form the "what" needs to be done to meet the safety criteria. We also note that there may be other elements, such as the design features, programs, barriers and mitigation that form the overall safety construct that defines "what" needs to be done to meet the safety criteria. We recommend that the NRC wait to address these requirements during the discussion on the overall safety construct.

ALARA – Achieving radiation exposure as low as reasonably achievable (ALARA) through the implementation of the licensee's radiation protection program is a wise policy. As the Commission has noted, "the ALARA concept is intended to be an operating principle rather than an absolute." 56 Fed. Reg. 23359, 23366 (May 21, 1991). The draft regulations, however, appear to treat ALARA as the latter. In reviewing the Atomic Energy Act, we note that there is no nexus between ALARA and statutory requirements for the NRC's regulation of nuclear reactors. Furthermore, regulations regarding ALARA drive costs for regulatory compliance without a commensurate safety benefit, and are therefore inconsistent with the development of more risk-informed, performance-based and efficient regulatory framework. The issue here is how ALARA applies to engineered features and the degree to which engineered features are required for ALARA purposes. We therefore recommend that the NRC avoid imposing ALARA requirements in Part 53 (e.g., 53.23(a) and 53.26(b) in NRC draft rule text.) The industry will implement ALARA practices regardless of the NRC's position on the topic. If there are concerns about the industry's commitment to ALARA, a potential solution would be to establish an NRC policy encouraging the industry to implement ALARA practices. Since ALARA requirements are included in 10 CFR Part 20 requirements for radiation protection, Part 53 will need to include an approach to incorporate radiation protection requirements (e.g., by either referencing 10 CFR Part 20, except for ALARA requirements, or establishing radiation protection requirements in Part 53).

Occupational Exposures – We agree with the NRC that occupational exposure limits need to be addressed, and we generally agree with the NRC's approach to reference Part 20. The NRC's approach to elevate occupational exposure to safety criteria is not consistent with the current regulatory framework and would effectively expand the regulation of the engineering design of the plant beyond what currently exists. Furthermore, occupational workers undergo extensive training on radiological exposures and protection. We

recommend that occupational exposures therefore be addressed under requirements for radiation protection, rather than as engineering-based safety criteria.

Performance-Based Language – We recognize that the NRC proposed rule text is a draft and likely will be revised to be more performance-based and clear. To aid these revisions, we have identified that the use of certain terminology (e.g., high-confidence, mean frequency) are not needed in the regulation, since they are details more appropriately addressed in guidance, and they can lead to later complications. Similarly, the NRC repeatedly uses the term "design features and programmatic controls" in describing what the applicant must do to meet the performance-based requirement. Defining the specifics of what must be provided is overly prescriptive. Furthermore, requirements related to the design and programs are better addressed in the safety construct, i.e., what needs to be done to meet the safety criteria, to be developed later.

Administrative Requirements – The NRC draft rule text includes a requirement, 53.22(c), that the NRC can impose additional requirements as deemed necessary. Our understanding is that this is not intended to allow staff to impose new requirements from one application to another, but is intended to document the NRC's authority to issue generally applicable requirements and orders, within certain limitations. While we agree that the NRC has this authority, we note that the NRC currently does not explicitly state this authority in the Part 50 requirements. If the NRC determines that it needs to be explicitly stated in Part 53, we recommend that it be included in a subpart dedicated to "administrative requirements" and not related to safety criteria. Furthermore, we recommend that the NRC clarify in the limitations to such authority, which could be done efficiently by combining it with provisions similar to 10 CFR 50.109.

There are two additional topics for which we have not reached a final position and believe would benefit from more discussion. We are providing our current thoughts on these topics to facilitate a discussion at the next NRC public meeting.

Quantitative Frequencies – The NRC draft rule text proposed to include quantitative frequencies (e.g., once per 10,000 years). While this is consistent with a risk-informed rule, we also note that using qualitative frequencies in the rule text (e.g., not expected to occur in the life of a nuclear power plant) and including the quantitative frequencies in guidance is consistent with a risk-informed rule. The concern with including quantitative frequencies in the rule text, which to our knowledge would be the first time quantitative frequencies are included in the rule text, is the possibility of creating unforeseen challenges to the review and approval of new reactor license applications. We have included both options in the alternative draft rule text in Attachment 2, as shown in bracketed italics, such as "*{are not expected to occur in the life of a nuclear power plant} OR [{have an expected frequency greater than once in 10,000 years}"*, to facilitate further discussion before making our recommendation on the preferred option. Finally, the "upper bound"

frequencies should not be used as it introduces an additional level of complication into quantitative metrics and effectively creates an undefined cap based on statistical inferences or temporal changes.

Beyond Design Basis Events - The NRC draft rule text proposed to include quantitative health objectives (QHOs) from the NRC's Safety Goal Policy. We note that applicants will need to evaluate their designs against the QHOs whether they are in the rule text or only in the Safety Goal Policy, and thus there is no difference in the level of safety achieved by either approach. While including the QHO in the rule text is a purer approach to meeting the Safety Goal Policy, doing so could also introduce unforeseen licensing complications, since this is the first time QHOs would be in the regulations. This is particularly true since the NRC proposed requirement for the QHOs does not include the dose limits associated with early fatalities or latent cancer fatalities. Since the NRC's inclusion of the QHO's appears to be used to address beyond design basis events, we believe a discussion of alternative requirements would be helpful. One option, consistent with the NRC's recent rulemaking to address Fukushima type accidents, would be to implement mitigation strategies for beyond design basis events. We have included both options in the alternative draft rule text in Attachment 2 to facilitate further discussion before making our recommendation on the preferred option. We further note that if the QHOs are included in the rule text, the language needs to be improved for clarity and consistency with the Safety Goal Policy.

ACRS Recommendations

The ACRS provided input on the NRC's plans for Part 53 in its October 16, 2020 letter to Chairman Svinicki. We would like to address the following ACRS recommendations for Part 53 that we believe are inconsistent with the direction in NEIMA to develop a risk-informed and performance-based rule.

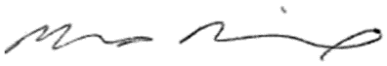
Addressing Uncertainties – We agree with the ACRS that uncertainties associated with limited information for the first reviews of novel technologies will need to be addressed in a systematic manner. However, we believe that the ACRS's recommendation to return to the methods used in the earliest days of licensing nuclear reactors would be a step back to more deterministic methods. The approach cited by the ACRS would seem to have the applicant postulate the worst possible accident, and then the ACRS try to postulate an even more severe accident based on "plausibility". This subjective, deterministic approach is inconsistent with the direction of NEIMA to pursue a risk-informed performance-based regulatory framework. This would also ignore the progress made in modern analysis methods capability to systematically identify initiating events, event sequences and address uncertainties, including the approach in NEI 18-04 *Modernization of Technical Requirement for Licensing of Advanced Non-Light Water Reactors* that was endorsed by the NRC in Regulatory Guide 1.233 and by the Commission in SRM-SECY 19-0117. The ACRS also recommends that the NRC include a pathway for licensing prototype facilities to address designs where there is a lack of operating experience or an inability to perform experiments with sufficient similitude to the planned full-scale design to reduce uncertainties to an acceptable level. While we agree that a pathway to licensing prototype facilities is one option to address these situations, we believe that it is not necessary to require a

prototype license and that applicants should be allowed to utilize other pathways to address uncertainties related to limited operating experience or full-scale testing data.

General Design Criteria – The ACRS recommended that the concept of the general design criteria (GDC) specified in Appendix A to 10 CFR Part 50 be incorporated into the Part 53 framework. They note that the GDC improved the predictability and efficiency of NRC reviews of licensing applications. We agree that the use of design criteria to establish design-specific requirements for the design, fabrication, construction, testing and performance is useful in ensuring that needed structures, systems and components are capable of providing their credited functions. Part 50 is able to utilize the GDC because it was developed solely around large light-water reactors (LWRs). However, the inclusion of GDC in the Part 53 regulations is problematic for a technology-inclusive Part 53 rule, since the variation in reactor technologies is so large that it is not possible to develop a single set of general criteria. This is reflected in the NRC's development of advanced reactor design criteria, which resulted in several technology-specific design criteria, which also are expected to lead to numerous deviations at the design-specific level. We recommend that Part 53 not specify design criteria in the regulations, and we expect further details of how they are addressed to be discussed related to the overall safety construct topic (rather than during the safety criteria topic).

We are not requesting a written response to this letter, but would appreciate NRC's response in a future public meeting. If you have questions concerning our input, please contact me at 202-739-8131 or mrn@nei.org.

Sincerely,



Marcus Nichol
Attachments
c: Mr. Ho Nieh, NRR, NRC
Mr. Rob Taylor, NRR, NRC
Mr. Mohamed K. Shams, NRR/DANU, NRC
Mr. Robert H. Beall, NMSS/REFS/RRPB, NRC
Mr. William D. Reckley, NRR/DANU/UARP, NRC
Ms. Nanette Valliere, NRR/DANU/UARP, NRC
Rulemaking.Comments@nrc.gov

Attachment 1 – Part 53 Success Criteria (a.ka., Project Requirements)

The purpose of these project requirements for the Part 53 rulemaking, based in part on a review of requirements from the Atomic Energy Act, is to define what functional requirements need to be specified in the final Part 53 rule. This will be a guide for both the Part 53 development and to ensure that the final rule achieves the pre-defined project success criteria. These use of success criteria will help to define what Part 53 must accomplish it (e.g., establish safety requirements), not how to do it (e.g., less than 25 Rem to the public) nor the process by which to develop it. We note that the inclusion of some success criteria will depend on the final scope of the Part 53 rule, for example whether decommissioning will be included. These success criteria align with the direction in the Nuclear Energy Innovation and Modernization Act, and the vision and goals that we proposed in our October 21st letter. While these success criteria are intended to be exhaustive, there could be additional criteria identified over the course of the rulemaking. The success criteria discussed below can become the subject of future NRC public meetings to ensure they are fully considered in the Part 53 rulemaking.

1. Define the scope of Part 53
    1.1. Define the types of licenses to be granted
        1.1.1. 103 commercial power reactor licenses
        1.1.2. Demonstration/Prototype reactors licenses
        1.1.3. {Decide on whether 104 non-power/research and test reactor licenses are granted during scoping stage}
    1.2. Define the types of activities to be regulated
        1.2.1. Licensing
        1.2.2. Manufacturing and construction
        1.2.3. Operations
        1.2.4. {Decide on whether decommissioning is to be included during scoping stage}
2. Define the requirements that provide reasonable assurance of adequate protection of public health and the common defense and security
    2.1. Define performance criteria to protect the public
        2.1.1. Public protection criteria must be consistent with the Safety Goals Policy or alternative as the Commission may establish (e.g., dose limits, or risk metrics)
        2.1.2. Requirements to prevent theft and sabotage
    2.2. Define the safety paradigm for reactors to provide reasonable assurance that the public protection performance criteria are met, the safety paradigm should include the following elements
        2.2.1. Radiological hazard (e.g., fuel and other radiological sources that could be released to the public)
        2.2.2. Events that could link to radiological risk to the public (i.e., internal, external and man-made)
        2.2.3. The safety construct (i.e., safety functions, design features, programs, barriers, human actions, mitigation, defense in depth, emergency preparedness)
        2.2.4. Analytical methods to demonstrating safety
        2.2.5. Role of quality assurance, including use of commercial QA standards
        2.2.6. Performance of design functions in operating environments and under conditions the functions must be operable

3. Define the information to be included in the licensing bases regulated by the NRC
   3.1. Clarify why required information in the licensing basis is necessary to make a determination of reasonable assurance of adequate protection
      3.1.1. Content of application (e.g., FSAR and Tech Specs)
   3.2. Include protections against unnecessarily requiring changes to the licensing basis (i.e., finality, backfit and forward fit protections)
   3.3. Include processes to control and change the licensing bases regulated by the NRC
      3.3.1. A process for licensees to change the licensing basis without prior NRC approval
      3.3.2. Conditions under which licensees must request prior NRC approval and the process for obtaining such approvals
4. Establish the requirements for obtaining licenses
   4.1. Define process (flexible/staged) for licenses to be granted
      4.1.1. Grant Construction Permit and Operating License (e.g., pursuant to Part 50 process)
      4.1.2. Grant Early Site Permit, Design Certification, Standard Design Approval, Combined Operating License (e.g., pursuant to Part 52 process)
      4.1.3. Decide on whether manufacturing licenses are to be granted to during scoping stage
      4.1.4. Must consider avenues or process for quickly raising significant policy disagreements between the NRC staff and applicant to Commission
   4.2. Define process for obtaining licenses (e.g., filing, granting)
      4.2.1. Allow limited work authorization
      4.2.2. Decide on whether an affirmative safety basis approach obviates the need for an exemption process during scope phase
   4.3. Must be able to achieve reasonable timelines and costs for reviewing applications and granting licenses
   4.4. Define the duration of the licenses granted and extensions
   4.5. Identify other Parts of 10 CFR that are applicable to Part 53 licenses (e.g., Part 20, Part 51)
   4.6. Describe requirements for licensee capabilities/ownership (e.g., financial qualification)
   4.7. Mechanism for applicants to challenge NRC staff decisions and reach Commission review on key policy matters quickly.
   4.8. Define the opportunities for public involvement
      4.8.1. Allow for contested hearings
      4.8.2. Include mandatory hearings
      4.8.3. Allow a process for hearing orders or early Commission engagement to address policy questions with a new reactor application
   4.9. Define the role of the ACRS and ASLB
5. Establish the requirements for NRC oversight during construction and operations
   5.1. Describe requirements for ensuring the as-constructed plant is the same as the as-approved design (e.g., inspections, testing, QA, programs)
   5.2. Describe requirements for ensuring the plant operations are within the NRC approved limits (e.g., Technical Specifications, inspections, QA, testing, radiation protection)
6. Guidance – *{Success criteria for guidance to be decided during the scoping phase}*

Attachment 2 – Safety Criteria

The safety criteria define, in terms of radiological impacts to the public, the limits that define adequate protection that will relate to other Part 53 requirements. This proposed draft rule language is intended to completely replace the draft rule text proposed by the NRC. A list of related requirements is provided below to provide more clarity on the context of the safety criteria in Part 53.

Proposed Draft Rule Language

10 CFR Part 53.20 – Adequate Protection of Public Health and Safety

Each power reactor licensed pursuant to *{reference applicable Regulations/Subpart that defines licenses, permits and certificates to be granted under Part 53}* must provide reasonable assurance of adequate protection of the public health and safety and the common defense and security. Adequate protection, which is focused on radiological risk, recognizes that some level of risk is expected when it comes to activities involving the use of a radioactive source, such that absolute protection is not required. The following criterion, when met by the power reactor, is necessary and sufficient to assure adequate protection of the public health and safety:

a) The contribution of total effective dose equivalent to an individual member of the public at the site boundary for infrequent event sequences, which may include one or more reactor modules, that *{are not expected to occur in the life of a nuclear power plant} OR* {*have an expected frequency greater than once in 10,000 years}* does not exceed:
    1) 25 rem (250 mSv) for any 2-hour period following the onset of the postulated fission product release
    2) 25 rem (250 mSv) from exposure to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage).

10 CFR Part 53.21 – Extra-Adequate Protection

Each power reactor licensed pursuant to *{reference applicable Regulations/Subpart that defines licenses, permits and certificates to be granted under Part 53}* must meet the additional criteria provided in paragraphs (a) and (b) of this section, which go above and beyond the requirements for adequate protection. Requirements above and beyond the requirements for adequate protection must have a reasonable nexus between the impacts being addressed and the statutory mission of protecting against radiological dangers. Requirements necessary to meet these criteria must provide a substantial safety improvement and be cost justified. Any such specific requirements must substantially improve the level of radiological safety as justified via a cost-benefit analysis that considers direct and indirect costs, and shall permit deviations from these requirements for licensees that demonstrate the application of these requirements to their specific design is not cost justified.

a) The contribution of total effective dose equivalent to an individual member of the public at the site boundary from normal plant operations, which may include one or more reactor modules, including events that are expected to occur one or more times during the life of a nuclear power plant does not exceed 0.1 rem (1 mSv) in a year and does not exceed 0.002 rem (0.02 millisievert) in any one hour in any unrestricted area.

b) *{Each applicant or licensee shall develop, implement, and maintain mitigation strategies and guidance for rare event sequences that are not addressed in 53.20, which may include one or more reactor modules, and that [are not expected to occur in the life of a nuclear power plant] OR [have an expected frequency greater than five times in 10,000,000 years] that are capable of being implemented site-wide and must include the following:*
   1) *The capability to maintain or restore the fundamental safety functions identified pursuant to 53.2X.*
   2) *The acquisition and use of offsite assistance and resources to support the functions required by paragraph (b)(1) of this section indefinitely, or until sufficient site functional capabilities can be maintained without the need for the mitigation strategies*
   3) *Strategies and guidance to provide the capabilities in (b)(1) under the circumstances associated with loss of large areas of the plant impacted by the event, due to explosions or fire, to include the following areas:*
      i. *Firefighting;*
      ii. *Operations to mitigate fuel damage; and*
      iii. *Actions to minimize radiological release.}*

   OR

b) *{The cumulative plant risk to an average individual:*
   1) *for early fatalities within 1 mile of the site boundary does not exceed 5 in 10,000,000 years*
   2) *for latent cancer fatalities within 10 miles of the site boundary does not exceed 2 in 1,000,0000 years.}*

Anticipated Topics in Other Part 53 Requirements

1. **Related to "What" Must be Done to Demonstrate Safety Criteria are Met – Expected to have connection to 53.20 and 53.21**
   - Radiological hazards/source term
   - Licensing Basis Events (internal, external and man-made)
   - Safety functions, design features, barriers, human actions, programs, mitigation, and defense-in-depth
   - Quality assurance, reliability and qualification

2. **Other Related Requirements**
   - Radiation Protection (e.g., clarify that non-ALARA requirements in Part 20 apply)
   - Application types (e.g., COL, DC, ESP, CP, OL)
   - Application contents (e.g., define "reasonable assurance")
   - Backfit

From:	NICHOL, Marcus
To:	Tappert, John
Cc:	Nieh, Ho; Taylor, Robert; Shams, Mohamed; Beall, Bob; Reckley, William; Valliere, Nanette; RulemakingComments Resource
Subject:	[External_Sender] NEI Input on the NRC's Rulemaking on, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)
Date:	Wednesday, December 23, 2020 12:56:46 PM
Attachments:	12-23-2020_NRC_Industry Comments on Part 53 Rulemaking Plan.pdf

THE ATTACHMENT CONTAINS THE COMPLETE CONTENTS OF THE LETTER

December 23, 2020

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Director, Division of Rulemaking, Environmental, and Financial Support
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In our October 21st letter, we recommended a five-step process for the Part 53 rulemaking process, with the first step being to "Frame the Part 53 Rulemaking Effort" by November 30, 2020. Step 1 was further divided into three activities, and in our letter, we provided input on the first activity to "establish a vision and goals for the final rule and the process steps for the

rulemaking". The second and third activities were to "identify requirements and constraints (e.g., Atomic Energy Act) for final rule" and "establish the success criteria for the final rule (a.k.a., project requirements) and key decisions that must be addressed in the rulemaking".

In Attachment 1, we provide input on the success criteria for the Part 53 final rule (a.k.a. project requirements), based in part on a review of requirements from the Atomic Energy Act. The purpose of these success criteria is to define what functionality needs to be provided in the final Part 53 rule, and will be a guide for the Part 53 development, and future discussions to be held between the NRC staff and industry to ensure that the final rule meets the pre-defined success criteria. These success criteria define what Part 53 must accomplish (e.g., establish safety requirements), not how to do it (e.g., specifying the dose limits for members of the public) nor the process by which to develop the new rule. We note that the inclusion of some success criteria will depend on the final scope of the Part 53 rule, for example whether decommissioning will be included. These success criteria align with the direction in the Nuclear Energy Innovation and Modernization Act, and the vision and goals that we proposed in our October 21st letter. While these success criteria are intended to be exhaustive, there could be additional criteria identified over the course of the rulemaking.

We encourage the NRC to use the list of success criteria in Attachment 1 to plan topics for discussion at future NRC public meetings.

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