



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

December 29, 2021

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

SUBJECT: RESPONSE TO NUCLEAR ENERGY INSTITUTE LETTERS DATED  
JULY 24, 2020, AND APRIL 20, 2021, THAT PROVIDED THE INDUSTRY  
POSITION REGARDING SAFETY MARGIN AND INDUSTRY-SUGGESTED  
EDITS TO INSPECTION MANUAL CHAPTER 0616 (APRIL 2021 VERSION)

Dear Ms. Schlueter:

I am responding to your letters, dated July 24, 2020 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML20211L714), and April 20, 2021 (ADAMS Accession No. ML21236A302), providing the industry position regarding safety margin and industry-suggested edits to the April 2021 revision of Inspection Manual Chapter 0616, "Fuel Cycle Safety and Safeguards Inspection Reports" (ADAMS Accession No. ML21082A281), respectively.

Responses to specific concerns, detailed in your letters, are enclosed.

If you have further questions, please contact Hipolito Gonzalez of my staff. He can be reached at (301) 415-5637 or [Hipolito.Gonzalez@nrc.gov](mailto:Hipolito.Gonzalez@nrc.gov).

Sincerely,

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

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

cc: J. Lubinski, NMSS  
R. Lewis, NMSS

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**ADAMS Accession Number: ML21336A763****\*via e-mail**

OFFICE	NMSS/DFM	NMSS/DFM	RII/DFFI	RII/DFFI
NAME	APearson	HGonzalez	EMichel*	LSuggs
DATE	11/08/2021	11/30/2021	11/23/2021	12/04/2021
OFFICE	RII/DFFI	OGC	NMSS/DFM	
NAME	CTaylor	CEngland*	G Miller for Shelton	
DATE	11/30/2021	12/28/2021	12/29/2021	

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## **Nuclear Regulatory Commission Responses to Nuclear Energy Institute Letters Dated July 24, 2020 and April 20, 2021**

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” (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).

This letter documents the NRC staff’s response to NEI’s concerns.

**NEI Concern:** 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)<sup>1</sup>, NEI expressed concerns with violations issued for failed or degraded management measures that do not result in failure to meet the performance requirements of 10 CFR 70.61. NEI also expressed concern with certain changes to IMC 0616 used to evaluate the severity of those violations and questioned the backfit implications of these changes.

**NRC Staff Response:** The staff is performing a backfit assessment of the specific changes to IMC 0616, as identified in the letter. Once the assessment is complete, the staff will provide a written response regarding the validity and significance of certain management-measure violations.

**NEI Concern:** In the section “Overarching Process Concerns Regarding IMC Revisions” of the July 24, 2020 letter (ML20211L714)<sup>1</sup>, NEI states that “[i]t is not NRC practice to issue an IMC under revision for public review and comment.... This practice does not allow industry or public stakeholders to receive proper clarity on the regulatory basis of a given revision(s) or transparency on the development of these changes.” The NEI also stated that it “would like to

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<sup>1</sup> “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).

better understand NRC's rationale for withholding IMC revisions from public stakeholder comment and engagement, which is not in line with the NRC's Principles of Good Regulation, specifically 'Openness' and 'Clarity.'" This position was partially reiterated in the April 20, 2021 letter, "Industry-Suggested Edits to Inspection Manual Chapter 0616 (April 2021 version) to Resolve Concerns Discussed in a July 24, 2020 Industry Letter and During NRC Public Meetings; Regarding the Regulatory Basis for Cited Violations Involving Degraded or Failed Management Measures" (ML21236A302).

**NRC Staff Response:** While the NRC practice is to not release draft inspection documents, there are certain circumstances in which these documents are made available for public comment. For example, under Section 06.04 *Regional and Office Comments* of IMC 0040 "Preparing, Revising, and Issuing Documents for the NRC Inspection Manual" (ML19352E640) "[o]n the rare occasion that an industry working group has been created to gain industry consensus on inspection documents, the agency may make the draft document public and available to industry . . . . This will be done at the discretion of the Document Lead and their Branch Chief, and only under rare circumstances." Additionally, final revisions to inspection guidance documents are, where appropriate, made available to the public to make information about the NRC oversight process transparent.

**NEI Concern:** Attachment 1 (markup of IMC 0616, April 2021) and Attachment 2 (change table) to the April 20, 2021 letter (ML21236A302) provide "edits that are intended to: 1) improve the guidance for assessing whether a violation is minor or more than minor; 2) clarify management measure related language to ensure it aligns with exi[s]ting requirements in 70.62(d); and 3) remove the revised risk screening information that was added to the August 2017 version of IMC 0616 which has been the primary source of confusion."

**NRC Staff Response:** The NRC staff is preparing the latest update to IMC 0616. Some of the edits suggested in your April 20, 2021 letter are being incorporated into the revised IMC 0616 to provide additional clarity for assessing whether a violation is minor or more than minor. The staff plans to issue the revision to IMC 0616 in the first quarter of 2022, after completing the backfit assessment discussed above.