NEI Responses to NRC Staff Comments from Enclosure 3 of ML093580216

NEI 08-02 "Corrective Action Processes for New Nuclear Power Plants During Construction," Revision 3

- **The changes made to revision 3 do not provide enough clarification on how the work processes include part of the corrective action process in place at a site. The document does not provide guidance on how licensees will interact with suppliers and vice versa in terms of the work processes' corrective actions. The guidance in place will not provide enough reassurance that the screening process will be conducted uniformly for individuals responsible for the work process and the CAP.**

    - NRC requested that if the intent of the definition of Construction Corrective Action Process was to define it as the umbrella concept for both the CAP and the corrective action process in the work processes it should have been explicitly stated in order to set the proper tone for the rest of the document.

        - §1, Definitions, modified definition of CCAP; §2.2 added a statement – No additional comments by NEI.

    - Per our discussion it was understood that the work process corrective action measures will occur with-in it, to handle CAQ and/or non-conformances. The way it is currently defined does not make it clear (as with the definition of CAP) that the work process will have management process/tools to correct CAQ/nonconformances in compliance with the requirements stated in the definition. Not mentioning that the work process has a corrective action process in place to handle issues, creates the impression of the work process being something completely different from the expected corrective action programs.

        - §5, 1st ¶ (about the middle) information was added. - No additional comments by NEI.

    - The document lacks a section were it provides guidance on the corrective action elements that the work process should have and how it should handle the screening, evaluation, and documentation of all items that would currently fall in Column one of Attachment 2 table. Section 5 should be were the corrective action elements pertaining to the work processes are discussed and explain how to best achieve those goals during implementation.

        - §5, 1st ¶, 2nd sentence was modified. - No additional comments by NEI.

    - Based on previous construction experience and issues identified during inspection of construction projects like MOX/LES corrective actions programs delegated to suppliers have not been implemented as intended. The document should try to provide more guidance/expectation on how the corrective action process in the work process will work in conjunction or communicate with the licensee. Section 3.4 seems like the right place to expand on these expectations. The sentence of … **suppliers been responsible for developing** … is not correct. Licensee should develop or validate

corrective action processes in the suppliers' work processes. Language should reflect this concept, similar to words in your previous revision.

- ❖ §4.2.1, last ¶ after the list was added. – Also, added statement to 3.1 2nd ¶

- Section 4 has good information on what the corrective action process should establish for an effective program. None the less it does not provide additional information to help clarify the concept of how conditions identified on site will be handled in either the CAP or the corrective action process with-in the work processes established for the different work activities. Some of this information could be inferred by the flow diagram but the document should be more explicit on how it is expected issues will be handled by these multiple corrective processes and how will the licensee be able to effectively keep oversight of them.

  - ❖ §5, 1st ¶, 2nd sentence was modified. – A 3rd sentence was also added.

- Section 4.2.1 should specify that the licensee should develop a screening process that shall be uniformly used on site. This will ensure that licensee personal evaluating issues entered into the CAP/work process and contracted personnel evaluating issues entered in the corrective action process of the different work processes will adequately evaluate these issues. As it is now it is not clear on whether it applies to the licensee's CAP, the work process corrective action elements, or the CCAP.

  - ❖ §4.2.1, last ¶, added text. –§4 provides the elements for the CCAP. The appropriate elements must be included into the processes, work or CAP as they are developed.

- Section 4.2.1 does not specify who is responsible/cognizant of the screening process. Whether an individual or screening organization; if it is an individual then it must be stated in the document and what would qualify an individual to make that determination. Criteria listed for screening is not common knowledge for individual at the work process level and this knowledge gap should be addressed in the document.

  - ❖ §4.2.1, 3rd ¶, added text. Also refer to §3.2 regarding management responsibility for training. – No additional comments by NEI.

- Section 4.2.2 should explicitly link or explain that when the document refers to how each organization will implement the corrective action processes it means each organizations implementation of the work processes, CAP and the path these issues can take from identification/handling in the work processes' corrective action process into the CAP. The current information is correct but it should put both concepts (CAP and Work Process) in the forefront of the document.

  - ❖ §2.1 has an added sentence. – Again, §4 is talking about elements that need to factored into the overall CCAP. Where multiple processes are used, e.g., supplier and licensee have separate processes, the interface need to established for proper communication.

- Section 4.2.2 should limit the use of the words low significance and just use defined terms as CAQ/SCAQ. The same comment on what is meant by otherwise significant.

- ❖ §4.2.2, 2nd ¶, 1st & 2nd sentences modified. – No additional comments by NEI.

- Section 5 still uses the words **some degree of corrective action**. Per our discussion, the work process will have with-in it part of the corrective action process that should have been discussed earlier in the document (previous comments). This choice of words is confusing as to what is intended. This section should mention (as it is our understanding) that the corrective action process with-in the work process will be (in addition to in procedures) in a management process/tool; to clearly indicate it is a stable program under the oversight of responsible management. This also seems a good section to add a few sentences on how work processes established by suppliers will comply with the requirements established by the licensee and how the licensee should conduct oversight to ensure compliance.

  - ❖ §5, deleted the phrase causing the confusion. Also, added information to §3.1, ¶2 and §3.4, ¶1. – No additional comments by NEI.

- In Section 5, the sentence **NQA-1-1994 Basic… discuss the resolution of non conformance…** should be put in context to explicitly state that all of those issues will be handled in the corrective action process with-in the work processes.

  - ❖ §5, 1st ¶, split into two paragraphs and added a new statement. – No additional comments by NEI.

- In Section 5, the paragraph beginning with **In addition to the corrective action requirements of Criterion XVI…** the writing remains confusing as to what is the intended purpose. It would be preferable that the document would elaborate on an example of what a work process would look like and how the corrective action process will accomplish the intended requirements. Then the document could mention the NQA-1 requirements as further examples to use by licensees to develop procedure requirements for the corrective action process in their respective work process.

  - ❖ §5, 3rd ¶ was clarified and added some examples to the listed items. – The paragraph now starts with NQA-1-1994.

- The last sentence of Section 5 should also state that it needs to be in compliance with Criterion XV of Appendix B, 10 CFR Part 50.

  - ❖ §5, last ¶ was removed as suggested by a later comment. – Refer to the next to last bullet on page 5 of the comments in Enclosure 3.

- Section 7 should address what actions need to be taken, if a transition to the operating CAP is going to occur in a subsystem well before fuel load. In terms of **ITAAC maintenance,** the operational CAP is designed to handle Tech Spec issues while the construction corrective action processes is designed to handle ITAACs. This needs to be addressed.

  - ❖ §7, last ¶, added a sentence at the end of the paragraph. – No additional comments by NEI.

- Attachment 1 inside the CAP if an issue is determined to not be a SCAQ/ITAAC the

third logic block says Implement Correction. This block should read similar to the block in Work Process: **Implement Correction, Document and trend.**

- ❖ Attachment 1, modified the chart. – No additional comments by NEI.

- Based on our discussion we recommend that a better approach for the columns in Attachment 2 would be to designate them as (from left to right): "conditions within the scope of the work process"; "conditions adverse to quality"; and "significant conditions adverse to quality". There is a need to have a better understanding on which issues will be handled through the process and be properly considered conditions adverse to quality. The concept of activities "inprocess" needs to be addressed to fully understand some of the examples provided in the document

  - ❖ Attachment 2, changed the table headings. §5, added text at the end of the 1st ¶ in conjunction with the next comment. – No additional comments by NEI.

- Additional guidance needs to be provided in either Section 4 or 5 that would explain which conditions will fall in column one. The document could have words to this effect: "In general, conditions that are still within control of the work process, where the work has not been declared complete, are not conditions adverse to quality and are not required to be entered in the corrective action program. Examples would be: design errors identified before all approvals are complete for a calculation; installation errors identified before the item is released and where correction is within the scope of the work process; certain non-conforming material where the work process contains guidelines for repairing the material; software errors identified during verification testing; etc".

  - ❖ §5, end of 1st ¶, added text. – No additional comments by NEI.

- If agreement can be reached on what constitutes a condition adverse to quality or when an issue is "in-process" based on our discussions it seems the best approach would be to have a site wide process to handle conditions adverse to quality.

  - ❖ (Will discuss with NRC reviewers at the January 15, 2010 meeting.)

- Specific comments:
  - Throughout document, change "action to preclude recurrence" to "action to preclude **repetition**."
    - ❖ Made corrections throughout
  - Provide consistent use of term "supplier" throughout document.
    - ❖ Made corrections throughout.
  - Provide consistent use of the term "item" throughout document. The term "equipment" is used in the document in lieu of "item." The term "item" has also been used in lieu of "conditions." Suggest refrain the use of "item" in an informal sense
    - ❖ Made corrections throughout.
  - Executive Summary, First sentence: Revise to "…guidance on how the **holder licensee** of a combined license (COL) **or Limited Work Authorization (LWA)** issued under…."
    - ❖ Suggestion implemented.

- Section 1, Paragraph 3: Last sentence: Suggest streamlining to: "New nuclear plant construction projects use similar corrective action elements, but the methods for documenting corrective actions may differ."
    - ❖ Suggestion implemented.
- Section 1, Paragraph 4: Third sentence: Revise to: "… is conducted after the **combined** license **(COL)** or limited work authorization (LWA) is issued…."
    - ❖ Suggestion implemented.
- Section 1, Paragraph 5: Second sentence: Revise to: "….method of satisfying NRC **regulatory** corrective action requirements."
    - ❖ Suggestion implemented.
- Section 1, Paragraph 5: Third sentence: Change "generated as" to "**documented** as."
    - ❖ Suggestion implemented.
- Section 1, Paragraph 5: Last sentence: Revise to: "When an onsite safety-related **contractor supplier** demobilizes and leaves the site, the licensee/supplier will review all open **items CAQs related to that specific supplier** for correct disposition and **that** ensure…."
    - ❖ Suggestion implemented.
- Section 1.1: Nonconforming Item definition, second sentence: Revise to: "….of the nonconforming items **(e.g., repair, use-as-is)** shall be…."
    - ❖ Suggestion implemented.
- Section 1.1: Suggest providing definition for "Reject."
    - ❖ This is not defined in NQA-1 and there is no special meaning implied within this document to the term reject, therefore it is not necessary to establish a definition. – No additional comments by NEI.
- Section 3.4: Add statement regarding the situation where a supplier is working to the licensee's QA program in lieu of its own QA program.
    - ❖ Added information to §3.4 to address this situation. – No additional comments by NEI.
- Section 4, Paragraph 4: Revise to: "…To make consistent and timely **significance** determinations, cause…."
    - ❖ Suggestion implemented.
- Section 4.2.2, Paragraph 1: First sentence: Revise to: "… are classified as SCAQ and therefore require **cause analysis and** actions to **preclude repetition prevent recurrence**."
    - ❖ Changed document to be consistent in use of "preclude repetition."
- Section 4.5, Paragraph 1: Suggest new title: "**Verification,** Closure, and Follow-up." Also, change Section 4, (e).
    - ❖ Title revised consistent with the changes made for the following comment.
- Section 4.5, Paragraph 1: Clarification - "Follow-up" is not discussed is this section, although the term is in the title. Is it the "effectiveness review"? It would be expected that CAQs would also be "closed," not just SCAQs, as the first sentence implies. Also, "closure" of SCAQ (and CAQ) is never discussed in the section, although the title states this action. Attachment 1 address the closure action, but not "follow-up." Because closure is not discussed in Section 4.5, it is also unclear at what point the effectiveness review is complete (before or after closure). The reader must review Attachment 1 to determine when the effectiveness review is complete. Guidance is not provided for what could

constitute an “effectiveness review.” Attachment 1 shows that SCAQ is closed AFTER the determination of effectiveness. It would seem that an SCAQ could be closed prior to a determination of effectiveness, and after some period of time after closure an effectiveness review could then be performed, instead of keeping an SCAQ open (that is, not closed) until an effectiveness review is completed. Attachment 1 is very specific regarding closure, THEN effectiveness review. Perhaps provide an option to conduct the effectiveness review either before or after closure, or provide specific guidance regarding when an effectiveness review is completed.

- ❖ Added clarification to §4.5, ¶1, modified the heading and Attachment 1 to be consistent. – Removed closure/closed.

- Section 5, Paragraph 7: Delete entire paragraph or clarify.-This sentence states that Requirement 15 of NQA-1 must be applied. Section 1, Paragraph 2, states “or other NRC endorsed QA standard.” A licensee may base its QA program on a QA standard other than NQA-1.
  - ❖ Paragraph deleted.
- Attachment 1: Revise two action blocks entitled “Document justification of significance” to “Document **justification determination** of significance.”
  - ❖ Boxes revised.