



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

October 25, 2023

MEMORANDUM TO: Kerri Kavanagh, Chief  
Quality Assurance and Vendor Inspection Branch  
Division of Reactor Oversight  
Office of Nuclear Reactor Regulation *Andrea Keim* Signed by Keim, Andrea  
on 10/25/23

FROM: Andrea Keim, Reactor Operations Engineer  
Quality Assurance and Vendor Inspection Branch  
Division of Reactor Oversight  
Office of Nuclear Reactor Regulation

SUBJECT: SUMMARY OF SEPTEMBER 27, 2023, NUCLEAR ENERGY  
INSTITUTE PRESUBMITTAL OF NEI 22-01 PUBLIC MEETING

On September 27, 2023, the U.S. Nuclear Regulatory Commission (NRC) staff held an observation meeting with representatives from the Nuclear Energy Institute (NEI) to discuss NEI's proposal of utilizing the International Organization for Standardization (ISO)-9001, "Quality Management Systems – Requirements," program with additional controls to satisfy the regulatory requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities" (hereafter referred to as Appendix B) for advanced reactors and operating reactors.

The meeting notice is available in the NRC's Agencywide Documents Access and Management System (ADAMS) at Accession No. [ML23263B082](#), and the presentation slides are available under ADAMS Accession No. [ML23261C379](#). The enclosure to this summary provides the attendees for the meeting as captured by Microsoft Teams.

Mr. Mark Richter from NEI, provided background information and the industry motivation for the proposed methodology of utilizing suppliers with an ISO-9001 quality management system program (hereafter referred as ISO-9001 suppliers) in anticipation of advanced reactor deployment. Mr. Richter also stated that the planned proposal to use ISO-9001 suppliers for the operating fleet, based on the decreasing number of suppliers with Appendix B quality assurance programs that are available to procure basic components needed to support the operating fleet.

Mark Richter introduced additional speakers to discuss different parts of the presentation. The additional speakers included Mike Dunkelburger (MPR Associates), Mark Coren (Duke Energy), Mark Tannenbaum (Electric Power Research Institute), and Ed Renaud (Westinghouse).

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The presenters discussed the development of the methodology incorporated in NEI 22-04, "Utilization of ISO 9001 and Other Non-nuclear Suppliers for Safety Related Application". A gap analysis was performed for ISO-9001:2015 to Appendix B of 10 CFR Part 50. NEI 22-04 provides guidance for determining the gaps and differences, supplemental requirements and actions needed to satisfy Appendix B of 10 CFR Part 50. In addition, the presenters discussed options for 10 CFR Part 21, "Reporting of Defects and Noncompliance," that are addressed in the proposed document.

The presentation included a discussion addressing how gaps were identified and recommendations to address a selection of gap examples. Mr. Coren and Mr. Renaud continued the NEI presentation and provided their experience on the two pilot assessments for two suppliers with ISO-9001 programs using the methodology in NEI 22-04.

At the completion of the NEI presentation, the NRC staff had an open dialogue with the NEI representatives. Ms. Kerri Kavanagh, Chief, Quality Assurance and Vendor Inspection Branch (IQVB) commented and emphasized the importance of the prevention of counterfeit, fraudulent, and suspect items from entering the supply chain when evaluating the gaps of the proposed ISO-9001 methodology and developing enhancements to meet Appendix B.

The NRC staff provided information and allotted time for stakeholder comments and questions. Stakeholders provided feedback on several topics and asked clarifying questions.

At the conclusion of the meeting, Ms. Kavanagh provided closing remarks for the meeting. NEI is planning to submit NEI 22-04 in November 2023

Please direct any inquires to Andrea Keim at 301-415-1671 or via email at [Andrea.Keim@nrc.gov](mailto:Andrea.Keim@nrc.gov) .

Enclosure:  
Attendance List

SUBJECT: SUMMARY OF SEPTEMBER 27, 2023, NUCLEAR ENERGY INSTITUTE  
PRESUBMITTAL OF NEI 22-01 PUBLIC MEETING DATED: October 25, 2023

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**NRC-001**

OFFICE	NRR/DRO/IQVB	NRR/DRO/IQVB	NRR/DRO/IQVB/
NAME	AKeim	GGalletti	KKavanagh
DATE	10/25/2023	10/23/2023	10/25/2023

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## Pre-submittal Public Meeting List of Attendees

September 27, 2023

<u>Name</u>	<u>Organization</u>
March Richter*	Nuclear Energy Institute (NEI)
Mark Coren	Duke Energy
Mike Dunkelberger*	MPR Associates
Marc Tannenbaum*	Electric Power Research Institute (EPRI)
Ed Renaud	Westinghouse
Greg Galletti	U.S. Nuclear Regulatory Commission (NRC)
Kerri Kavanagh*	NRC
Andrea Keim*	NRC
Raju Patel	NRC
Katie Wagner	NRC
Lesslie Fields	NRC
Deanna Zhang	NRC
Bruce Montgomery	NEI
Michael Torbit	GE Vernova
Rachel Czuba	
Mark Mlachak	
Taylor Blake	GE Vernova
Trace Orf	
Eddie Neville	
Jonathan Thomas	
Zachary Betsill	
Les Taggart	
Olimpio Brandy Torres	
Milton Concepcion	Constellation Nuclear
Adrienne Hudson	
Henry Pollock	
RJ Roux	
Rodney McCullum	
Tracy Honeycutt	
Rob Burg	
Andrea Segiet	
Paul Ragan	GE Vernova
Mark Svajger	GE Vernova
Stephen Kimura	
Ewa Muzikova	
Steven Shelton	GE Vernova
Allison Read	EPRI
Steven Pope	
Jack Bastermaji	
Aaron Thomlinson	
Monica Gaul	GE Vernova

Enclosure

Brandon Chisholm	
Ararat Torosyan	
Camille Zozula	
Elliot Korb	
David Ethington	GE Vernova
Stanely Griffin	GE Vernova
Diane Mlynarczyk	
Timothy Franchuk	
Sineaid Wilding	
B Janal	
Jana Bergman	Curtiss-Wright
Mary Miller	

\*On-Site at NRC Headquarters

Attendance list based on Microsoft Teams Participant list. This list does not include all individuals that connected via phone.