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

December 22, 2017

Mr. Joseph E. Pollock
Vice President, Nuclear Operations
and Interim Chief Nuclear Officer
1201 F Street, NW, Suite 1100
Washington, DC 20004

SUBJECT: THE U.S. NUCLEAR REGULATORY COMMISSION'S OBSERVATIONS ON THE NUCLEAR ENERGY INSTITUTE'S DRAFT TECHNICAL REPORT NEI 16-07, REVISION A, "IMPROVING THE EFFECTIVENESS OF ISSUE RESOLUTION TO ENHANCE SAFETY AND EFFICIENCY," DRAFT, ISSUED MAY 2017

Dear Mr. Pollock:

This letter responds to the Nuclear Energy Institute (NEI) draft technical report 16-07, "Improving the Effectiveness of Issue Resolution to Enhance Safety and Efficiency, Draft, May 2017," which was provided to the U.S. Nuclear Regulatory Commission (NRC) for information only on May 31, 2017, (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17152A242).

NEI did not request NRC endorsement of the draft guidance, but the staff reviewed the draft technical report to identify potential changes that could affect inspection processes and activities. In an effort to gain a better understanding of NEI's proposed approach to issue resolution in the draft guidance, the NRC attended NEI-led information sessions used to brief industry personnel on NEI 16-07. The NRC also held a public meeting on the draft report on August 16, 2017 (meeting summary available at ADAMS Accession No. ML17284A356). In addition, NEI provided a brief presentation on the industry initiative at each of the four NRC regional counterpart meetings during the week of December 4, 2017. We understand that the draft guidance sent to us is subject to future changes. The observations below pertain to the document NEI sent on May 31, 2017.

Consistent with NEI's decision not to seek formal NRC review, the NRC does not endorse, accept, or reject NEI 16-07. From its consideration and interactions, the NRC staff has the following observations on the draft document for NEI and industry consideration:

First, NEI 16-07 conveys that regulations and regulatory standards must be identified and addressed within the corrective action program (CAP), but it emphasizes compliance with Title 10 of the Code of Federal Regulations (10 CFR) Part 50, Appendix B, Criterion XVI, "Corrective Action." Many issues that are subject to criterion XVI requirements are also subject to other pertinent requirements of Appendix B. Further, several 10 CFR Part 50 and non-10 CFR Part 50 requirements refer or otherwise utilize licensee CAPs (e.g., 10 CFR Part 26, "Fitness for Duty Programs," and 10 CFR Part 73, "Physical Protection of Plants and Materials"). In implementing their CAP, licensees must ensure adherence to all relevant requirements.

Licensees should not narrowly focus on Criterion XVI compliance without complying with other pertinent requirements.

Second, NEI 16-07 describes conditions adverse to quality (CAQs) and conditions adverse to regulatory compliance, and it describes how these issues would be addressed by approved processes outside the formal CAP. NEI 16-07 also describes the direct entry of these types of issues into an approved process as a substitute for entry into the CAP. The NRC notes that decentralization of CAQ tracking, trending, correction, and prevention from the formal CAP to other processes could make it more difficult for licensees and the NRC to identify and address adverse trends and cumulative impacts related to corrective actions and corrective action backlogs. In addition, relocating a CAQ from the CAP to another approved process does not alter the applicability of relevant appendix B requirements; rather, upon "receipt" of a CAQ, the CAP or other process would become subject to all pertinent requirements of Appendix B for that CAQ.

Third, in the case of a significant condition adverse to quality (SCAQ), Criterion XVI requires licensees to take steps to "assure that the cause of the condition is determined and corrective action taken to preclude repetition." The NEI 16-07 proposed matrix describes a root cause analysis (RCA) only when (a) the SCAQ is determined to involve high risk and (b) the cause of the condition is judged to be ambiguous or complex. NEI 16-07 describes a non-RCA level of investigation when (a) the SCAQ is determined to involve medium or low risk or (b) the SCAQ cause is judged to be clear. The assessment of SCAQ risk would thus usually entail a case-by-case determination of compliance with NRC requirements within this framework. Licensee failure to conduct an adequate causal analysis could result in a licensee not correcting the cause of a SCAQ, as required by Appendix B to Part 50.

Finally, NEI 16-07 states, "If a SCAQ cannot be eliminated or it is not practical to do so, then the corrective action to preclude repetition must be able to mitigate the consequences of the condition to an acceptable level should it occur again." As discussed above, Criterion XVI requires that for SCAQs, licensees must "assure…corrective action taken to preclude repetition."

Each licensee is responsible for ensuring compliance with NRC regulations. While the NRC does not endorse, accept, or reject NEI 16-07, the NRC will continue to oversee implementation of licensees' CAPs through the NRC's inspection program. The NRC appreciates the opportunity to interact with NEI and the industry on draft NEI 16-07.

If you have any questions, please contact Serita Sanders by telephone at 301-415-2956 or by e-mail to Serita.Sanders@nrc.gov.

Sincerely,

/RA/

Michael R. Johnson
Deputy Executive Director for Reactor
and Preparedness Programs
Office of the Executive Director for Operations

SUBJECT: NRC OBSERVATIONS ON THE NUCLEAR ENERGY INSTITUTE'S DRAFT TECHNICAL REPORT NEI 16-07, REVISION A, "IMPROVING THE EFFECTIVENESS OF ISSUE RESOLUTION TO ENHANCE SAFETY AND EFFICIENCY, DRAFT, MAY 2017" DATED December 22, 2017

DISTRIBUTION:
SAnderson, NRR
SSanders, NRR
JBowen, OEDO
RidsNrrDirsIrib
RidsNrrDirs
RidsNrrDlpPlpb
RidsNrrDlp
RidsOgcMailCenter
RidsNrrOd
RidsEdoMailCenter
RidsRgn1MailCenter
RidsRgn2MailCenter
RidsRgn3MailCenter
RidsRgn4MailCenter

ADAMS Accession Number: ML17319A140

OFFICE	NRR/DIRS/IRIB	NRR/DIRS	NRR/DPR/PLPB	QTE*
NAME	SAnderson	CMiller (MKing for)	DMorey	JDougherty
DATE	11/13/17	11/15/17	11/16/17	11/17/17
OFFICE	NRR/DLP	OGC	NRR	OEDO
NAME	LLund (MJRoss-Lee for)	AGendelman	BHolian	MJohnson
DATE	11 /21/17	12 /14/17	12/19/17	12 / 22 / 17

OFFICIAL RECORD COPY