Tennessee Valley Authority, 1101 Market Street, Chattanooga, TN 37402

CNL-18-049

April 9, 2018

10 CFR 52, Subpart A

ATTN: Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Clinch River Nuclear Site
NRC Docket No. 52-047

Subject: Response to NRC Request for Additional Information 12 in Support of Early Site Permit Application for Clinch River Nuclear Site

References:
1. Letter from TVA to NRC, CNL-17-151, "Revision 1 of Application for Early Site Permit for Clinch River Nuclear Site," dated December 15, 2017
2. NRC Electronic Mail, "CRNS ESP Final QA01_eRAI_8798.pdf," dated March 9, 2018

By letter dated December 15, 2017 (Reference 1), Tennessee Valley Authority submitted Revision 1 of the application for an early site permit for the Clinch River Nuclear (CRN) Site in Oak Ridge, TN. By electronic mail dated March 9, 2018 (Reference 2), Nuclear Regulatory Commission (NRC) issued requests for additional information regarding the Quality Assurance Program as it applies to the CRN Site.

The enclosure to this letter provides the responses to the NRC questions posed in Reference 2.

There are no new regulatory commitments associated with this submittal. If any additional information is needed, please contact Dan Stout at (423) 751-7642.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 9th day of April 2018.

Respectfully,

J. W. Shea
Vice President, Nuclear Regulatory Affairs and Support Services

Enclosure:

cc: See Page 2

Enclosure

Response to NRC Request for Additional Information 12

cc (enclosure):

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M. Sutton, Project Manager, Division of New Reactor Licensing, USNRC

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Response to NRC Request for Additional Information 12

By letter dated December 15, 2017 (Reference 1), Tennessee Valley Authority (TVA) submitted Revision 1 of the application for an early site permit for the Clinch River Nuclear (CRN) Site in Oak Ridge, TN. Included in CRN Site Early Site Permit Application (ESPA), Revision 1, was an updated version of Site Safety Analyses Report (SSAR) Section 17.5, *Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants*. By electronic mail dated March 9, 2018 (Reference 2), Nuclear Regulatory Commission (NRC) issued requests for additional information regarding the Quality Assurance Program as it applies to the CRN Site.

As a part of analysis performed to compare the criteria and commitments in NUREG-0800, *Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants - LWR Edition*, Section 17.5, Revision 1 (SRP 17.5), with the description and commitments contained in the TVA Nuclear Quality Assurance Program (NQAP), several changes to the TVA NQAP were identified. The changes are required to resolve gaps between the SRP 17.5 Acceptance Criteria and the TVA NQAP, to provide clarifications of conformance, and propose alternatives to some of the SRP 17.5 Acceptance Criteria and commitments. The TVA NQAP revision is in-process and is anticipated to be available during the upcoming NRC Quality Assurance Inspection.

As the result of the in-process revisions being made to the TVA NQAP, the CRN Site ESPA, Part 2, Site Safety Analysis Report (SSAR), Section 17.5, will also require revision. It is anticipated that a revised SSAR Section 17.5, as well as other conforming ESPA changes, will be available during the upcoming NRC Quality Assurance Inspection. These changes to the ESPA will be submitted by May 31, 2018.

NRC Question 17.5-01

Gap Analysis Summary

Provide a description of where gaps exist and how they will be resolved to demonstrate that 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.

TVA Response

a. To address the request to describe where gaps exist and how the gaps will be resolved, TVA compared the criteria and commitments in NUREG-0800, *Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants - LWR Edition*, Section 17.5, Revision 1 (SRP 17.5), with the description and commitments contained in the TVA NQAP. Although several of the SRP 17.5 criteria and commitments were not included in the TVA NQAP, some of the SRP 17.5 criteria and commitments were not applicable to the CRN Site ESPA. This determination was informed by either the criterion or commitment being marked as "not applicable" in the SRP or the criterion or commitment did not apply to site suitability QA activities associated with the CRN Site ESPA.

   A majority of the applicable SRP 17.5 criteria and commitments were determined to by met by the current TVA NQAP. For the remaining SRP 17.5 criteria and commitments, TVA is in the process of either revising the NQAP to conform with the SRP 17.5 criteria and commitments or is proposing an alternative that provides an acceptable method of compliance. TVA has initiated condition reports in the Corrective Action Program to identify and address these differences. The identified differences are addressed as follows:

   - A revision is in-process to the main body of the TVA NQAP to address the identified gaps with SRP 17.5 Acceptance Criteria F.4, G.12, Q.7, Q.10, Q.11, Q.12, Q.13, Q.14, Q.15, Q.16, R.6, and commitments within SRP 17.5 Acceptance Criterion V.2, items i through m (NIRMA [Nuclear Information and Records Management Association]) electronic records management guidelines). These TVA NQAP revisions are summarized in Table 1 below.

   - A revision is in-process to add Appendices K, L, and M to the TVA NQAP that will only apply to the CRN Site. These appendices will address the identified gaps with SRP 17.5 Acceptance Criteria Q.1, Q.2, and Q.3, and commitments to the following documents contained in Acceptance Criterion V.1.a, b, d, and e: RG 1.26, *Quality Group Classifications and Standards For Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants*, Revision 4, RG 1.29, *Seismic Design Classification for Nuclear Power Plants*, Revision 5, Generic Letter (GL) 89-02, *Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products*,

and GL 91-05, *Licensee Commercial-Grade Procurement and Dedication Programs*. These TVA NQAP revisions are summarized in Table 1 below.

In addition to addressing the above identified gaps with SRP 17.5, a revision is in-process to add proposed alternatives to the following SRP 17.5 Acceptance Criteria and commitments that apply to the CRN Site, thereby providing an acceptable method of compliance. These proposed alternatives will appear in TVA NQAP, Appendix M.

- S.4 - Qualification of Auditors

  Alternative: The current TVA NQAP complies with the S.4 criterion with the exception of the participation in five audits. TVA complies with RG 1.146 with an alternative to ANSI N45.2.23 to replace the five audit requirement.

- V.1.c - RG 1.37, *Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants*, Revision 1

  Alternative: TVA currently commits to RG 1.37, Revision 0. TVA will add a commitment to the applicable regulatory position guidance in RG 1.37, Revision 1, with the following alternatives:

  Regulatory Position (RP) C.1: TVA commits to ANSI N45.2.1. Acceptable Codes and Standards are identified in ANSI N45.2.1, Sections 3 and 12. This position is an equivalent RG 1.37, Revision 1, RP C.1.

  Regulatory Position C.2: TVA commits to ANSI N45.2.1. ANSI N45.2.1, Section 3.4, with the following clarification, “The water quality for final flushes of fluid systems and associated components should be at least equivalent to the quality of the operating system water.” This position is an equivalent RG 1.37, Revision 1, RP C.2.

  Regulatory Position C.3: In lieu of the commitments identified in this position, TVA commits to ANSI N45.2.1 and ANSI N45.2.15. These standards are equivalent to the referenced ASME NQA-1-1994 parts. In addition, the following clarification is added: A suitable chloride stress cracking inhibitor should be added to the fresh water used to flush systems containing austenitic stainless steels. This position is an equivalent RG 1.37, Revision 1, RP C.3.

- V.2.a - Subpart 2.2 of ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition

  Alternative: TVA currently commits to ANSI N45.2.2 - 1972, with alternatives listed in TVA NQAP Appendix B, Table 2.

- V.2.b - Subpart 2.4 of ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition

  Alternative: TVA currently commits to ANSI N45.2.4 - 1972, with alternatives listed in TVA NQAP Appendix B, Table 2.

- V.2.c - Subpart 2.5 of ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition

Alternative: TVA currently commits to ANSI N45.2.5 - 1974, with alternatives listed in TVA NQAP Appendix B, Table 2.

- V.2.d - Subpart 2.7 of ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition

  Alternative: TVA currently commits to RG 1.152, *Criteria for Use of Computers in Safety Systems of Nuclear Power Plants*, Revision 0, with alternatives listed in TVA NQAP Appendix B, Table 2. TVA will add a commitment to the applicable regulatory position guidance in RG 1.152, Revision 3.

- V.2.e - Subpart 2.8 of ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition

  Alternative: TVA currently commits to ANSI N45.2.8 - 1975, with alternatives listed in TVA NQAP Appendix B, Table 2.

- V.2.f - Subpart 2.14 of ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition

  Alternative: TVA currently commits to RG 1.123, *Quality Assurance Requirements for Control of Procurement of Items and Service for Nuclear Power Plants*, with alternatives listed in TVA NQAP Appendix B, Table 2. TVA will add commitments to GL 89-02 and GL 91-05.

- V.2.g - Subpart 2.15 of ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition

  Alternative: TVA will add a commitment to ANSI N45.2.15 - 1972

- V.2.h - Subpart 2.20 of ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition

  Alternative: TVA will add a commitment to ANSI N45.2.20 - 1979

b. With regard to the request to address the differences between RG 1.28, Revision 3, and RG 1.28, Revision 4, in the TVA NQAP, TVA identified that RG 1.28, Revision 4, added the NRC's endorsement of NQA-1, Part II. NQA-1, Part II contains amplifying QA requirements for certain specific work activities that occur at various stages of a facility's life. A revision to the TVA NQAP is in-process to add Appendix M to the TVA NQAP that will include CRN Site commitments to equivalents or alternatives to the documents endorsed in RG 1.28, Revision 4, Appendix A, Table A-3.

c. With regard to the request to address the applicability of 10 CFR Part 52 to the TVA NQAP, a revision is in-process for TVA NQAP, Section 14.1, "Regulations." The revision will add a reference to 10 CFR Part 52. In addition, Appendix K is being added that will describe the methods and establish QA and administrative control requirements that meet 10 CFR 50, Appendix B, and 10 CFR 52 for the CRN Site.

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Table 1

SRP Criterion	Identified TVA NQAP Gap	Resolution
F.4	No commitment to RIS 2000-18.	TVA NQAP Section 6.3.1 and Appendix B, Table 1, are being revised to incorporate the requirements of ANSI/ANS-3.2.2012, Section 3.17, which is consistent with the intent of RIS 2000-18 and the associated NIRMA Technical Guides (TGs).
G.12	Performance of a documented review of supplier's accreditation not clearly specified. No reference to supplier's ISO/IEC 17025-2005 program.	TVA NQAP, Appendix B, Table 2, is being revised to ensure performance of a documented review of supplier's accreditation, replace the term "audit" with the term "survey," and require validation to be performed at receipt inspection in accordance with supplier's ISO/IEC 17025:2005 program and that all purchase order requirements have been met.
Q.1	No mention of the specific CRN records that should be stored and maintained.	Adding list of typical CRN ESP QA records to Appendix K of the TVA NQAP.
Q.2	No mention of the specific CRN records that should be stored and maintained.	Adding list of typical CRN ESP QA records to Appendix K of the TVA NQAP.
Q.3	No mention of the specific CRN records that should be stored and maintained.	Adding list of typical CRN ESP QA records to Appendix K of the TVA NQAP.
Q.7	No commitment to Regulatory Issue Summary (RIS) 2000-18.	TVA NQAP Section 6.3.1 and Appendix B, Table 1, are being revised to incorporate the requirements of ANSI/ANS-3.2.2012, Section 3.17, which is consistent with the intent of RIS 2000-18 and the associated NIRMA TGs.
Q.10	No commitment to RIS 2000-18.	TVA NQAP Section 6.3.1 and Appendix B, Table 1, are being revised to incorporate the requirements of ANSI/ANS- 3.2.2012, Section 3.17, which is consistent with the intent of RIS 2000-18 and the associated NIRMA TGs.
Q.11	No commitment to RIS 2000-18.	TVA NQAP Section 6.3.1 and Appendix B, Table 1, are being revised to incorporate the requirements of ANSI/ANS- 3.2.2012, Section 3.17, which is consistent with the intent of RIS 2000-18 and the associated NIRMA TGs.
Q.12	No commitment to RIS 2000-18.	TVA NQAP Section 6.3.1 and Appendix B, Table 1, are being revised to incorporate the requirements of ANSI/ANS- 3.2.2012, Section 3.17, which is consistent with the intent of RIS 2000-18 and the associated NIRMA TGs.

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Table 1

SRP Criterion	Identified TVA NQAP Gap	Resolution
Q.13	No commitment to RIS 2000-18.	TVA NQAP Section 6.3.1 and Appendix B, Table 1, are being revised to incorporate the requirements of ANSI/ANS- 3.2.2012, Section 3.17, which is consistent with the intent of RIS 2000-18 and the associated NIRMA TGs.
Q.14	No commitment to RIS 2000-18.	TVA NQAP Section 6.3.1 and Appendix B, Table 1, are being revised to incorporate the requirements of ANSI/ANS- 3.2.2012, Section 3.17, which is consistent with the intent of RIS 2000-18 and the associated NIRMA TGs.
Q.15	No commitment to RIS 2000-18.	TVA NQAP Section 6.3.1 and Appendix B, Table 1, are being revised to incorporate the requirements of ANSI/ANS- 3.2.2012, Section 3.17, which is consistent with the intent of RIS 2000-18 and the associated NIRMA TGs.
Q.16	No commitment to RIS 2000-18.	TVA NQAP Section 6.3.1 and Appendix B, Table 1, are being revised to incorporate the requirements of ANSI/ANS- 3.2.2012, Section 3.17, which is consistent with the intent of RIS 2000-18 and the associated NIRMA TGs.
R.6	No commitment to RIS 2000-18.	TVA NQAP Section 6.3.1 and Appendix B, Table 1, are being revised to incorporate the requirements of ANSI/ANS- 3.2.2012, Section 3.17, which is consistent with the intent of RIS 2000-18 and the associated NIRMA TGs.
V.1.a RG 1.26, Rev 4	No commitment to RG 1.26.	Adding Appendix M to the TVA NQAP for CRN to commit to the applicable regulatory position guidance in RG 1.26, Revision 4.
V.1.b RG 1.29, Rev 5	No commitment to RG 1.29.	Adding Appendix M to the TVA NQAP for CRN to commit to the applicable regulatory position guidance in RG 1.29, Revision 5.
V.1.d GL 89-02	No commitment to GL 89-02.	Adding Appendix M to the TVA NQAP for CRN to commit to GL 89-02.
V.1.e GL 91-05	No commitment to GL 91-05.	Adding Appendix M to the TVA NQAP for CRN to commit to GL 91-05.

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Table 1

SRP Criterion	Identified TVA NQAP Gap	Resolution
V.2, items i through m (NIRMA electronic records management)	No commitment to the NIRMA TGs.	TVA NQAP Section 6.3.1 and Appendix B, Table 1, are being revised to incorporate the requirements of ANSI/ANS- 3.2.2012, Section 3.17, which is consistent with the intent of RIS 2000-18 and the associated NIRMA TGs.

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NRC Question 17.5-02

Organizational Elements

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 tructures, 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.

TVA Response

The CRN ESP QA Program is the top-level policy document that establishes the quality assurance policy and assigns major functional responsibilities for ESP activities conducted by or for the CRN Site. The TVA NQAP describes the methods and establishes QA and administrative control requirements that meet 10 CFR 50, Appendix B and 10 CFR 52, including organization elements. The organizational elements which function under the QA Program for ESP include design, engineering, licensing, personnel qualifications and training, and procurement. The organizational structure includes offsite and on-site functions including interface responsibilities for multiple organizations performing non-safety-related functions. Implementing documents assign more specific responsibilities and duties, and define the organizations interfaces involved in conducting activities and duties within the scope of the NQAP.

The TVA NQAP is being revised to clarify and describe the organizational elements for the CRN Site. The TVA NQAP revision will describe the TVA organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying the implementation of quality assurance requirements for the CRN Site. The revision will also include an Organization Chart for the CRN Site.

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NRC Question 17.5-03

SMR Management Position

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, and provide a summary of the contents of the implementing procedures.

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.

TVA Response

The management position responsible for SMR Technology is responsible for applying the appropriate NQAP requirements to the development of new nuclear generation projects.

The SMR Technology Manager's responsibilities include:

- Regularly review the status and adequacy of those parts of the NQAP, which they are executing;
- Develop, control, and maintain procedures and instructions as appropriate to implement quality-related activities and processes;
- Ensure appropriate controls for documents and records generated within the organization or received from external sources;
- Ensure appropriate controls are developed and implemented to maintain housekeeping and cleanness requirements of facilities, systems, and components during the performance of work activities;
- Identify and resolve adverse conditions and perform related corrective action activities including assessing trends for internally and externally identified problems;
- Ensure personnel and resources available during audit performance and ensure that audit responses and corrective actions are completed within established timeframes;
- Develop certification programs as appropriate and ensure that trained, qualified, and, where required, certified employees are used in the performance of quality-related activities; and
- Initiate stop work within their area of responsibilities when warranted.

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The TVA NQAP is being revised to clarify and describe management position responsible for quality assurance of small module reactors for the CRN Site. The TVA NQAP revision will clarify the responsibilities and include an organization chart for the CRN Site organization.

The NQAP will include responsibilities for the management position responsible for SMR Technology and other CRN Site management positions. These responsibilities are also addressed in implementing procedure, SMRDP-1, "Organization and Responsibilities."

NRC Question 17.5-04

Clinch River Independent Assessment

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.

TVA Response

The 10 CFR 50, Appendix B, Criterion II requirement to regularly review the status and adequacy of the quality assurance program is being satisfied by the TVA NQAP Section 4.1.2.B.

TVA NQAP, Section 4.1.2.B, requires that TVA organizations that work directly under the TVA NQAP "Regularly review the status and adequacy of those parts of the NQAP, which they are executing."

As indicated in NQAP, Appendix B, Table 1, TVA commits to RG 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3. RG 1.28 allows continued implementation of ANSI N45.2-1971, as previously committed. ANSI N45.2, Section 2, states, in part, "The program shall provide for the regular review, by management of organizations participating in the program, of the status and adequacy of that part of the quality assurance program for which they have designated responsibility."

Also, as addressed in the NQAP Policy Statement, line management is responsible for pursuing continuous improvement through self-assessment practices and prudent application of the corrective action program.

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The TVA NQAP is being revised to clarify the applicability of the NQAP to the CRN Site. The TVA NQAP revision will include clarification that line managers for CRN SMR will assess the adequacy of that part of the QA program for which they are responsible and ensure its effective implementation at least once each year.

NRC Question 17.5-05

Not used.

NRC Question 17.5-06

International Laboratory Accreditation Cooperation Conditions

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.

TVA Response

The TVA NQAP is being revised to ensure performance of a documented review of the supplier's accreditation, replace the term "audit" with the term "survey" to be consistent with the guidance provided in NEI 14-05, and require that validation be performed at receipt inspection. The validation will ensure that the contracted calibration or test service has been performed in accordance with the supplier's ISO/IEC 17025:2005 program, has been performed within the scope of the supplier's accreditation, and that all purchase order requirements have been met.

NRC Question 17.5-07

Notifications for Affected Organizations

Clarify how the TVA NQAP provides measures to notify affected organizations in regards to nonconforming items and provide a summary of the contents of the implementing procedures.

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.

TVA Response

10 CFR 50, Appendix B, Criterion XV requirements to notify affected organizations in regards to nonconforming items is being satisfied by the TVA NQAP Section 10.0, Adverse Conditions. TVA NQAP Section 10.0 requires: "Measures shall be established to ensure that items that do not conform to requirements are controlled to prevent their inadvertent installation or use. Adverse conditions, including nonconforming items …shall be identified, evaluated, corrected, tracked, trended, and when required, reported to appropriate levels of management. Procedures or instructions implementing the corrective action program shall establish the criteria for documenting and tracking adverse conditions."

As indicated in NQAP, Appendix B, Table 1, TVA currently commits to RG 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3, which allows continued implementation of ANSI N45.2-1971. Section 16, Nonconforming Items, states in part: "Measures shall be established and documented to control items, services, or activities which do not conform to requirements. These measures shall include as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations."

In addition, a revision to the TVA NQAP is in-process to add Appendix M to the TVA NQAP that will include CRN Site commitments to equivalents or alternatives to the documents endorsed in RG 1.28, Revision 4, Appendix A, Table A-3. In this case, that equivalent is ANSI N45.2-1971.

The TVA implementing procedures include the appropriate controls by the initiation of the appropriate corrective action program document for nonconforming items.

Nonconforming items identified during ESP activities are documented in the Corrective Action Program. The Corrective Action Program procedures establish the processes and responsibilities for documenting and resolving conditions, including conditions adverse to quality and significant conditions adverse to quality, as required by 10 CFR 50, Appendix B Criterion XVI. The procedures include steps to initiate Condition Reports, screening reviews, reportability reviews, management reviews, review by affected organizations (including engineering reviews if necessary), and disposition approval by management.

For nonconforming items identified during receipt inspection, the implementing procedures include initiation of an Over, Short, Damaged and Discrepant (OSD&D) Report, tagging and segregation requirements, notification to materials management, engineering reviews (if necessary), and disposition approval.

Also, TVA implementing procedures address the reportability reviews, notification reports, and postings required to address 10 CFR Part 21, *Reporting of Defects and Noncompliance*.

NRC Question 17.5-08

Quality Assurance Records

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.

ENCLOSURE

Response to NRC Request for Additional Information 12

TVA Response

The TVA NQAP is being revised to clarify the types of documents to be included as quality assurance records as it relates to the Clinch River ESPA. The revision to the TVA NQAP will clarify that sufficient records be maintained to furnish evidence of activities affecting quality, as related to the Clinch River ESPA, and complies with applicable ANSI N45.2.9-1974 requirements for ESP.

Typical Clinch River ESPA records include but are not limited to: geotechnical data, topographic and geological maps, plot plans showing locations of major structures and explorations, boring logs and logs of explanatory trenches and excavations, geologic profiles showing excavation limits of structures, geophysical data, photographs of soil samples and rock cores, field and final logs of all borings, program or design plan, qualified investigation procedures, procurement control records, personnel qualification records, measuring and test equipment control and calibration records, test records, and procedures.

NRC Question 17.5-09

Electronic Quality Records

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.

ENCLOSURE

Response to NRC Request for Additional Information 12

TVA Response

The NQAP is being revised to address the storage of quality assurance records in electronic media. With respect to electronic media, the revised NQAP will incorporate the requirements of ANSI/ANS-3.2-2012, Section 3.17, which states:

> *The storage of quality assurance records in electronic media shall be consistent with the intent of Regulatory Issue Summary (RIS) 2000-18, dated October 23, 2000 and associated Nuclear Information and Records Management Association (NIRMA) Technical Guides (TGs): NIRMA TG 11-1998, NIRMA TG 15-1998, NIRMA TG 16-1998, and NIRMA TG 21-1998. The guidance of RIS 2000-18 should also be applied to the records keeping and maintenance requirements in other parts of the regulations that accept the storage of records in the form of electronic media.*
>
> *The use of optical disks for electronic records storage and retrieval systems shall comply with the NRC guidance in Generic Letter 88-18.*

NRC Question 17.5-10

Not used.

References

1. Letter from TVA to NRC, CNL-17-151, "Revision 1 of Application for Early Site Permit for Clinch River Nuclear Site," dated December 15, 2017

2. NRC Electronic Mail, "CRNS ESP Final QA01_eRAI_8798.pdf," dated March 9, 2018