ClinchRiverESPHFNPEm Resource

From: Fetter, Allen
Sent: Friday, February 09, 2018 3:36 PM
To: Schiele, Raymond Joseph; Stout, Daniel Paul
Cc: ClinchRiverESPSafNPEm Resource; Jackson, Terry; Savwoir, Nicholas; Kavanagh, Kerri; Colaccino, Joseph; Sutton, Mallecia
Subject: Draft RAI pertaining to Section 17.5, Quality Assurance Program Description (RAI Number 12, eRAI-8798)
Attachments: CRNS ESP Draft QA01_eRAI_8798.pdf

Good Afternoon,

Attached is a draft RAI pertaining to Section 17.5, Quality Assurance Program Description (RAI Number 12, eRAI-8798), for the Clinch River Nuclear Site ESP application review.

This is the 12th draft safety RAI prepared (Number 12) for the Clinch River Nuclear Site ESP application review, and it has a unique e-RAI identifying number of eRAI-8798.

TVA has ten working days to review this draft RAI and to decide whether a conference call is needed to clarify any of portion of the RAI and/or if TVA identifies any proprietary information or security-related information (SRI) located in the question(s). After the call, or after ten days, NRC will finish processing the RAI through the eRAI system and issue it to TVA as a final RAI. Subsequent to receipt of the final RAI, TVA will have 30 calendar days to respond to the RAI unless additional time is specifically requested.

Please let me know if you have any questions.

Thanks,

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Draft Request for Additional Information, Number 12, eRAI-8798
Draft Issue Date: 02/09/18
Application Title: Clinch River Nuclear Site, ESP
Operating Company: Tennessee Valley Authority
Docket No. 52-047
Review Section: 17.5 - Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants
Application Section: 17.5

QUESTIONS

17.5-01

Provide a gap analysis and supporting documentation, including SSAR markups, as necessary, to demonstrate how the Tennessee Valley Authority (TVA) Nuclear Quality Assurance Program (NQAP) description meets the requirements of 10 CFR 52.17(a)(1)(xi) and (xii) for an early site permit application (ESP).

Title 10 of the *Code of Federal Regulations* (10 CFR), “Domestic Licensing of Production and Utilization Facilities,” Part 52.17(a)(1)(xii) requires, in part, an evaluation of the site against the applicable sections of the Standard Review Plan (SRP) that are in effect 6 months prior to the docket date of the application. The evaluation should address all differences in analytical techniques and procedural measures proposed for a site and those corresponding techniques and measures given in the SRP acceptance criteria. Where such a difference exists, the evaluation shall discuss how the proposed alternative provides an acceptable method of compliance.

TVA submitted their application for an ESP in accordance with the requirements of 10 CFR Part 52. TVA states the site suitability quality assurance program for the Clinch River ESP is carried out in accordance with TVA’s NQAP which commits to Regulatory Guide (RG) 1.28, “Quality Assurance Program Criteria (Design and Construction),” Revision 3 (which endorses ANSI N.45.2-1971). Guidance in the latest revision of the SRP, Chapter 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," Revision 1, is aligned with RG 1.28, Revision 4, and ASME NQA-1-1994 or ASME NQA-1-2008/2009a. RG 1.28, Revision 4, was in effect more than six months prior to submittal of the ESP application, and it extends the scope of the NRC’s endorsement to include Part II of ASME NQA-1. Part II contains amplifying quality assurance (QA) requirements for certain site-specific work activities occurring at various stages of a facility’s life. Work activities include, but are not limited to, management, planning, site investigation, design, computer software use, commercial-grade dedication, procurement, fabrication, installation, inspection, and testing. Describe how TVA’s NQAP addresses the differences between RG 1.28, Revisions 3 and 4; particularly with regards to ASME NQA-1, Part II.

Additionally, TVA’s NQAP Section 14.1, “Regulations,” does not reference 10 CFR Part 52 nor provide an indication the NQAP commits to 10 CFR Part 52. Address the applicability of 10 CFR Part 52 to the TVA NQAP.

17.5-02

Describe the organizational elements which function under the cognizance of the QA program specifically for small modular reactor (SMR) activities at the Clinch River site.

10 CFR Part 50, Appendix B, Criterion I, “Organization,” states, in part, “The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing.” Neither Section 4.1.8, “Small Modular Reactor,” nor Appendix I, “TVA NQAP Organization Chart,” of the TVA NQAP clearly identify the organizational elements which function under the cognizance of the QA program for an SMR at the Clinch River site. QA programs encompass organizational elements such as design, engineering, procurement, manufacturing, construction, inspection, test, instrumentation and control, nuclear engineering, operations and maintenance, and the lines of responsibility. Describe the organizational elements which function under the cognizance of the QA program specifically for SMR activities at the Clinch River site.

17.5-03

Describe how the management position responsible for quality assurance of small module reactors has the responsibility and authority to apply the appropriate NQAP requirements for new nuclear generation projects.

10 CFR Part 50, Appendix B, Criterion I, “Organization,” states, in part, “The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing.” It is unclear how the management position responsible for SMRs, as discussed in TVA NQAP Section 4.1.8, has the responsibility and authority delegated to apply the appropriate NQAP requirements of the new nuclear generation projects. Describe the scope of responsibility and authority of the management position responsible for SMRs at the Clinch River site.

17.5-04

Clarify how TVA’s NQAP ensures effective implementation of the SMR Project QA program independent assessment at the Clinch River site.

10 CFR Part 50, Appendix B, Criterion II, “Quality Assurance Program,” states, in part, “The applicant shall regularly review the status and adequacy of the quality assurance program. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.” TVA NQAP, Section 3.3.3, does not specify how TVA ensures effective implementation of the independent assessment for the site (Clinch River) in the ESP application. TVA’s NQAP, Revision 34, does not mention Clinch River, nor provide any indication of Clinch River as stated in the ESP application. Address how the status and adequacy of the quality assurance program related to the Clinch River site would be reviewed.

17.5-05

Describe how the TVA NQAP provides measures, instructions, controls and procedures required for computer tests, including (as appropriate) verification tests, hardware integration tests, and in-use tests. In addition, address the verification of design and analysis software for acceptability to use on quality-related activities associated with the Clinch River site.

10 CFR Part 50, Appendix B, Criterion III, “Design Control,” states, in part, the design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The TVA NQAP does not provide design control measures for computer tests. For instance, the NQAP does not demonstrate it satisfies design control quality assurance requirements in lieu of Supplement 11 S-2, "Supplementary Requirements for Computer Program Testing," and Subpart 2.7, “Quality Assurance Requirements of Computer Software for Nuclear Facility Applications,” of ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a. Describe the quality assurance processes used to verify computer design, test and analyses results associated with the Clinch River site activities.

17.5-06

Clarify how the following conditions in NEI 14-05, "Guidelines for the use of Accreditation in lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services" (ML14322A535) are addressed in the applicant’s NQAP.

a. A documented review of the supplier’s accreditation is performed.

b. The NRC’s endorsement of NEI 14-05 provides a QA alternative in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process acceptance method; however, not in lieu of an audit.

c. At receipt inspection, accreditation is validated to ensure that licensees and suppliers of basic components verify there is objective evidence that the laboratory has certified that it provided the service in accordance with its accredited ISO/IEC 17025:2005 program.

10 CFR Part 50, Appendix B, Criterion VII, “Control of Purchased Material, Equipment, and Services,” states, in part, “measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear power plant or fuel reprocessing plant site prior to installation or use of such material and equipment.” NEI 14-05 states, in part, licensees and suppliers of basic components may use the International Laboratory Accreditation Cooperation (ILAC) process in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process. Furthermore, conditions are required that licensees and suppliers of basic components verify, at receipt inspection, that there is objective evidence that the laboratory provided the service in accordance with its accredited ISO/IEC 17025:2005 program and scope of accreditation and have complied with any other requirements specified in the procurement documents. The TVA NQAP lists the majority of NEI 14-05 conditions that licensees and suppliers of basic components must follow to accept the accreditation of calibration and test laboratory services by ILAC Mutual Recognition Agreement signatories. However, the TVA NQAP does not ensure the review of ILAC accreditation is a documented process or procedure per Section 4.3.2 of NEI 14-05. Second, TVA NQAP, Section 15, provides the definition of an audit and considers that ILAC can be used in lieu of an audit of a supplier. However, NEI 14-05 does not state the ILAC process is acceptable in lieu of audits, but rather it is acceptable for use in lieu of a commercial grade survey as part of the commercial grade dedication process. Third, TVA does not demonstrate the NQAP provides controls to validate accreditation during receipt inspection. The dedication of

the calibration and testing service is not complete until a documented review of the calibration and testing records has been performed to assure that all of the purchase order requirements have been met.

17.5-07

Clarify how the TVA NQAP provides measures to notify affected organizations in regards to nonconforming items.

10 CFR Part 50, Appendix B, Criterion XV, “Nonconforming Materials, Parts, or Components,” states, in part, that measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures. The TVA NQAP does not establish controls for the notification to affected organizations. Describe the controls to notify affected organizations of nonconforming materials, parts, or components.

17.5-08

Identify the documents that are considered quality assurance records as it relates to the Clinch River ESP application.

10 CFR Part 50, Appendix B, Criterion XVII, “Quality Assurance Records” states, in part, the records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. TVA NQAP, Sections 6.3.2 and 6.3.3, list quality assurance record program elements and responsibilities. However, it fails to identify the types of documents that are to be included as quality assurance records. Identify the types of documents that should be included as quality assurance records as it relates to the Clinch River ESP application.

17.5-09

Describe how the TVA NQAP controls electronic quality records with respect to training, responsible individuals, identification, retention, mitigation, regeneration, record authentication, data transfer, electronic record storage, and electronic record correction as described in RIS 2000-18 and NIRMA (TG-11,15,16, and 21).

10 CFR Part 50, Appendix B, Criterion XVII, “Quality Assurance Records” states, in part, that sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records shall be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility. TVA commits to ANSI N45.2.9-1974, but the controls established in the TVA NQAP and supporting Nuclear Power Group (NPG) procedures do not demonstrate how the NQAP satisfies controls and measures for electronic records as described in RIS 2000-18 and NIRMA (TG-11,15,16, and 21). Describe the controls and measures for quality-related electronic records.

17.5-10

Describe how the applicant demonstrates subsurface investigations and related data usage, performed by TVA contractors and subcontractors, address quality assurance criteria in Subpart 2.20 of ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a for sub-surface investigations in accordance with 10 CFR 52.17(a)(1)(xi) and (a)(1)(xii).

10 CFR 52.17(1)(a)(xi) requires that ESP applications provide a description of the QA program 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 TVA NQAP does not address quality assurance requirements for sub-surface investigations. Provide a description of site-specific, safety-related design basis activities in the quality assurance program. Site-specific, safety-related design basis activities are defined as those activities, including sampling, testing, data collection, and supporting engineering calculations and reports, that will be used to determine the bounding physical parameters of the site.