



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 16, 2022

Janet Schlueter
Nuclear Energy Institute
1201 F Street, NW, Suite 1100
Washington, DC 20004

SUBJECT: RESPONSE TO NUCLEAR ENERGY INSTITUTE LETTERS REGARDING SAFETY
MARGIN FOR FUEL FACILITIES

Dear Janet Schlueter:

The Nuclear Energy Institute (NEI) submitted two letters to the U.S. Nuclear Regulatory Commission (NRC) dated July 24, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20211L714), and April 20, 2021 (ML21236A302). These letters outlined NEI's position regarding safety margin for fuel facilities and suggested edits to the April 2021 revision of Inspection Manual Chapter (IMC) 0616, "Fuel Cycle Safety and Safeguards Inspection Reports" (ML21082A281), respectively.

In a December 29, 2021, letter (ML21336A763), the NRC staff responded to some of NEI's concerns regarding the process for issuance and revision of IMCs (ML21336A763). In that letter, the NRC staff further stated that it would conduct a backfit assessment of certain changes to IMC 0616. This letter summarizes the results of our backfit assessment and responds to your concerns regarding validity and significance of certain management-measure violations.

If you have further questions, please contact Aida Rivera-Varona of my staff. She can be reached at (301) 301-415-4001 or aida.rivera-varona@nrc.gov.

Sincerely,

A handwritten signature in cursive script that reads "Shana R. Helton".

Signed by Helton, Shana
on 08/16/22

Shana R. Helton, Division Director
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Enclosure:
NRC Responses to Concerns in NEI
Letters Dated July 24, 2020
and April 20, 2021

cc: John Lubinski, NMSS
Robert Lewis, NMSS

SUBJECT: FOLLOW-UP RESPONSE TO NUCLEAR ENERGY INSTITUTE LETTERS THAT PROVIDED THE POSITION REGARDING SAFETY MARGIN AND SUGGESTED EDITS TO INSPECTION MANUAL CHAPTER 0616 (APRIL 2021 VERSION)

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ADAMS Accession Nos.: ML22115A256 (pkg); ML22115A257 (letter & enclosure)

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NUCLEAR REGULATORY COMMISSION STAFF RESPONSES TO NEI LETTERS DATED JULY 24, 2020, AND APRIL 20, 2021

Background

In April 2019, the U.S. Nuclear Regulatory Commission (NRC) staff established a working group (WG) to conduct a holistic assessment of the fuel cycle inspection program to improve its effectiveness and efficiency, as detailed in “Approval of the Working Group Charter for Building a Smarter Fuel Cycle Inspection Program” (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19074A159). The WG solicited input from internal and external stakeholders and held nine public engagements in 2019 and 2020 to obtain feedback on potential improvements to the program. On March 18, 2020, the WG issued its final report and proposed recommendations, “Proposed Recommendations for Building a Smarter Fuel Cycle Inspection Program” (ML20073G659), that were approved by the Director of the Division of Fuel Management in “Final Decision on Working Group Recommendations for Building a Smarter Fuel Cycle Inspection Program” (ML20077L247) and subsequently implemented. During the implementation of the recommendations in 2020 and 2021, the NRC staff continued to keep the public informed of the progress made in implementing the program improvements.

During that time, the Nuclear Energy Institute (NEI) submitted two letters to the NRC staff primarily related to the validity or significance of certain management-measure violations at fuel cycle facilities, the NRC process for issuing Inspection Manual Chapter (IMC) revisions, and industry-suggested edits to IMC 0616 “Fuel Cycle Safety and Safeguards Inspection Reports” (ML21082A281). The staff discussed these letters during public discussions in October 2020, “Summary of October 28-29, 2020, Meeting with the Nuclear Energy Institute, Fuel Cycle Industry Representatives, and Stakeholders to Discuss Fuel Cycle Regulatory Activities and Cumulative Effects of Regulation” (ML20338A211); March 2021, “Summary of March 24-25, 2021, Fuel Facility Stakeholder Public Meeting” (ML21120A058); and June 2021, “Summary of June 15, 2021, Discussion with Fuel Facilities on Safety Margin, Smarter Licensing, and Low Safety Significance Issue Resolution” (ML21200A120).

By letter dated December 29, 2021 (ML21336A763), the NRC staff responded to some of NEI’s concerns regarding the process for issuance and revision of Inspection Manual Chapters (IMCs). In that letter the NRC staff stated that it would perform a backfit assessment of specific changes to IMC 0616, “Fuel Cycle Safety and Safeguards Inspection Reports” (ML21082A281). The NRC staff further stated it would provide a response regarding the validity and significance of certain management measure violations.

This document serves as the NRC’s response on these remaining concerns. In particular, this document summarizes the results of the staff’s backfit assessment of the changes to IMC 0616 and responds to NEI’s concern regarding the oversight process in circumstances where safety margins are reduced but performance requirements are met. The NEI positions are summarized below, along with NRC staff responses.

NEI Position 1: In NEI’s July 24, 2020, letter, titled “Industry Position Regarding Safety Margin: Dispositioning Degraded or Failed Management Measures Above and Beyond Regulatory Requirements, and Meeting Performance Criteria; Follow-Up to May 6, 2020, letter on Smarter Program Inspection Priorities” (ML20211L714), NEI expressed concerns with violations issued for failed or degraded management measures that do not result in failure to meet the performance requirements of Title 10 of the *Code of Federal Regulations* (10 CFR),

Enclosure

Section 70.61. NEI also expressed concerns with certain changes to IMC 0616 related to the evaluation of the severity of those violations and questioned the backfit implications of these changes.

As explained in the section titled “Industry Concerns with New and Problematic IMC 0616 Risk-based Noncompliances and ‘Example j’ in August 2017 revision” of NEI’s July 24, 2020, letter, NEI stated that: “Since the August 2017 revision of IMC 0616, there have been a number of Severity Level IV violations issued to fuel cycle licensees citing ‘Example j’ of IMC 0616 as the basis for these violations.... Example j was added in the August 2017 revision of IMC 0616, and its addition appears to indicate a significant change in NRC direction.... [T]he staff appears to be using the IMC to impose a new or different interpretation of the requirements in Subpart H to Part 70.... Industry believes that regulating in this fashion is inconsistent with both the backfitting requirements of 10 CFR 70.76 and the agency’s Principles of Good Regulation. It is [NEI’s] firm position that Example j and the Appendix B text regarding ‘Screening Process’ in the 2017 revision of IMC 0616 regarding risk-based noncompliances should be removed from the IMC.”

NRC Staff Response 1: The NRC backfit assessment included consideration of the 2017 addition of Example j and of the description of the practice used for risk-based noncompliance to IMC 0616. For the reasons stated below, the NRC staff determined these changes do not constitute a backfit.

The practice described for risk-based noncompliance described in the 2017 revision of IMC 0616, Appendix B, in the section titled “Screening Process,” is the NRC staff’s practice of using a systematic approach that considers risk to assess the significance of certain noncompliances (“risk-based noncompliances” is the nomenclature used in IMC 0616). Similarly, the NRC staff incorporated Example 1.j into the 2017 Revision of IMC 0616 Appendix B to document the NRC staff’s existing practice to using risk when assessing severity level for violations of 10 CFR 70.62(d). Prior to the incorporation of Example 1.j, the NRC staff dispositioned several management measures noncompliances as minor or SL IV violations consistent with the guidance NRC staff would eventually add in Example 1.j.¹ Therefore, the inclusion of Example 1.j did not represent a new position, but rather documented the standing NRC staff practice. Thus, while specific citations to Example 1.j did not exist prior to its inclusion in IMC 0616, NRC staff has historically issued minor and SL IV violations for failures to implement adequate management measures. Additionally, because Example 1.j documents the staff’s existing practice, adding Example 1.j to IMC 0616 Appendix B fosters both openness and clarity. Its addition to IMC 0616 Appendix B is, therefore, consistent with the NRC’s Principles of Good Regulation.

Further, to the extent that Example 1.j or the practice described for risk-based noncompliances altered the assessment of severity level for a given violation, Example 1.j and the practice described for risk-based noncompliance do not fall within the scope of backfitting in 10 CFR 70.76. This is because Example 1.j and the practice described for risk-based noncompliance are related to severity level, which is only relevant once the NRC staff has

¹ “Global Nuclear Fuel-Americas, L.L.C.-U.S. Nuclear Regulatory Commission Integrated Inspection Report 70-1113/2016-004 and Notice of Violation” (ML16302A139); “Global Nuclear Fuel – Americas, LLC – NRC Integrated Inspection Report 07001113/2016003, April 1, 2016, through June 30, 2016” (ML16210A299); “BWXT Nuclear Operations Group – Nuclear Regulatory Commission Integrated Inspection Report 70-27/2015-005 and Notice of Violation” (ML16028A298); and “Babcock and Wilcox NRC Integrated Inspection Report 70-27/2012-005 October 1 – December 31, 2012” (ML13030A007).

already determined that there is a noncompliance. While Example 1.j and the practice described for risk-based noncompliance use the possibility of less severe violations to incentivize licensees to take certain actions, they do not require licensees to take said actions.

Therefore, the addition of Example 1.j and other language related to risk-based noncompliances do not represent a new or different regulatory NRC staff position interpreting the requirements of 10 CFR Part 70, Subpart H. These changes thus do not meet the 10 CFR 70.76(a)(1) definition of backfitting.

NEI Position 2: In the section “Safety Margin Credit and Violations When in Compliance” of its July 24, 2020, letter, NEI states that “Industry raised the topic of credit for ‘safety margin’ that has been long since established by licensees most recently in the context of the NRC ‘Smarter Programs’ fuel cycle inspection initiative.... [T]he industry recommend[ed]... that a robust safety margin that goes beyond regulatory requirements combined with a strong safety and security performance record... be the basis for reduced inspection frequency/hours of certain licensed program areas. As part of the discussion regarding this recommendation, industry recalled recent enforcement cases where licensees received Severity Level IV violations due to reduced safety margin, despite the fact that applicable performance requirements were met.” NEI also asserted that, “[t]he basis for these Severity Level IV violations was, and is still, not transparent.” Specifically, NEI argued that “it is not clear that a failed or degraded management measure that *does not* result in failure to meet the performance requirements of 10 CFR 70.61 is a violation at all” (emphasis in the original). NEI also stated that, “[p]utting [the existence of a violation] aside, the severity of these violations was evaluated by the NRC staff using the 2017 version of [Inspection Manual Chapter (IMC)] 0616, [Appendix B,] with the new ‘Example j’ and ‘risk-based noncompliance’ concept found in the Screening Process.” NEI stated that “industry does not agree with the discussion of ‘risk-based noncompliance’ contained in Appendix B to IMC 0616, or ‘Example [1.]’” and that “such violations should be considered ‘minor’ and (at most) result in a non-cited violation.” Finally, NEI argued that “issuing a Severity Level IV violation for reduced safety margin when performance requirements are met creates a strong disincentive for licensees to maintain additional safety margin.”

As noted in NEI’s April 20, 2021, letter “Industry-Suggested Edits to IMC 0616 – April 2021 Version” (ML21236A302), at a March 2021 public meeting, both the NRC and “industry... acknowledged that any two persons could interpret—and have interpreted—the plain English language of existing Part 70 requirements and related enforcement guidance (including [IMC] 0616) differently.” In this letter, NEI also reiterated its disagreement with the NRC’s position.

NRC Staff Response 2: The NRC staff appreciates the NEI’s participation in the Smarter Inspection Program. The practice described for credit for safety margin expanded the discussion of options considered while developing the Smarter Inspection Program and has helped bring to light NEI’s concerns over violations involving failed management measures.

Regarding inspections, the NRC staff evaluates the licensee’s implementation of its integrated safety analysis (ISA) and associated safety program, including management measures, to determine whether reasonable assurance of adequate protection exists and whether the licensee is in compliance with 10 CFR Part 70, Subpart H. As noted in NUREG-1513, “Integrated Safety Analysis Guidance Document,” Section 2.2, “[o]ne of the results of an ISA is the identification of controls, both engineered and administrative, that are needed to limit or prevent accidents or mitigate their effects. The identification of controls, however, is not sufficient to guarantee an adequate level of safety. In addition, an effective safety program is needed to ensure that, when called on, these controls are in place and are operating properly.”

The ISA, together with adequate management control systems, provides the NRC reasonable assurance of adequate protection of public health and safety.

Licenses determine what controls or control systems are necessary to meet the performance requirements of 10 CFR 70.61. Under 10 CFR 70.61(e), once the licensee designates a control or control system as an item relied on for safety (IROFS), it falls within the envelope of the safety program required by 10 CFR 70.62. Under 10 CFR 70.62(d), licensees must establish management measures as part of the safety program to ensure that items designated as IROFS are designed, implemented, and maintained, as necessary, to ensure they are available and reliable to perform their function when needed, to comply with the performance requirements of 10 CFR 70.61.

As stated in 10 CFR 70.61(e), “each item relied on for safety will be available and reliable to perform its intended function when needed and in the context of the performance requirements of this section.” Adherence to management measures is a key contributor to assuring an effective safety program is in place. Management measures ensure that the items designated as IROFS are designed, implemented, and maintained, as necessary, to ensure they are available and reliable to perform their function when needed to prevent accidents or mitigate the consequences of accidents to an acceptable level. Non-adherence to management measures (or the failure to establish management measures), even when the performance requirements of 10 CFR 70.61 are met, could negatively affect the reliability of the underlying IROFS, which the licensee is crediting in its ISA to ensure that the performance requirements are met. Consequently, a licensee would fail to meet 10 CFR 70.62(d) when management measures are inadequately designed, implemented, or maintained, such that they will not ensure that each IROFS is available and reliable to perform its function when needed to comply with the 10 CFR 70.61 performance requirements, even when the requirements of 10 CFR 70.61(b), (c), and (d) are satisfied.

IMC 0616, Appendix B provides a screening process for inspectors to determine whether a violation is minor or more than minor. The NRC staff intended for the 2017 revisions to Appendix B to standardize this evaluation and improve consistency in the NRC staff’s decision-making. These revisions provided additional clarity, transparency, and consistency in the disposition of violations related to the requirements of 10 CFR 70.61(e) and 10 CFR 70.62(d) that occur when the performance requirements of 10 CFR 70.61 (b), (c), and (d) are still met. Per the NRC’s enforcement policy, “NRC Enforcement Policy Revision 2020” (ML19352E921), SL IV violations include a failure to meet the requirements of 10 CFR 70.61, “Performance Requirements” (including 10 CFR 70.61(e)), that does not result in SL I, II, or III.

IMC 0616 Appendix B complements the enforcement policy by providing a framework for assessing the impacts to safety when determining the significance of certain violations (“risk-based noncompliances” is the nomenclature used in IMC 0616). This framework reflects the fact that noncompliances involving a substantial change in the overall risk of the applicable accident sequence(s) are generally more significant than those that result in a negligible change in risk.

A failure to meet the requirements of 10 CFR 70.61(e) (failure of an IROFS) as a result of the failure to meet 10 CFR 70.62(d) (management measures) is often dispositioned as a SL IV or minor violation even if the requirements of 10 CFR 70.61 (b), (c), and (d) are met. For example, if the management measure for an IROFS is inadequate to ensure the IROFS is available and reliable, to comply with the 10 CFR 70.61 performance requirements, but the noncompliance does not result in an actual safety-significant outcome, the violation would likely

be SL IV or minor. However, there may be instances in which a failed management measure that does not result in the failure of an IROFS could result in a more than minor violation, for example, if it is deemed to be a programmatic deficiency.

Finally, NEI asserted “that issuing a Severity Level IV violation for reduced safety margin when performance requirements are met creates a strong disincentive for licensees to maintain additional safety margin.” The NRC staff disagrees with this position. While licensees are not required to maintain additional safety margin beyond the minimum required by the regulations, under Appendix B, doing so can result in less severe violations. Thus, Appendix B does incentivize licensees to maintain safety margin beyond the minimum required by the regulations.

NEI Position 3: In laying out its position in Attachment 2 to its July 24, 2020 letter, NEI asserted that it “believe[s] that the NRC should examine the backfitting implications of what appears to be a new or different interpretation of the requirements of 10 CFR 70, Subpart H, i.e., that a failed or degraded management measure that *does not* result in failure to meet the performance requirements of 10 CFR 70.61 constitutes a violation of Subpart H.... [NEI] believe[s] this position is inconsistent with ‘Example e’... of IMC 0616, which predated the addition of the ‘risk-based noncompliance’ concept... in August 2017. In the event that the NRC determines that the position taken in the 2017 revision to IMC 0616 does not constitute a backfit, or can be appropriately justified pursuant to 10 CFR 70.76, it is the position of NEI’s Fuel Cycle Facility members (including Part 40 and Part 70 licensees) that, in scenarios where the NRC determines that a failed or degraded management measure which *does not* result in failure to meet the performance requirements of 10 CFR 70.61 constitutes a violation of Subpart H, such violations should be considered minor” (emphasis in the original).

NEI partially reiterated this position in the April 20, 2021, letter, “Industry- Suggested Edits to IMC 0616 – April 2021 Version” (ML21236A302).

NRC Staff Response 3: The NRC backfit assessment included consideration of revisions to Example 7.e made in 2016, 2017, and 2021. For the reasons stated below, the NRC staff determined these changes do not constitute a backfit.

The NRC has maintained a consistent interpretation regarding violations for failure of management measures, in that if a licensee fails to adequately design, implement, or maintain management measures, then the licensee is not in compliance with 10 CFR 70.62(d), which requires licensees to establish management measures to ensure compliance with the performance requirements of 10 CFR 70.61. Management measures ensure that each IROFS is designed, implemented, and maintained, as necessary, to ensure it is available and reliable to perform its function when needed, to comply with the performance requirements of 10 CFR 70.61. Therefore, when a licensee fails to design, implement, or maintain management measures, even if the requirements of 10 CFR 70.61(b), (c), and (d) are satisfied through other means, including both IROFS from other accident sequences and items that licensees have not designated as IROFS, the licensee is not in compliance with 10 CFR 70.62(d).

As noted in the Attachment 1 to IMC 0616, which documents changes to IMC 0616, the relevant language was removed in 2016 because it was “inaccurate.” To the best of the NRC staff’s knowledge, this language was re-introduced inadvertently during the 2017 revisions and was never relied on as the basis for any enforcement decision. The NRC staff corrected this mistake in 2021 and removed the language again as an administrative correction.

The NRC staff conducted a backfit assessment for three changes related to Example 7.e. Those changes are:

- 2016 revision: Deletion of “; or the licensee could credit IROFS from other accident sequences to ensure the accident remains highly unlikely”;
- 2017 revision: Re-addition of that same language; and
- 2021 revision: Re-removal of that language.

The NRC staff determined that none of these changes met the definition of backfitting in 10 CFR 70.76(a)(1).

The NRC staff concluded that the 2016 revision did not meet the 10 CFR 70.76(a)(1) definition of backfitting because the NRC staff did not impose its interpretation on licensees merely by revising Example 7.e. Although the NRC staff concludes that backfitting is not present here, the NRC staff recognizes that this change could lead to the imposition of a backfit in certain circumstances, such as through issuance of a violation to a licensee. The NRC staff’s backfit analysis concluded that, even if those circumstances existed, this change to the IMC would be excepted from the backfit analysis requirements in 10 CFR 70.76(a)(2) and (a)(3) because, in accordance with 10 CFR 70.76(a)(4)(iii), the “regulatory action [would be] necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security.”

The NRC staff reached this conclusion because adherence to management measures is a key contributor to assuring an effective safety program is in place. The performance of an IROFS, by itself, will not provide adequate protection. Instead, an effective management system is needed to ensure that items designated as IROFS are available and reliable to perform their function when needed. Management measures provide that management system. Non-adherence to management measures (or the failure to establish management measures), even when the performance requirements of 10 CFR 70.61 are met, could negatively affect the reliability of the underlying IROFS that the licensee is crediting in its ISA to ensure that the performance requirements are met. This is true, even when the licensee would continue to meet the 10 CFR 70.61 performance requirements without the underlying IROFS. This is because absent appropriate management measures, there is not assurance the items designated as IROFS will perform their intended functions and there is, therefore, increased potential for accidents.

Consequently, both management measures and items designated as IROFS play an important role in providing reasonable assurance of adequate protection. Therefore, in accordance 10 CFR 70.76(a)(4)(iii), the NRC staff concludes that removing the relevant language in 2016 was “necessary to ensure that... facility[ies] provide adequate protection to the health and safety of the public and [are] in accord with the common defense and security.” Accordingly, the NRC staff concludes that any backfits resulting from the removal of this language would be necessary to ensure adequate protection and, pursuant to 10 CFR 70.76(a)(4)(iii), the requirements in 10 CFR 70.76(a)(2) and (a)(3) are inapplicable and no backfit analysis is required.

Further, neither the 2017 revision nor the 2021 revision would have “result[ed]” in “the modification of, or addition to, systems, structures, or components of a facility; or to the procedures or organization required to operate a facility.” Specifically, with regard to the 2017 revision, because of the nature of the change— i.e., re-addition of language—management measures sufficient to comply with the regulations under the 2016 version of Example 7.e would also have been sufficient to comply with the regulations under the 2017 version of Example 7.e.

Therefore, no modification would have been required for licensees to meet the relevant requirements, and, therefore, this change does not constitute backfitting under the definition in 10 CFR 70.76(a)(1).

With regard to the 2021 revision, as noted above, this language was previously removed because it was “inaccurate.” To the best of the NRC staff’s knowledge, this language was re-introduced inadvertently during the 2017 revisions and was never relied on as the basis for any enforcement decision. Thus, Example 7.e, as written post-2017 revision, did not accurately capture NRC staff’s interpretation of the relevant regulations.

Therefore, the NRC staff views the 2021 revision as an administrative correction designed to align Example 7.e with how NRC staff has interpreted the relevant regulations since, at least, 2016. Because NRC staff’s interpretation of the regulations did not change when it mistakenly re-added in 2017 the language it had deleted in 2016, licensees would not have been required modifications in order to avoid receiving a violation under NRC staff’s regulatory interpretation. Therefore, this change also does not meet the 10 CFR 70.76(a)(1) definition of backfitting.

NEI Position 4: The April 20, 2021, letter (ML21236A302) section “Overview of Industry Suggested Edits” states “Attachment 1 contains a markup of IMC 0616 (April 2021 version). Attachment 2 contains a ‘change table’ to provide the specific reference, suggested edits and bases. At the May 17, 2021, Fuel Facility Stakeholders Meeting NEI asked when the NRC staff would respond to its suggested edits.

NRC Staff Response 4: The NRC staff has initiated updates to IMC 0616. Several of the editorial edits suggested in the NEI April 20, 2021, letter are being incorporated into the updated IMC 0616 to provide additional clarity to the guidance. Some of the edits suggested to the language regarding management measures and risk screening do not align with the NRC staff position reiterated in earlier sections of this letter and, therefore, will not be included in the upcoming revision to IMC 0616. The NRC staff is exploring whether additional clarifications are needed to ensure the guidance is clear and transparent.

Response to NEI Letter Regarding Industry Position on Safety Margin DATE August 16, 2022

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