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Subject: Draft RAIs on the Review of the SNC LWA Supplement
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Jim,

Attached are draft RAIs pertaining to the staff's review of the LWA supplement Chapter 17. The final version will provide the RAIs in a table with a numbering scheme assigned to the request. Please take a look and let me know if you would like to have a conference call for the staff to further clarify these draft RAIs. Thanks.

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**Draft Request for Additional Information Regarding the
Southern Nuclear Company (SNC) Nuclear Development
Quality Assurance Manual (NDQAM), Version 5**

The staff has reviewed the Southern Nuclear Company (SNC) Nuclear Development Quality Assurance Manual (NDQAM), Version 5, in accordance with the provisions of Standard Review Plan Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants."

Introduction

1. 10 CFR 52.17 (a)(1)(xi) requires that the applicant of an early site permit (ESP) include a quality assurance program description (QAPD) to be applied to site-related activities for the future design, fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site. The QAPD shall include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied. Part I, Section 1.1 of the SNC NDQAM provides information on activities to which the NDQAM applies.
 - a. For consistency with the above regulations, the staff needs clarification of the overall scope (e.g., ESP/LWA) that applies or to which the NDQAM could apply, in addition to the list of activities already mentioned. The staff also recommends deletion of all references to COL activities.

Organization

2. SRP Section 17.5, paragraph II.A.4, states that there should be independence between the organization performing checking functions from the organization responsible for performing the functions. In order to satisfy the Three Mile Island (TMI)-related requirement contained in 10 CFR 50.34(f)(3)(iii)(A), clarify how SNC will implement measures to control the independence of organizations consistent with Section 17.5 of the SRP.
3. SRP Section 17.5, paragraph II.A.7, states that management ensures that the size of the QA organization is commensurate with its duties and responsibilities. In order to satisfy the TMI-related requirement contained in 10 CFR 50.34(f)(3)(iii)(F), clarify how SNC will implement measures to ensure that the size of the QA organization is commensurate with its duties and responsibilities.

Quality Assurance Program

4. SRP Section 17.5, paragraph II.B.1, states that management implementing portions of the QAPD should assess the part of the program for which they are responsible and assure is effective implementation at least once each year or at least once during the life of the activity, which ever is shorter, or may extend it to once every two years. Section 2

of the SNC NDQAM states that senior management is regularly apprised of audit results evaluating the adequacy of implementation of the Nuclear Development Quality Assurance Program (NDQAP) through the audit functions described in the Section 18, Audits, of the NDQAM. Section 2.4 of the SNC NDQAM states that reviews of the status and adequacy of the NDQAP and its implementation will be conducted on an ongoing basis via senior management review of quality assurance audit reports. In addition, Section 18.1 of the SNC NDQAM provides measures for the performance of audits, and states that internal audits of selected aspects of licensing, design and construction phase activities are performed with a frequency commensurate with safety significance and in a manner which assures that audits of safety-related activities are completed. Clarify how the SNC NDQAM will assess the part of the program for which they are responsible and assure is effective implementation consistent with Section 17.5 of the SRP.

5. SRP Section 17.5, paragraph II.S.2, states the qualification requirements for individuals responsible for managing the implementation of the QA plan. Section 2.6 of the SNC NDQAM provides the minimum qualifications of the Quality Assurance Manager and the Nuclear Development Quality Assurance Project Engineer. However, these qualifications do not provide for requirements for management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Clarify how the SNC NDQAM will address these requirements consistent with Section 17.5 of the SRP.
6. SRP Section 17.5, paragraph II.S.3, states the qualification requirements for individuals responsible for planning, implementing, and maintaining the QA plan. Clarify how the SNC NDQAM will provide for these requirements consistent with Section 17.5 of the SRP.

Control of Purchased Material, Equipment, and Services

7. SRP Section 17.5, paragraph II.L.8, states that for procurement of commercial-grade calibration services for safety-related applications, laboratory accreditation programs administered by the National Institute of Standards and Technology and by the American Association for Laboratory Accreditation (A2LA) are acceptable in lieu of a supplier audit, commercial-grade survey, or in-process surveillance, provided that certain conditions are met. Paragraph II.L.8.h also states that the proposed alternative is limited to domestic (within the United States) calibration service suppliers. Clarify how the SNC NDQAM will implement the procurement of commercial-grade calibration services consistent with Section 17.5 of the SRP.

Control of Measuring and Test Equipment

8. SRP Section 17.5, paragraph II.L.4, states that measuring and test equipment are calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration are documented. Section 12 of the SNC NDQAM provides the controls for the calibration of measuring and test equipment, and includes alternate methods for calibration. Clarify if the bases for these alternate calibration methods are documented to ensure consistency with

Section 17.5 of the SRP.

Handling, Storage, and Shipping

9. Section 13 of the SNC NDQAM provides measures to control the handling, shipping, and storage of items important to safety. In Section 13.2 of the NDQAM, titled "NQA-1-1994 Commitment/Exceptions," SNC commits to and provides clarifications and exceptions to Basic Requirement 13, Supplement 13S-1, Subpart 2.1, Subpart 2.2, and Subpart 2.3 of NQA-1-1994. The exception to Subpart 2.1 states the following:

"Subpart 2.1, sections 3.1 and 3.2, establish criteria for classifying items into cleanliness classes and requirements for each class. Instead of using the cleanliness level system of Subpart 2.1, SNC plants may establish cleanliness requirements on a case-by-case basis, consistent with the other provisions of Subpart 2.1. SNC establishes appropriate cleanliness controls for work on safety related equipment to minimize introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities, including documented verification of absence of foreign materials prior to system closure."

Describe how SNC will implement measures to control the cleaning of materials and components without implementing the cleanliness level system of Section 3.2 of Subpart 2.1, to ensure consistency with RG 1.37, Revision 1. In addition, the staff recommends removing the last sentence of this paragraph since it only applies to operational quality assurance program descriptions, as stated in Section 17.5, paragraph II.M.8, of the SRP.

10. In Section 13.2 of the NDQAM, titled "NQA-1-1994 Commitment/Exceptions," SNC commits to and provides clarifications and exceptions to Subpart 2.2 of NQA-1-1994. The first exception to Subpart 2.2 states the following:

"Subpart 2.2, sections 3.2 and 3.5: For items in storage, as determined by facility management, the packaging requirements described under section 3, Packaging, may include alternate methods of affording required protection such as maintaining a storage atmosphere free from harmful contaminants in concentrations that could produce damage to the stored items, or utilizing storage practices that obviate the need for capping all openings."

Describe how SNC will implement measures to ensure protection of items during storage against corrosion, contamination, physical damage, or any other effect that would lower the quality of the items, consistent with the four levels of protection described in Section 2 of Subpart 2.2.

11. RG 1.38, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants," Revision 2, describes quality assurance requirements for the packaging, shipping, receiving, storage, and handling of items. The RG endorses the guidance contained in ANSI N45.2.2-1972, "Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants." Section 13.2 of the NDQAM establishes the commitment to

NQA-1-1994, Subpart 2.2, and includes clarifications and exceptions to these requirements. The third exception to Subpart 2.2 states the following:

“Subpart 2.2, section 7.1 refers to Subpart 2.15 for requirements related to handling of items. The scope of Subpart 2.15 includes hoisting, rigging and transporting of items for nuclear power plants. This scope exceeds the scope of the NRC’s original endorsement of ANSI N45.2.2 in Regulatory Guide 1.38, and establishes requirements for which there is no NRC regulatory position. In lieu of compliance with Subpart 2.15, SNC establishes and implements controls over hoisting, rigging and transport activities to the extent necessary to protect the integrity of the items involved, as well as potentially affected nearby structures and components. For re-rating of lifting equipment to allow “special lifts,” SNC performs dynamic load testing over the full range of the lift using test loads at least 110% of the lift weight. Dynamic tests include raising, lowering and traversing the load. Where required, SNC complies with applicable hoisting, rigging and transportation regulations and codes.”

The staff request SNC to describe the extent of the program for hoisting, rigging and transport activities, including exceptions to Subpart 2.15, if any.

Corrective Action

12. SRP Section 17.5, paragraph II.P.3, states that specific responsibilities within the corrective action program may be delegated, but the applicant or holder maintains responsibility for the program’s effectiveness. Section 16 of the SNC NDQAM does not explicitly address these criteria. Clarify how the SNC NDQAM will provide for this requirement consistent with Section 17.5 of the SRP.
13. SRP Section 17.5, paragraph II.P.4, states that the corrective action program should require all personnel to identify conditions that are adverse to quality. Section 16 of the SNC NDQAM does not explicitly address these criteria. Clarify how the SNC NDQAM will provide for this requirement consistent with Section 17.5 of the SRP.

Quality Assurance Records

14. SRP Section 17.5, paragraph II.Q.4, states that document access controls, user privileges, and other appropriate security controls must be established. The SNC NDQAM does not provide measures for security control of records. Clarify how the SNC NDQAM will implement measures to provide document access controls and security controls consistent with Section 17.5 of the SRP.
15. SRP Section 17.5, paragraph II.Q.5, states, in part, that design documentation and records include not only the final design documents, such as drawings and specifications, and revisions thereto, but also documentation which identifies the important steps, including sources of design inputs that support the final design. The SNC NDQAM does not provide measures for incorporation of documentation of design input sources that support the final design as part of the record retention program. Clarify how the SNC NDQAM will implement measures to control design records consistent with Section 17.5 of the SRP.

Audits

16. SRP Section 17.5, paragraph II.R.5, states that periodic inspections of systems, software applications, and media are performed to ensure electronic records retrievability, integrity, and retention period. Clarify how the SNC NDQAM will implement measures to inspect electronic record systems, software applications, and media consistent with Section 17.5 of the SRP.
17. SRP Section 17.5, paragraph II.R.10, states that when any work carried out under the requirements of the QA program is delegated to others, the work is to be audited by the QA audit program. Clarify how the SNC NDQAM will provide measures to address the audit of QA program requirements delegated to others, consistent with Section 17.5 of the SRP.

Regulatory Commitments

18. SRP Section 17.5, paragraph II.U.1, states that the applicant commits to the most recent revision of the regulatory guides (RGs). Part III of the SNC NDQAM commits to revision 3 of RGs 1.26, 1.29, and RG 1.97. RGs 1.26 and 1.29 were revised in March 2007, and RG 1.97 was revised in June 2006. Justify why the SNC NDQAM does not commit to the latest revisions of these RGs consistent with Section 17.5 of the SRP.
19. SRP Section 17.5, paragraph II.U.1, states that the applicant commits to the most recent revision of the regulatory guides (RGs). Part III of the SNC NDQAM does not include a commitment to RG 1.37. Justify why the SNC NDQAM does not commit to the latest revision of this RG, consistent with Section 17.5 of the SRP. SRP Section 17.5, paragraph II.U.2, states that the applicant commits to the standards listed in this section. Part III of the SNC NDQAM does not include a commitment to Subpart 2.20 of NQA-1-1994. Justify why the SNC NDQAM does not commit to this Subpart, consistent with Section 17.5 of the SRP.
20. SRP Section 17.5, paragraph II.U.2, states that the applicant commits to the standards listed under that section. Part III of the SNC NDQAM does not commit to Subpart 2.20 of NQA-1-1994. Justify why the SNC NDQAM does not commit to Subpart 2.20 of NQA-1-1994 consistent with Section 17.5 of the SRP.