



**UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, DC 20555 - 0001**

August 2, 2022

The Honorable Christopher T. Hanson
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: FOURTH INTERIM LETTER ON 10 CFR PART 53 RULEMAKING LANGUAGE

Dear Chairman Hanson:

During the 697th meeting of the Advisory Committee on Reactor Safeguards (ACRS), July 6-7, 2022, we continued to discuss staff's efforts on developing rulemaking language for Title 10 of the *Code of Federal Regulations* (10 CFR) Part 53. As efforts to develop 10 CFR Part 53 have evolved, staff decided to propose two 10 CFR Part 53 options, Framework A and Framework B (with numerous subparts in each framework).

This is our fourth interim letter on 10 CFR Part 53. Our initial letter in November 2020 documented our thoughts on the staff's plan at the outset of the endeavor and the technical and policy issues involved; the second letter in May 2021 provided comments on the first draft of language, now designated as Framework A; and our third letter in February 2022 focused on Subpart F, "Requirements for Operations." In their response to our third letter, staff indicated that they accepted our recommendations, but needed more time to develop details of how best to address the comments regarding the proposed certified operator program and engineering expertise on-shift.

This letter focuses on draft language for Frameworks A and B. Our letter was informed by discussions during our Regulatory Rulemaking, Policies and Practices: Part 53 Subcommittee (formerly the Future Plant Designs Subcommittee) meetings on May 19, 2022, and June 23-24, 2022. During these meetings we had the benefit of discussions with representatives of the Nuclear Regulatory Commission (NRC) staff and stakeholders. We also benefited from the referenced documents.

CONCLUSIONS AND RECOMMENDATIONS

1. There are limitations of the existing quantitative health objectives (QHOs) to fully capture the value and risk of nuclear technologies and the large uncertainties associated with evaluating individual and societal risk. This could inhibit flexibility and

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opportunities for more innovative approaches as the regulator and applicants learn from new nuclear technologies and associated missions.

2. Critical safety functions are foundational to the licensing process. As such, the requirements for identifying critical safety functions should be common to both frameworks.
3. The staff should require, early in the preapplication process, each applicant to identify numeric safety dose criteria, the critical safety functions, the safety design criteria, and the underlying rationale for their selection and application in the design.
4. The staff needs to ensure that the fire protection requirements in both frameworks are fully technology-inclusive.
5. The current approach with self-contained requirements for each of the two frameworks is very long. Furthermore, the rule has a significant amount of implementation detail that could be better located in regulatory guidance. The optics of this approach run counter to a streamlined more efficient licensing process, which is an expectation for many stakeholders. As a result, the rule may be too cumbersome to implement and may not be used.
6. The proposed general licensed reactor operator description should provide for qualified operating personnel. However, the associated guidance for implementing 10 CFR Part 55 can be amended to accommodate the objectives of the proposed rule without the additional voluminous text.
7. The results of the probabilistic risk assessment (PRA) can be used to inform structures, systems and components (SSC) classification by aligning the risk assessment and deterministic safety analysis. This should result, in most cases, in just two tiers for classification of SSCs: Safety Related/Safety Significant and Not Safety Related/Low Safety Significant.
8. The simple novel analysis that provides the technical basis for the entry criteria to be able to use the Alternative Evaluation of Risk Insights (AERI) should be documented either in an appendix to the draft regulatory guide (DG)-1414 or in another appropriate document (e.g., NUREG).

OVERVIEW

10 CFR Parts 50 and Part 52 were largely developed for light water reactors (LWRs). Currently, non-LWRs must use either 10 CFR Part 50 or Part 52 and apply for exemptions from certain LWR-specific requirements.

10 CFR Part 53 will be a new licensing pathway for both LWRs and non-LWRs. Currently, there are two options or frameworks for licensing. Both frameworks are (a) technology-inclusive and performance-based, (b) intended to provide flexibility for a range of reactor technologies and missions, and (c) structured to reduce the need for exemptions to licensing requirements. A major difference is the balance between the use of PRA and traditional deterministic safety approaches in the two frameworks. Many subparts of each framework are purposely identical and largely repeated so that regulatory requirements are self-contained within each framework.

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BACKGROUND

The first framework (Framework A) uses a top-down approach to establish:

- numeric safety dose criteria,
- critical safety functions that a design uses to meet the criteria,
- functional safety design criteria that describe how each safety function is met, and
- licensing basis events (LBEs).

PRA is used as a centerpiece in evolving the design to meet licensing requirements; in making risk-informed judgements about various aspects of the design; and, along with engineering judgement, in assessing the adequacy of defense-in-depth (DiD). The enhanced use of PRA in this framework approach is consistent with recent Nuclear Energy Institute (NEI) guidance NEI 18-04 endorsed in Regulatory Guides 1.232 and 1.233.

The second framework (Framework B) uses a traditional approach to design and licensing where deterministic safety analyses are complemented by risk insights from either a PRA (in a supporting role) or the AERI if certain dose criteria are satisfied to demonstrate that the bounding accident from such a facility would be of very low consequence. Principal design criteria are established early in the design and licensing process, and subsequent design activities are performed to ensure relevant safety criteria are met. This approach, which aligns more with 10 CFR Parts 50 and 52, is consistent with international safety standards and approaches.

In addition, staff developed two pre-decisional draft regulatory guides. The first guide, DG-1413, "Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants," identifies licensing bases for each licensing framework and provides an integrated approach for:

- conducting a systematic and comprehensive search for initiating events,
- delineating a systematic and comprehensive set of event sequences and
- grouping the lists of initiating events and event sequences into licensing events.

DG-1413 recommends using at least one inductive method and one deductive method when searching for initiating events. It points the reader to helpful references but does not endorse or recommend any specific method. The DG is intended to apply to both LWRs and non-LWRs licensed under 10 CFR Parts 50, 52 or 53 (Frameworks A and B). The staff approach recommends starting with a clean sheet of paper to stimulate creative thinking. Also, for the first time, the staff identifies several alternative approaches to reduce the likelihood that any significant event will be missed during the search process. Use of multiple approaches is necessary to enhance completeness, especially for unique designs and missions. The second guide, DG-1414, "Alternative Evaluation for Risk Insights (AERI) Framework," applies to LWRs and non-LWRs licensed under 10 CFR Part 53, Framework B. Key components of the AERI approach are:

- identifying and characterizing the bounding event and outlining when multiple events may need to be considered as bounding events,
- determining a consequence estimate for the bounding event to confirm that the reactor design meets the AERI entry conditions,

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- establishing a demonstrably conservative risk estimate for the bounding event to demonstrate that the QHOs are met,
- searching for severe accident vulnerabilities for the entire set of licensing events,
- identifying risk insights for the entire set of licensing events, and
- assessing DiD adequacy for the entire set of licensing events.

DISCUSSION

The staff has done an excellent job of balancing the flexibility and predictability in the rule, as well as considering the various views of stakeholders and this committee. We offer several comments for consideration.

Safety Goals

Because of the limitations of the existing QHOs to fully capture the value and risk of nuclear technologies and the large uncertainties associated with evaluating individual and societal risk, the references to existing QHOs in 10 CFR Part 53 could be problematic, inhibiting flexibility and opportunities for more innovative approaches as the regulator and applicants learn from new nuclear technologies and associated missions. However, we support the use of the subsidiary objectives such as core damage frequency and large early release frequency whenever they are applicable and can be estimated with confidence. We look forward to discussing new metrics and safety goals in greater detail with the staff.

Safety Functions

The requirement for identifying critical safety functions should be common to both frameworks because both have the same goals. Critical safety functions are fundamental for:

- establishing the facility safety bases,
- promoting completeness in the processes used to identify initiating events that could challenge the safe operation of the reactor, and
- developing functional or principal design criteria.

To accommodate the range of anticipated designs, Framework A has adopted a flexible approach for identifying critical safety functions. The primary safety function is "limiting the release of radioactive materials," and applicants are allowed to identify supporting safety functions appropriate for their design, such as control of reactivity, heat generation, and chemical reactions. Using the same approach in Framework B would promote regulatory efficiency, clarity, and consistency. The text describing the Framework A approach should be moved to the common section of the rule, so it applies to both frameworks. In addition, the text regarding critical safety functions should be revised in DG-1413.

Design Criteria

Both frameworks require the development of safety design criteria (functional design criteria in Framework A versus principal design criteria in Framework B) to guide the design of safety-related SSCs. The staff should develop relevant guidance to direct each applicant to identify, early in the preapplication process, the numeric safety dose criteria, the critical safety

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functions, the associated safety design criteria, and the underlying rationale for their selection and use. This would facilitate a common understanding of these key items at the start of the licensing interaction and as the design evolves.

Organization of the Rule

The staff adopted Framework A requirements for Framework B when the requirements were independent of the analysis methodology. In addition, technology-inclusive requirements in 10 CFR Parts 50 and 52 were copied into Framework B or were used with conforming changes. The result is a largely self-contained set of requirements in both Framework A and Framework B. However, the entire rule is very long given the large volume of duplicative text in each option. Furthermore, the rule has a significant amount of implementation detail that could be better located in regulatory guidance. This enables such information to remain contemporary, making it adaptable as future circumstances warrant. Thus, the rule would be more concise and enduring. Examples of text in the rule include: fire protection (§§53.875); operator licensing (§§53.730); and maintenance, repair and inspection (§§53.715).

The optics of the current approach run counter to a streamlined, more efficient licensing process, which is the expectation for many stakeholders. There is a potential risk the rule may be cumbersome to implement and may not be useful for future applicants. The Preamble of the rule should state where the applicable parts for a specific type of license can be found.

Fire Protection

Some of the fire protection requirements assume the use of water. However, in some non-LWRs (e.g., sodium fast reactor), water could be detrimental. The wording should be revisited to allow for other fire extinguishing agents and preclude the need for an exemption.

SSC Classification/Special Treatment

If a new design was developed using a PRA, the optional four-tier structure for SSC classification in Framework B, which parallels the approach in 10 CFR 50.69, may be overly complex. Using the PRA to select LBEs and to inform and align what is important to risk assessment and to deterministic safety analysis should, in most applications, result in just two categories: Safety Related/Safety Significant and Non-Safety Related/Low Safety Significant.

The two remaining categories from 10 CFR 50.69, Safety Related/Low Safety Significant and Non-Safety-Related/Safety Significant, would not be expected to occur if the PRA is integrated into the design process. However, in some instances, there might be some SSCs in these two categories. If this occurs, SSCs that are of low safety significance should be considered for exclusion from safety-related quality assurance requirements. Non-Safety-Related/Safety Significant SSCs should be considered for special treatment.

10 CFR Part 53, Subpart F, "Requirements for Operations"

The staff responded to our comments concerning staffing in Subpart F of Framework A. Regarding the engineering expertise available to the on-shift operators during transients and other operational challenges, the staff proposed that expertise follow traditional qualifications for the level of knowledge, abilities, and expertise of the person fulfilling the role. However, the rule enables flexibility to implicitly permit a range of options for delivering the expertise from including an on-shift Shift Technical Advisor to maintaining capabilities for off-site engineering

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support. Although the details remain to be worked out, the concept should provide comparable expertise to on-shift personnel if there is an equivalency in the ability to provide access to and from the on-shift operators, technological support in the form of data integrity, and reliability of communication. The rationale for the applicant's proposed approach would be subject to staff approval.

The replacement language for the certified operator program in the earlier draft addresses a new operator qualification regime, termed a generally licensed reactor operator (GLRO), for a new class of reactors. The facility would be required to license operators under a general license for the facility rather than a specific, NRC-issued license to each individual reactor operator or senior reactor operator. For the operator to be licensed under a general license, the facility must be able to achieve safety functions without the need for human action, including consideration of DiD. The program for training, examination, requalification, and proficiency is approved during the review phase of a license application and is essentially equivalent to that used for traditionally licensed operators. The rule contains some ambiguity when DiD and protection against human errors are considered. An important aspect of DiD depends on operator response, especially when one considers beyond design basis events. The operator also may act contrary to the technology-designed response, either in error or through a well-meaning, yet errant action. The staff needs to carefully consider how the criteria are specified and how they can be evaluated to assure the desired impact on the operator licensing process.

Although the proposed GLRO description should assure qualified personnel, the present operator licensing process using 10 CFR Part 55 and associated NUREGs has proven to reliably provide highly consistent and qualified licensed operators. Detailed guidance exists for power reactors (NUREG-1021), research and test reactors (NUREG-1478), and knowledge and abilities catalogues for pressurized water reactors (PWRs) (NUREG-1122), boiling water reactors (BWRs) (NUREG-1123), AP1000 (NUREG-2103) and advanced BWRs (NUREG-2104). New or revised NUREGs applicable to new technologies, such as molten salt reactors and micro reactors, could be established. This scheme is a flexible approach that can tailor the NUREGs to the specific technology without a rule change to 10 CFR Part 55. 10 CFR Part 55 then continues to be the centralized regulation for operator qualifications.

Staff indicated they are preparing guidance documents that will provide the details of the required staffing plans and other portions of 10 CFR Part 53, Subpart F. We appreciate the staff's approach and discussions at our subcommittee meeting and look forward to reviewing this guidance. In addition, the new Subpart F requirements on the different types of operators should also be reflected in Subpart P of Framework B.

DG-1413 Identification of Licensing Events

The use of DG-1413 for any licensing option (10 CFR Part 50, 52 or 53) will help provide completeness and consistency in identification of licensing events for LWRs and non-LWRs. The tables in the DG are quite helpful in understanding how the licensing pathway and use of risk insights influence the approach to licensing event identification. The flowchart figure (DG-1413, Figure 1) depicts the depth and breadth of the overall process quite well. The need to use both inductive and deductive methods is important; the description of the historical

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strengths of each of the methods (FMEA, HAZOP, MLD, etc.)¹, as applied in the nuclear, chemical, and aerospace industries, provides some assurance that they can be used effectively for non-LWR technologies. The steps necessary to assure completeness in the flowchart are notable given the concern about completeness for technologies with little or no operating experience. Finally, the references show that such an approach is already being applied to some non-LWR technologies. As noted above, the discussion about critical safety functions in Section C.2.5 in the DG should be revised.

DG-1414 Alternative Evaluation for Risk Insights

DG-1414 outlines a novel approach for evaluating risk insights in a design where a complete PRA is not performed and can only be used for designs that pose a very low risk of radioactive release from the most severe potential accident. It retains many of the key ideas that exist in all the licensing options including identification of a range of accidents (from which to select the bounding event(s)), searching for severe accident vulnerabilities, identifying risk insights, and assessing defense in depth. The entry criteria to use this alternative approach are formulated in terms of dose at 100 meters from the facility and are consistent with the U.S. Environmental Protection Agency Protective Action Guidelines. Meeting the AERI entry dose criteria implies that the facility meets the NRC safety goals, but dose calculations would still be required to demonstrate compliance.

The staff presented a simple analysis that provides the technical basis for the entry criteria to be able to use AERI. The corresponding MACCS² calculations using sample source terms to support the technical bases for the AERI entry criteria should continue. The completed technical bases should be documented either in an appendix to DG-1414 or in another appropriate document (e.g., NUREG).

SUMMARY

10 CFR Part 53 is a new licensing pathway for both LWRs and non-LWRs. As currently configured, there are two options or frameworks for licensing. Both frameworks are technology-inclusive and performance-based, are intended to provide flexibility for a range of advanced reactor technologies and missions, and should reduce the need for exemptions to licensing requirements. A major difference is the balance between the use of PRA and traditional deterministic safety approaches in the two frameworks. DGs-1413 and 1414 provide valuable additional guidance to help amplify on key aspects of this new rulemaking. Our detailed comments on these documents are in the body of this letter.

No response to this letter is necessary at this time. Instead, we look forward to continuing discussions on these matters when we review the entire proposed rule language in the Fall of 2022.

¹ FMEA = Failure Mode and Effect Analysis, HAZOP = Hazard and Operability Analysis, MLD = Master Logic Diagram

² MACCS = MELCOR Accident Consequence Code System

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Added comments by ACRS Members Bier, Brown and March-Leuba and by ACRS Member Dimitrijevic are attached to this Letter.

Sincerely,

A handwritten signature in black ink, appearing to read "Joy L. Rempe".

Signed by Rempe, Joy
on 08/02/22

Joy L. Rempe
Chairman

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**Added Comments by ACRS Members Vicki Bier, Charles Brown,
and Jose March-Leuba**

We are concerned about new advanced reactors using remote or autonomous operation because of the potential safety significance of maintaining the integrity of the bidirectional communication link; we cannot find a single example where the safety of a reactor is not reduced when operated remotely. Even though the staff is aware that some concepts currently in the design stage may request remote or autonomous operation, the draft of 10 CFR Part 53 is silent on the issue, suggesting that, at least implicitly, these designs are acceptable. It should not.

Control of access is a key safety issue that has been the subject of multiple Committee letters. Just a few years ago, it was being addressed exclusively with physical access measures for both insider (internal employee access) and outsider (external personnel access) threats. The use of computer-based systems with bidirectional communication capability introduced the need to control electronic access from external plant sources during the safety-system design phase, since anti-virus software cannot be incorporated in safety-system software. As such, today, when control of access is not enforced, cyber threats become a significant risk because the sophistication and quantity of attacks have risen exponentially. For example, NIST maintains a database of identified software vulnerabilities (<https://nvd.nist.gov/>); it grows at a rate of ~200 new vulnerabilities per day. The rate of identified VPN-specific vulnerabilities grows at approximately one every three days. VPN technology is the foundation for secure communications; with this number of identified vulnerabilities, VPNs cannot possibly achieve the extreme reliability levels required in the nuclear industry. In addition, maintenance activities and software updates, if performed remotely, create serious failure scenarios that must be considered. There is no indication that these trends will change in the future, and the problem is compounded by the fact that, if implemented, the 10 CFR Part 53 rule would license new reactors for 60 to 80 years. Implementing software-controlled remote operation is akin to protecting the control room with a combination lock but writing the combination on a Post-it Note.

The staff understands the complexities and safety implications of remote operation and has prepared an unofficial white paper entitled "Ground Rules for Regulatory Feasibility of Remote Operations of Nuclear Power Plants" (ML21291A024), where they provide eleven ground rules that would apply to licensing such facilities. This white paper identifies items that must be addressed but additional regulatory work is required to formalize it, especially if the 10 CFR Part 53 rule remains silent on the issue. We also note that autonomous operation is not addressed in the ground-rules paper. It would be difficult to imagine an autonomous reactor without remote capabilities; therefore, all these ground rules should apply, and they would need to be expanded with requirements specific to autonomous operation. In our opinion, however, even if all the ground rules were implemented, significant vulnerabilities would remain in preventing electronic access.

In summary, we cannot find a single example where the safety of a reactor is not reduced when operated remotely because communications are not likely to have nuclear-grade reliability in the current cybersecurity environment. In our opinion, it would be prudent for the regulation to be written conservatively by explicitly stating in the Preamble that "Nothing in this rule presumes approval for either remote or autonomous operation." If an applicant can develop a good technical basis, the exemption process provides an implementation route.

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Added Comments by ACRS Member Vesna Dimitrijevic

SSC Classification/Special Treatment: In my opinion, the proposed two-tier SSCs classification and the related discussions in the letter, should not be considered applicable to 10 CFR Part 53 Framework B, but to Framework A instead. In the 10 CFR Part 53 structure, Framework B represents a traditional approach to design and licensing where deterministic safety analyses are complemented by risk insights. A four-tier classification, as defined in the 10 CFR 50.69, is a perfect example of such an approach. A change in the treatment requirements for two of these four categories, as anticipated in 10 CFR 50.69, would lead to results similar to the two-tier classification proposed in the letter, without requiring a development of a new safety classification.

Safety Goals: While I agree with the conclusions and recommendations of my colleagues in the letter, as related to the safety goals, I believe that the committee should have taken a step further and propose replacing the QHOs in 10 CFR Part 53 with the Qualitative Safety Goals. In the history of development of the safety goals, it was recognized that existing QHOs do not perfectly represent the intent of the original qualitative safety goals. Stepping back to a Level 1 hierarchy of safety goals (qualitative goals), could, through anticipated future interactions between applicants and the staff, lead to an emergence of more meaningful quantitative goals. Some advantages of this approach are summarized below:

- i. It could give an applicant an option to define plant-specific and site-specific acceptance criteria, depending on the size and nature of the facility, the effectiveness of evacuation plans, the remoteness of the site, etc.
- ii. It could consider the societal and economic risk, based on new experience with nuclear accidents at Chernobyl and Fukushima.
- iii. The new goals would not necessarily be associated with cancer and prompt fatalities, thus minimizing a reliance on dose-response assumptions.

AERI Entry Conditions: I disagree with my colleagues' conclusions that the analysis that provides the technical basis for the entry criteria to AERI (versus developing a PRA) in Framework B should be documented. In my opinion this criterion should be reconsidered. The supporting calculation is based on numerous assumptions, most of them minor or conservative, but some of them more important and controversial (e.g., estimating the number of cancer deaths per person-rem, estimating dose based on a 50-year period). A simpler criterion, such as twice or three times the background level of radiation, would lead to similar conclusions. Such simplicity would result in an understandable basis for the selection, which would not be dependent on the QHOs, and whose validity and conservatism could be evaluated.

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August 2, 2022

SUBJECT: FOURTH INTERIM LETTER ON 10 CFR PART 53 RULEMAKING LANGUAGE

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