

July 7, 2016

Mr. Russell Bell, Senior Director, New Plant Licensing
Nuclear Generation Division
Nuclear Energy Institute
1201 F Street, NW, Suite 100
Washington, DC 20006-3708

SUBJECT: RESULTS OF THE U.S. NUCLEAR REGULATORY COMMISSION STAFF
REVIEW OF NEI 08-02 "CORRECTIVE ACTION PROCESSES FOR NEW NUCLEAR POWER
PLANTS DURING CONSTRUCTION," DRAFT REVISION 4.

Dear Mr. Bell:

By letter dated October 28, 2015, the Nuclear Energy Institute (NEI) submitted NEI 08-02, draft Revision 4, "Corrective Action Processes for New Nuclear Plants During Construction," for review and endorsement in a Regulatory Guide. The submittal letter and NEI 08-02, draft Revision 4 can be accessed through the NRC's Agencywide Documents Access and Management System (ADAMS) at Accession Number ML15306A510 and ML15306A511 respectively. The submittal letter of NEI 08-02, draft Revision 4, stated in part that the updates to the guidance reflect experience gained during the construction of the first new nuclear plants licensed under 10 CFR Part 52.

In addition, the NEI submittal letter stated that the guidance had been modified to reflect the NRC's acceptance of ASME/ANSI Standard NQA-1-2008 with 2009 addenda and references to NQA-1-1994 had been retained for the benefit of existing licensees and applicants. On November 18, 2015, during a Category 3 public meeting (ADAMS Accession No. ML15321A285), NEI provided the NRC staff an overview of the draft revision to NEI 08-02. During this meeting, a representative from NEI provided a presentation of NEI 08-02, which NEI briefly discussed an outline of the content of the document and that the document reflected experience gained at construction sites; including implementing multiple corrective action processes on-site; establishing and implementing consistent thresholds for problem identification, screening and evaluation to identify significant conditions; and analyzing for adverse trends.

The NRC staff would like to recognize NEI's efforts in developing NEI 08-02. However, the NRC staff has approved and/or endorsed several other guidance documents where there is an industry need for guidance to adequately implement regulatory requirements. The staff is currently working on the review of additional guidance documents such as, but not limited to, acceptance of commercial grade design and analysis software for safety-related applications; dedication of commercial grade items; and 10 CFR Part 21 evaluation and reporting requirements. After careful consideration of evidence indicating adequate existing corrective action program implementation based on construction reactor oversight process inspection results, the staff believes that additional guidance in corrective action processes during construction is not warranted at this time.

The staff would like to present our basis for this conclusion during the upcoming Category 3 public meeting, to be held on July 19, 2016. In preparation for this meeting and as requested during a teleconference between the NRC staff and NEI on May 19, 2016, this letter provides examples of our observations from the review of NEI 08-02, Draft Revision 4.

If you have any questions regarding the information contained in this letter, please contact Ms. Kerri Kavanagh at 301-415-3743.

Sincerely,

Michael Cheok, Director **/RA/**
Division of Construction Inspection
and Operational Programs
Office of New Reactors

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Michael Cheok, Director **/RA/**
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Enclosure
NRC Staff Comments for Discussion at
Public Meeting July 19, 2016

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NRC Staff Comments for Discussion at Public Meeting on July 19, 2016

NEI 08-02, "CORRECTIVE ACTION PROCESSES FOR NEW NUCLEAR POWER PLANTS DURING CONSTRUCTION," DRAFT REVISION 4

- A. The NRC's staffs evaluation of NEI 08-02, Draft Revision 4, concluded that this document does not provide enough prescriptive measures in the following relevant areas of a robust corrective action program during construction: (1) nexus to Part 21/50.55(e) regulations; (2) trending of conditions adverse to quality (CAQs); (3) documentation, identification and classification of CAQs (4) interface with other organizational structures; (5) defining what is a CAQ versus a significant condition adverse to quality (SCAQ) and how to address the difference; and (6) lessons learned in NUREG-1055, "Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants." The concepts used in the document to describe compliance with 10 CFR 50, Appendix B need to be more specific in explaining how CAQs and SCAQs would be handled in a licensee's corrective action processes.

NEI 08-02, Draft Revision 4, Section 2.2, "Applicability," states in part that, "This document does not address requirements for reporting to the NRC of deviations, failures to comply, or other reportable occurrences under 10 CFR 50.55(e), 10 CFR Part 21, or 10 CFR Part 52." When this document describes Part 21/50.55(e) implementation, clarification should be provided on how to incorporate the regulations into the procedural measures proposed in the industry guidance document. Specifically, the unique aspects that should be considered for reporting to the NRC of deviations and failures to comply under 10 CFR 50.55(e) or 10 CFR Part 21 during construction.

NEI 08-02, Draft Revision 4, Section 1, "Introduction and Background," states in part that, "The licensee is responsible for assuring that conditions adverse to quality (CAQs) are identified, corrected, and managed in accordance with the requirements and commitments of the facility quality assurance program (QAP)." Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," Criterion XVI, "Corrective Action," states in part, that, "Measures shall be established to assure that conditions adverse to quality are promptly identified and corrected." Standard Review Plan (SRP), Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," Revision 1, Section P, "Corrective Action," states in part that, "Measures shall be established to ensure that conditions adverse to quality, are promptly identified, documented, classified and corrected." NEI 08-02, Draft Revision 4 does not describe how to identify, document, classify or correct a CAQ. Procedural measures should be proposed in the industry guidance document to incorporate these actions.

NEI 08-02, Draft Revision 4, Section 1, "Introduction and Background," states in part that, "This document also provides guidance for implementation of an interface management process for Construction Corrective Action Program (CCAP) for projects that use multiple interfacing corrective action programs (CAPs) rather than a single CAP. The CCAP interface process involves joint screening between licensee and contractor(s), identification and classification of significant/conditions adverse to quality (SCAQs/CAQs), and disposition of the conditions in a timely manner. NEI 08-02, Draft Revision 4 provides information related to a tiered oversight approach by the licensee and contractor(s) for issues entered into CCAP." Furthermore, Section 2.2, "Applicability," states in part that, "When multiple processes are used to implement corrective action, then interface measures shall be defined and implemented. These interface measures shall ensure identified problems are adequately and appropriately evaluated. The measures shall ensure that CAQs are addressed in accordance with 10 CFR Part 50, Appendix B, Criterion XVI." When this document describes interface/organizational measures, clarification should be provided on how NEI incorporates NRC Appendix B requirements into the procedural measures proposed in the industry guidance document. Specifically, in regards to clearly defining the responsibilities, interfaces, and authority of each organization as well as the external interfaces between organizations and the internal interfaces between organizational units.

NEI 08-02, Draft Revision 4, Section 4.3, "Cause Analysis," states in part that, "Management may also require causal analysis for other significant conditions even though they are not SCAQ." The guidance document should provide examples of what would be considered other significant conditions even though they are not SCAQ.

NEI 08-02, Draft Revision 4, Section 1.2, "References," identifies NUREG-1055, as a reference that was used to assist in the development of this guidance document. However, upon review, it appears that this guidance document does not include the substantial previous operating experience and lessons learned at both operating plants and during prior construction. Due to the significant challenges in implementing multiple and diverse corrective action processes onsite, this document should address those challenges such as, but not limited to the following:

- establishing and implementing consistent thresholds for problem identification;
- initial screening for safety significance; and
- adequate trending for generic implications.

B. NEI 08-02, Draft Revision 4, Section 1, "Introduction and Background," states in part that, "This document provides guidance for meeting the requirements of Criterion XVI, Corrective Action, of Appendix B to 10 CFR Part 50, Quality Assurance for Nuclear Power Plants and Fuel Reprocessing Plants, that are identified in a licensee's approved QA

program that is based on NQA-1-1994, Regulatory Guide (RG) 1.28, or other Nuclear Regulatory Commission (NRC) endorsed QA standard. CCAP implements the requirements of Criterion XVI of Appendix B to 10 CFR Part 50, as identified in NRC Regulatory Guide 1.206, NUREG-0800 Standard Review Plan, Section 17.5, and ASME/ANSI Consensus Standard NQA-1-1994 or NQA-1-2008/1a- 2009, as applicable, through defined processes that address failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances that are documented as specified in NQA-1-1994 and NQA-1-2008/1a-2009.”

NEI 08-02, Draft Revision 4, Section 4.1, “Identification, Documentation, and Reporting,” states in part that, “In general, conditions that are still within control of the work process, where the work has not been declared complete, are not required to be entered in the CAP if they can be corrected within the work process. Examples would be: design errors identified before all approvals are complete for a calculation, installation errors identified before the QA/QC verification is complete and where correction is within the scope of the work process, and certain nonconforming material where the work process contains guidelines for repairing the material.” This document should provide the basis as to how the regulations, regulatory guide and NRC endorsed standards, are met by the NEI 08-02, Draft Revision 4 submittal. Specifically, in regards to conditions that are still within control of the work process, where the work has not been declared complete, that are not required to be entered in the CAP. Additionally, this document should provide guidance on what conditions require identification, documentation, classification and correction of in-process (not identified by the quality organization) failures, malfunctions, deficiencies, deviations, defective items, and nonconformances.

NEI 08-02, Draft Revision 4, Section 4.6, “Adverse Trends,” states in part, that “CAQ identified through the Corrective Action Program(s) should be periodically analyzed for adverse trends.” As stated above, this document should provide the basis for determining whether the appropriate regulations and SRP acceptance criteria were considered in the NEI 08-02, Draft Revision 4.

- C. The document should correct or clarify the following comments to make the document more consistent with NRC’s regulations and understanding of those concepts.

NEI 08-02, Draft Revision 4, dated October 2015, Section 1, “Introduction and Background,” states in part that, “It was not written for use in correcting industrial safety, security, environmental, or other non-quality-related conditions; however, the principles may be applied to those areas as deemed appropriate by the implementing organization.” 10 CFR 50.34, “Contents of applications; technical information,” states in part that, “Each applicant for an operating license for a utilization facility that will be subject to the requirements of 10 CFR 73.55 of this chapter must include a physical security plan, a training and qualification plan in accordance with the criteria set forth in appendix B to part 73 of this chapter, and a cybersecurity plan in accordance with the criteria set forth in 10 CFR 73.54 of this chapter.” 10 CFR 73.55(b)(10), “Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage,” state in part that, “The licensee shall use the site corrective action program to track, trend,

correct and prevent recurrence of failures and deficiencies in the physical protection program.” In order for this document to be considered all-inclusive for a construction CAP, this document should provide guidance on how NEI incorporates the regulations into the proposed industry guidance document.