

**Responses to NRC Staff Comments for Discussion at Public Meeting on
October 28, 2009**

***NEI 08-02, Revision 2, Corrective Action Processes for
New Nuclear Power Plants During Construction***

- **The concepts used in the document to describe compliance with 10 CFR 50, Appendix B Criterion XVI need to be more specific in explaining how Conditions Adverse to Quality (CAQ) and Significant Conditions Adverse to Quality (SCAQ) would be handled in a licensee’s corrective action processes. The distinction between “work process” and the CAP need to clearly describe how they both are part of the corrective action processes.**

NEI Response: Corrective action is an element of the Quality Assurance Program (QAP) that is applied within multiple processes (such as designing, procuring, constructing, installing, etc) subject to 10 CFR Part 50, Appendix B. Thus, it is appropriate to address corrective action as it relates to other aspects of the Appendix B criteria. The following clarifications have been made to NEI 08-02:

- Environmental requirements are not subject to Appendix B and thus have been removed from the scope of NEI 08-02. Licensees may address environmental and other areas that are not subject to Appendix B within their quality-related corrective action processes at their discretion.
 - The Introduction and Background sections of NEI 08-02 have been modified.
 - Section 5 has been re-titled “Identification and Correction of Conditions through Work Processes,” and the first paragraph of Section 5 has been modified.
- Section 4.1 and 4.2 describes how CAQs will be corrected by work process. As we have mentioned in our past public meetings the use of this term/concept still does not explicitly state that it is part of the corrective action program or that it is a quality process with all the necessary controls in place set forth by the Quality Assurance Plan (QAP). We recognize that you have incorporated elements and descriptions to the “work processes” that mention proper review, trending, verification of results; but on those occasions you refrain from stating that it applies to CAQs. Instead you use terms adverse condition, condition and non-conformance which cause the impression that issues can be handled outside the established corrective process. When these sections describe the screening process, it does not identify that it happens within the “work process” or the established corrective action program.

NEI Response: The document has been made consistent in the use of the terms “condition adverse to quality” and “significant condition adverse to quality,” as appropriate. The phrase “adverse condition” has been clarified in Section 4.1 and Attachment 2.

The screening process described in NEI 08-02 must be built into both the work process and the CAP so that conditions identified through either process are screened to make the determination as to whether a “condition adverse to quality” exists so that corrective action is implemented. Attachment 1 of NEI 08-02 has been modified to more clearly depict the screening process.

- The definitions of corrective action processes, corrective action and corrective action program are helpful but are not adequately used in the document. It can be assumed that the “work processes” is one of the corrective action processes but that distinction is never made.

NEI Response: As previously stated, NEI 08-02 has been made consistent in the use of the terms “condition adverse to quality” and “significant condition adverse to quality,” as appropriate. In addition, Section 5 has been clarified in describing that the work processes include appropriate corrective action elements.

- Section 5 incorporates several of the comments NRC has provided in the past like proper evaluation, establishing of procedures, use of trends, proper notification, and adherence to the established QA program. The section needs to clearly make the distinction of how CAQ will be handled by the in-process work or the work process (the section should keep the same terminology), which per our understanding is the purpose of the section. The section needs to make more explicit how corrective actions will be carried out for all the CAQs identified. The term CAQ is not consistently (as mentioned in previous comment) used causing a sense of vagueness. The section incorporated 8 requirements from NQA-1 which in your previous revision were determined to be work processes, but upon closer look at NQA-1, most lack proper guidance on how CAQs should be handled or how they will interface with the corrective action program. Their inclusion is a cause for confusion as to how will this information help in the corrective actions of CAQs. The common understanding of these NQA-1 requirements is that they will feed into the corrective action program but that interaction is absent from the section.

NEI Response: Section 5 of NEI 08-02 has been made consistent regarding the identification and correction of conditions adverse to quality through the work processes so that the appropriate elements of corrective action are incorporated into the work processes. The following text has been added to paragraph 1 of Section 5:

“Work processes are quality processes subject to the applicable requirements of 10 CFR Part 50, Appendix B, and the QAP and include appropriate corrective action process elements (e.g., identification, documentation, correction of conditions adverse to quality, etc.) within their procedures.”

In addition, the second paragraph of Section 5 has been modified to explain that as the work processes/procedures are developed, they must include the applicable requirements from NQA-1-1994 supplements, including any requirements for correcting conditions adverse to quality specific to a work process.

- Attachment 1 needs to be refined to illustrate how issues will be screened and corrected in accordance with Sections 4 and 5 from the document. The document needs to provide examples or a description of what is meant by conditions identified within and outside a work process. These sections and Attachment 1 should use more the terms CAQ and SCAQ instead of terminology like “not significant” because it can be misleading in describing CAQs as not significant within the scope of corrective action. The document describes how CAQs should be trended and the diagram should illustrate as well when/where it should happen (Section 4.6).

NEI Response: As stated in a previous response, Attachment 1 has been modified to more clearly show the screening process and its application to both (1) conditions identified within a work process and (2) those identified outside a work process that are managed through the CAP. In addition, Section 4.1 has been modified to include a discussion (see paragraph 3) of conditions identified external to a work process.

- The document needs to describe how a licensee should integrate a contractor’s corrective action process with the licensee’s process.

NEI Response: NEI 08-02 is not intended to prescribe how licensees should accomplish this objective, but to describe the corrective action principles and process elements that must be implemented. Section 3.1 does clearly state that interfaces between the licensee and contracted organizations responsible for the corrective action processes must be established. Section 3.1 also establishes that the licensee is responsible for conducting oversight of the implementation of the corrective action processes by their suppliers.

- **All conditions determined to be material to an ITAAC should be entered into the CAP. The implication that only conditions identified by NRC will be entered into the CAP should be removed.**

- Section 4.2.3 should be modified to state that all violations of NRC requirements should be placed in the corrective action program which includes ITAACs, Construction Findings, and minor violations. The document should not imply that violations of NRC requirements could be corrected via the “work process” is not in agreement with the Enforcement Policy.

NEI Response: As discussed with the staff on October 28, we agree that all conditions determined to be material to an ITAAC should be addressed via corrective action processes in accordance with the licensee’s QAP and Appendix B. As discussed in response to a previous NRC comment, NEI 08-02 has been modified to clarify that work processes should contain appropriate corrective action process elements (e.g., identification, documentation, correction of conditions adverse to quality) in accordance with the licensee’s QAP and Appendix B. Thus all conditions determined to be material to an ITAAC will be addressed via corrective action processes in accordance with the licensee’s QAP and Appendix B. Section 4.2.3 has been modified to state more clearly that conditions material to ITAAC identified after the ITAAC Closure Letter has been submitted and any ITAAC-Related Construction Findings should be entered into CAP.

Section 4.1 has been modified to more generally state that conditions identified through NRC inspections (ITAAC-related or otherwise) should be entered into the CAP as conditions identified external to a work process.

- The definition of ITAAC finding and ITAAC Related Construction Finding must match the definitions in IMC 0613.

NEI Response: The NEI 08-02 definitions have been modified to include the additional statements from IMC 0613.

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

- The description of how the transition should occur needs to be consistent between Section 2.2 and Section 7.

NEI Response: Section 7 has been revised to be consistent with the discussion in Section 2.2.

- The inclusion of other programs to report problems seems to be outside the scope of the document.

NEI Response: The discussion of other programs in the sixth paragraph of Section 1 was not that these are included in the corrective action processes, but to acknowledge their existence. In the event that a “condition adverse to quality” is identified through one of these means, such a condition would be treated as a “condition identified external to a work process” as shown in Attachment 1 and discussed in Section 4.1.

- The term purchaser in section 3.4 should be defined or changed to what NRC considers to be the licensee in the context of the section.

NEI Response: Section 3.4 has been modified to remove the term purchaser. The licensee’s oversight and interface responsibility for corrective action processes delegated to suppliers is described in Section 3.1.

- The document fails to reference the requirements of 10 CFR 50.55 “Construction Deficiencies,” which constitute the cornerstone of significant conditions adverse to quality.

NEI Response: As discussed with the staff on October 28, we understand the staff comment concerns 10 CFR 50.55(e), which addresses requirements for reporting construction deficiencies to NRC. NEI 08-02, Section 4.2.1, appropriately identifies Part 21, Section 50.55(e) and Section 52.6 as reporting requirements to NRC that may be applicable to certain conditions. Section 1.2 identifies 10 CFR Part 50 as a reference document, and has been modified to explicitly identify Sections 50, 55(e) and 52.6.

- The document is not intended to provide guidance on compliance with all of Appendix B. The introduction should only make mention of Criterion XVI as the scope for the document.

NEI Response: As discussed in response to the first NRC comment, the introduction has been modified to clarify that this document is addressing the actions necessary to comply with Criterion XVI of 10 CFR 50, Appendix B.