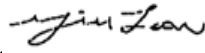




UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 15, 2021

MEMORANDUM TO: Kerri A. Kavanagh, Chief
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

FROM: Yiu Law, Reactor Operations Engineer  Signed by Law, Yiu Kui
Quality Assurance and Vendor Inspection Branch on 12/15/21
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

SUBJECT: SUMMARY OF THE OBSERVATION PUBLIC MEETING TO
DISCUSS NEI'S PLANNED PROPOSAL OF QUALITY ASSURANCE
STANDARD ISO-9001 AND ITS POTENTIAL USE TO SATISFY THE
REGULATORY REQUIREMENTS OF QUALITY ASSURANCE

On November 30, 2021, the U.S. Nuclear Regulatory Commission (NRC) held an observation public meeting with representatives from the Nuclear Energy Institute (NEI) to discuss NEI's planned proposal of utilizing the International Organization for Standardization (ISO)-9001 quality assurance standard 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 as Appendix B) for advanced reactors and operating reactors. The meeting notice can be found in the Agencywide Documents Access and Management System (ADAMS) under Accession Number ML21327A458. The presentation slides can also be found under ADAMS Accession Number ML21327A263.

The meeting was opened by Ms. Kerri Kavanagh, Chief, Quality Assurance and Vendor Inspection Branch (IQVB), Division of Reactor Oversight (DRO), Office of Nuclear Reactor Regulation (NRR). Ms. Kavanagh provided opening remarks and stated that the meeting was held at the request of NEI. It was noted that the NRC staff has not endorsed ISO-9001 to meet the requirements of Appendix B.

Mr. Mark Richter from NEI, provided background information and industry motivation in NEI's planned proposal to use suppliers that have an approved ISO-9001 QA program (hereafter referred as ISO-9001 suppliers) in anticipation to support the development of advanced reactors and the rulemaking effort of 10 CFR Part 53, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors." Mr. Richter also stated that the planned proposal to use ISO-9001 suppliers may provide near-term benefits for the operating fleet with the decreasing number of suppliers with Appendix B QA programs that are available to procure components needed to support the operating fleet.

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Mr. Mark Coren from Duke Energy continued the NEI presentation and provided his perspectives on recent audits of several manufacturing suppliers with both ISO-9001 and Appendix B QA programs. In his presentation, Mr. Coren also presented a table identifying the high level gaps between the requirements from ISO-9001 and the requirements from Appendix B.

Mr. Marc Tannenbaum from the Electric Power Research Institute (EPRI) closed the NEI presentation and provided his perspectives on the reasons and benefits of using ISO-9001 suppliers in procuring components for the nuclear industry. Mr. Tannenbaum stated that to address the gaps between the requirements from ISO-9001 and the requirements from Appendix B, a proposed solution would be for the ISO-9001 suppliers to accept contractual requirements to address these gaps in the procurement process, and to provide the licensees with rights of access to their facilities for the purpose of assessment and oversight. A targeted assessment plan would be developed to assess the areas of disparity between the requirements from ISO-9001 and requirements from Appendix B. An inspection and test plan would also be developed from the ISO-9001 suppliers during the procurement process.

At the end of the NEI presentation, the NRC staff had an open dialogue with the NEI representatives. Ms. Kavanagh commented and emphasized the importance of understanding the scope of safety-related components as it relates to advanced reactors, which is not yet well-defined. It is likely that the number of safety-related components will decrease in advanced reactors and therefore, meeting the requirements of Appendix B may not be an impediment for supplying safety-related components for advanced reactors. In addition, the resources spent to bridge the gaps between the requirements from ISO-9001 and the requirements from Appendix B may not be fully realized as a cost saving for the industry. Mr. Paul Prescott from the NRC also commented that a similar effort to what NEI's currently proposing has been attempted before, and since the scope of safety-related components for advanced reactors is not yet well-defined, it may be beneficial for NEI to introduce a different approach to secure suppliers for advanced reactors, as opposed to trying to bridge the gaps between ISO-9001 and Appendix B for both advanced reactors and operating reactors.

After discussion with the NRC staff, Mr. Richter, Mr. Coren, Mr. Tannenbaum and Mr. Edward Renaud from Westinghouse, collectively provided the following additional information:

- One major difference between NEI's planned proposal to adopt ISO-9001 and the current regulation on commercial grade dedication in securing safety-related components is that commercial grade dedication is predicated on not knowing the initial acceptance requirements of a safety-related item, thus having to determine the safety functions and failure modes of such item. Another difference is that the ISO-9001 approach is a more holistic approach, as opposed to commercial grade dedication being an assessment for every different item being procured.
- To address gaps between the requirements of ISO-9001 and the requirements of Appendix B, such as special processes like welding, the licensee procuring the safety-related item or service and the ISO-9001 supplier supplying the item or service would have to address these gaps through procurement specifications and contractual agreements.
- 10 CFR Part 21 requirements would be contractually passed down from the licensee procuring an item to the ISO-9001 supplier supplying the item through the procurement specifications.

- To provide oversight of an ISO-9001 supplier, the licensee would extend their Appendix B QA program requirements to the ISO-9001 supplier.

After discussion between the NRC staff and the NEI representatives, the NRC staff provided the public an opportunity to provide comments or ask questions. A comment was made by a member of the public on the history of QA and safety of nuclear power plants in relation to NUREG-1055, "Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants: A Report to Congress," which is publicly available on the NRC website.

At the conclusion of the meeting, Ms. Kavanagh provided closing remarks for the meeting. NEI is planning to submit a white paper providing a more detailed proposal of using ISO-9001 to satisfy Appendix B requirements in 2022 for NRC review.

Enclosure:
List of Attendees

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PLANNED PROPOSAL OF QUALITY ASSURANCE STANDARD ISO-9001 AND
ITS POTENTIAL USE TO SATISFY THE REGULATORY REQUIREMENTS OF
QUALITY ASSURANCE Dated: December 15, 2021

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OFFICE	NRR/DRO/IQVB	NRR/DRO/IQVB
NAME	YLaw*	KKavanagh*
DATE	12/8/2021	12/15/2021

OFFICIAL RECORD COPY

List of Attendees

Name	Organization
Mark Richter	Nuclear Energy Institute (NEI)
Marcus Nichol	NEI
Mark Coren	Duke Energy
Marc Tannenbaum	Electric Power Research Institute (EPRI)
Marc Albert	EPRI
Allison Read	EPRI
Jessica Lemieux	EPRI
Rick Way	EPRI
Minneva Taltoan	Next Era Energy
Aixa Belen	X Energy
Theo Odendaal	X Energy
Charlotte Geiger	X Energy
Travis Chapman	X Energy
Ingrid Nordby	X Energy
Jon Facemire	X Energy
Steve Vanugh	X Energy
Zenas McLucas	X Energy
Earl Mayhorn	Ameren
Roy Linthicum	Exelon
Phil Couture	Entergy
Ron Gaston	Entergy
Edward Renaud	Westinghouse
Rob Burg	Engineering Planning and Management Inc.
Robert Thompson	Energy Harbor Nuclear
William Coll	Energy Harbor Nuclear
William Avery	Energy Harbor Nuclear
Vince Gilbert	Model Performance, LLC
Robert Seipel	Shine Technologies
Mike Dunkelberger	MPR Associates
Shanrokhi Farshid	FRA-CORP
Ewa Muzikova	Ultra Safe Nuclear Corporation
Jana Bergman	Curtiss-Wright
Michael Keegan	State of Michigan

Enclosure

Kerri Kavanagh	U.S. Nuclear Regulatory Commission (NRC)
Yiu Law	NRC
Yamir Diaz-Castillo	NRC
Paul Prescott	NRC
Greg Galletti	NRC
Deanna Zhang	NRC
Andrea Keim	NRC
Dong Park	NRC
Laura Smith	NRC
Frankie Vega	NRC
Timothy Drzewiecki	NRC
Ian Jung	NRC
Steven Lynch	NRC
Philip McKenna	NRC
Eric Oesterle	NRC
Joseph Sebrosky	NRC
John Segela	NRC
Adam Stein	
Ernest Bates	
Zachary Betsill	
Bob Thompson	
Michael Anthony Brown	
Fred Madden	
Fred Mizell	
Jamie Schlarb	
Jason Christensen	
Jerry Ice	
Paul Martyak	
Rick Way	
Ross	
Mike Ruffolo	
Sam M.	
Wayne Massie	
Zackary Rad	