FINAL SAFETY EVALUTION BY THE OFFICE OF NUCLEAR REACTOR REGULATION REGARDING THE TOPICAL REPORT ON THE QUALITY ASSURANCE PROGRAM DESCRIPTION FOR THE TENNESSEE VALLEY AUTHORITY NEW NUCLEAR PROGRAM

EPID NO. L-2022-TOP-0055

1.0 INTRODUCTION

By letter dated August 25, 2022 (Reference 1), the Tennessee Valley Authority (TVA) submitted Topical Report (TR) NNP-TR-001-NP, Revision 0, "Quality Assurance Program Description [(QAPD)] for TVA New Nuclear Program," (hereafter referred to as TVA New Nuclear QAPD) to the U.S. Nuclear Regulatory Commission (NRC). In this letter, TVA requested the NRC staff's review and approval of the TVA New Nuclear QAPD to be used to satisfy the quality assurance (QA) requirements for use by nuclear power plant applications submitted in accordance with Title 10 of the *Code of Federal Regulations*, (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," for:

- Limited Work Authorizations (LWA) pursuant to 10 CFR 50.10(d)(3)(i)
- Construction Permit (CP) Applications pursuant to 10 CFR 50.34(a)(7)
- Operating License (OL) Applications pursuant to 10 CFR 50.34(b)(6)(ii)
- Early Site Permit (ESP) Applications pursuant to 10 CFR 52.17(a)(1)(xi)
- Design Certification (DC) Applications pursuant to 10 CFR 52.47(a)(19)
- Combined Operating License (COL) Applications pursuant to 10 CFR 52.79(a)(25) and 10 CFR 52.79(a)(27)
- Standard Design Approval (SDA)) Applications pursuant to 10 CFR 52.137(a)(19)

The TVA New Nuclear QAPD states that since the ESP for the Clinch River Small Modular Reactor (SMR) Project was produced under the TVA-NQA-PLN89-A, "TVA Nuclear Quality Assurance Plan," Revision 39, the quality activities encompassed by this ESP are excluded from compliance with the TVA New Nuclear QAPD. ESPs for future SMR projects will comply with this QAPD.

The TVA New Nuclear QAPD is based on the applicable portions of both Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 and American Society of Mechanical Engineers (ASME) NQA-1-2015, "Quality Assurance Program Requirements for Nuclear Facilities," (Reference 2), as endorsed by NRC Regulatory Guide (RG) 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5 (Reference 3), with certain exceptions and clarifications.

The NRC staff requested additional information by letter dated January 27, 2023 (Reference 4). TVA submitted its response by letter, dated February 22, 2023 (Reference 5), in which TVA included the request for additional information (RAI) responses and Revision 1 of the TVA New Nuclear QAPD, as Enclosures 1 and 2, respectively. The NRC staff provided additional questions to TVA to provide clarifications on the RAI responses and Revision 1 of the TVA New Nuclear QAPD (Reference 6 and 7). In response to these clarification questions, TVA submitted supplemental responses by letter, dated July 7, 2023 (Reference 8), in which TVA included its supplemental responses to the clarification questions and Revision 2 of the TVA New Nuclear QAPD in Enclosures 1 and 2, respectively.

2.0 REGULATORY EVALUATION

The Commission's regulatory requirements related to QA programs are set forth in the following regulations:

- Appendix B to 10 CFR Part 50, which establishes QA requirements for the design, manufacture, construction, and operation of structures, systems, and components (SSCs) that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those SSCs; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying for nuclear power plants and fuel reprocessing plants.

- 10 CFR 50.10(d)(3)(i), which requires an application for LWA to include a safety analysis report that demonstrates that activities conducted under the LWA will be conducted in compliance with the technically relevant Commission requirement in 10 CFR Chapter I applicable to the design of those portions of the facility with the scope of the LWA.

- 10 CFR 50.34(a)(7), which requires an application for a CP to include a description of the quality assurance program (QAP) to be applied to the design, fabrication, construction, and testing of SSCs of the facility. The description of the QAP for a nuclear power plant or a fuel reprocessing plant shall include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

- 10 CFR 50.34(b)(6)(ii), which requires an application for an OL to include information concerning facility operation related to managerial and administrative controls to be used to assure safe operation. The information on the controls to be used for a nuclear power plant or a fuel reprocessing plant shall include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

- 10 CFR 52.17(a)(1)(xi), which requires an application for an ESP to include a description of the QAP applied to site-related activities for the future design, fabrication, construction, and testing of the SSCs of a facility or facilities that may be constructed on the site. The description of the QAP for a nuclear power plant site shall include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

- 10 CFR 52.47(a)(19), which requires an application for a DC to include a description of the QAP applied to the design of the SSCs of the facility. The description of the QAP for a nuclear power plant shall include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 were satisfied.

- 10 CFR 52.79(a)(25), which requires an application for a COL to include a description of the QAP, applied to the design, and to be applied to the fabrication, construction, and testing, of the SSCs of the facility. The description of the QAP for a nuclear power plant must include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 have been and will be satisfied, including a discussion of how the QAP will be implemented.

- 10 CFR 52.79(a)(27), which requires an application for a COL to include a description of the managerial and administrative controls to be used to assure safe operation. Appendix B to 10 CFR Part 50 sets forth the requirements for these controls for nuclear power plants. The information on the controls to be used for a nuclear power plant shall include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

- 10 CFR 52.137(a)(19), which requires an application for an SDA to include a description of the QAP applied to the design of the SSCs of the facility. The description of the QAP for a nuclear power plant shall include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 were satisfied.

3.0 EVALUATION

In evaluating the adequacy of the TVA New Nuclear QAPD, Revision 2, the NRC staff utilized the guidance contained in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants," Revision 1 (Reference 9). Standard Review Plan (SRP) Section 17.5 provides guidance to the NRC staff for the review of a QAPD for DC, ESP, COL, CP, and OL applications. Section 17.5 of the SRP is based on Appendix B to 10 CFR Part 50 and describes regulatory and industry guidance determined to be acceptable methods for meeting the requirements of Appendix B to 10 CFR Part 50. Section 17.5 of the SRP does not specifically address SDAs and LWAs. However, the requirements of Appendix B to 10 CFR Part 50 that would be applied to a COL encompasses the quality-related activities for an SDA or an LWA. The ASME standard NQA-1-2015 Edition, upon which the TVA New Nuclear QAPD is based, is endorsed with certain exceptions and clarifications by the NRC in RG 1.28, Revision 5.

3.1 Quality Assurance Program Overview

TVA states that the TVA New Nuclear QAPD, Revision 2, and associated implementing documents control TVA New Nuclear activities that affect quality of safety-related nuclear plant SSCs and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in-service. The TVA New Nuclear QAPD describes quality controls (QCs) that may be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where other NRC guidance establishes program requirements. The TVA New Nuclear QAPD does not specify the reactor technology that the QAPD is applied to since TVA's intent is to apply the QAPD to any type of reactor technology. TVA will specify the specific reactor technology type when it submits an application for an SDA, a DC, an ESP, a CP, an OL, a COL, or an LWA. Part I, Section 1.1 of the TVA Nuclear QAPD, Revision 2 states, in part, that "the QAPD applies to design phase, construction phase, and operations phase activities, including those in support of SDA, DC, ESP, CP, construction/operation, OL, and COL, and operation activities affecting quality and performance of safety-related SSCs…. [T]he QAPD may be applied to certain activities where regulations other than 10 CFR Part 50 and 10 CFR Part 52 establish QA requirements for activities within their scope." If an application for an SDA, a DC, an ESP, a CP, an OL, a COL, or an LWA, as applicable, intends to credit the approved version of the TVA New Nuclear QAPD TR for activities where the regulations other than 10 CFR Part 50 and Part 52 establish QA requirements, the application must include an analysis that demonstrates the QA requirements

set forth in these other regulations are met by the TVA New Nuclear QAPD. This is Plant Specific Action Item (PSAI) 4.1.

3.1.1 Organization

Part II, Section 1, "Organization," of the TVA New Nuclear QAPD describes the TVA New Nuclear organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The TVA New Nuclear organization is divided into the New Nuclear Program Group and New Nuclear Projects group, as described in the Subsections 3.1.1.1 and 3.1.1.2 of this safety evaluation (SE). In establishing its organizational structure, Part II, Section 1.8 of the TVA New Nuclear QAPD, states that TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 1. Design, engineering, and construction services may be provided to the TVA New Nuclear organization by contractors in accordance with their QAPDs compliant with Appendix B of 10 CFR Part 50, or contractors shall be required to meet the requirements of the TVA New Nuclear QAPD or TVA Fleet QAPD. Note that the NRC has approved the TVA Fleet QAPD, and as such, the contractors adhering to the TVA Fleet QAPD are governed by the NRC staff's SE for the TVA Fleet QAPD.

Figure II.1-1 of the TVA New Nuclear QAPD depicts the reporting relationships, functional responsibilities, and authorities for organizations implementing and supporting the QAP. Part II, Section 1.2.1 of the TVA New Nuclear QAPD states that the Senior Vice President, Engineering and Operations Support has governance, oversight, and support of TVA New Nuclear; however, Figure II.1-1 depicts the Senior Vice President, Engineering and Operations Support only has responsibility over TVA New Nuclear Programs. As such, an application for an SDA, a DC, an ESP, a COL, a CP, an OL, or an LWA that references the TVA New Nuclear QAPD must include an organizational diagram that aligns with the description of the roles and responsibilities of the Senior Vice President, Engineering Operations Support in Part II, Sections 1.2.1 and 1.3.2.2.3 of the TVA New Nuclear QAPD. This is PSAI 4.2.

Part II, Section 1.3.2.2.3, "Operations Phase Management Team," of the TVA New Nuclear QAPD states, "no later than six months prior to fuel load of a unit, those positions which are identified for Operations will be staffed and have the appropriate authority required to perform operations activities under the oversight of the Senior Vice President, Engineering and Operations Support." Part II, Section 1 and Figure II.1-1 in the TVA New Nuclear QAPD do not identify (1) the reporting relationship between the Senior Vice President, Engineering and Operations Support and the Operations Phase Management, and (2) site-specific positions required for operations. As such, an application for a COL or an OL that references the TVA New Nuclear QAPD must include (1) a description of site-specific positions required for operations, and (2) an organizational diagram that depicts these site-specific positions in the organizational structure. This is PSAI 4.3.

3.1.1.1 New Nuclear Program Group

The New Nuclear Program group is responsible for programmatic matters with siting, licensing, and planning for multiple New Nuclear Projects across multiple sites. The New Nuclear Program group operates under the oversight of the General Manager, Quality Assurance, who reports to the Executive Vice President/Chief Nuclear Officer (CNO). The CNO is responsible for supporting the New Nuclear Program activities through the Senior Vice President, Engineering and Operations Support.

The Senior Vice President, Engineering and Operations Support reports directly to the CNO and is responsible for organizations that coordinate and integrate efforts and initiatives into day-to-day TVA Nuclear business. The Senior Vice President, Engineering and Operations is also responsible for governance, oversight, and support of TVA New Nuclear.

The Vice President, New Nuclear Program reports to the Senior Vice President, Nuclear Engineering and Operations Support, and is responsible for nuclear site development, fabrication, supply chain, site characterization, document control and advanced design engineering. The Vice President, New Nuclear Program is responsible for licensing activities related to the New Nuclear Program and New Nuclear Project sites. The Vice President, New Nuclear Programs interfaces with the Vice President, Site Project for project-related advanced nuclear technology development, Licensing, Supply Chain, and Safety during the design phase and for corporate support during construction and operations.

The General Manager, Quality Assurance is the management position responsible for the nuclear operating fleet, vendors, and the TVA New Nuclear Program. While the General Manager, Quality Assurance is responsible for TVA New Nuclear Program, this position does not have the responsibility for verifying the development and effective implementation of the TVA New Nuclear QAPD. The General Manager of New Nuclear Projects, Quality Assurance, has the responsibility for verifying the development and effective implementation of the TVA New Nuclear QAPD.

As discussed in Part II, Section 1.2.2 of the TVA New Nuclear QAPD, the QA function has sufficient independence from other TVA Nuclear Priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas regarding TVA Nuclear activities as appropriate. The QA organization may make recommendations to management regarding improving the quality of work processes. If the QA organization disagrees with any actions taken by the New Nuclear Program group and is unable to obtain resolution, the QA organization shall inform QA management and bring the matter to the attention of the CNO, who will determine the final disposition.

3.1.1.2 New Nuclear Projects Group

The New Nuclear Projects group is responsible for engineering, procurement, construction, startup, and operational development activities of specific projects at designated sites. The New Nuclear Projects group operates under the oversight of the General Manager, New Nuclear Projects Quality Assurance, who reports to the Executive Vice President, Chief Operating Officer (COO). The COO supports the New Nuclear Projects activities through the Senior Vice President, New Nuclear Projects.

The Senior Vice President, New Nuclear Projects is responsible for oversight and execution of design, construction, and operations activities for Site Projects. Responsibilities include oversight and execution of engineering, fabrication, supply chain, and document control during the design phase; and construction, engineering, fabrication, supply chain, construction testing, and document control during the construction phase. The Senior Vice President, New Nuclear Projects is responsible for establishing and managing oversight and execution activities of the Nuclear Steam Supply System (NSSS) Supplier. The NSSS Supplier provides engineering services for plant design and licensing of specific plant types for TVA New Nuclear. The Senior Vice President, New Nuclear Projects is also responsible for establishing and managing oversight and execution activities of the NSSS Supplier and Architecture/Engineering (A/E) Suppliers. As stated in Part II, Section 1.5 of the TVA New Nuclear QAPD, the A/E Suppliers

provide engineering services for the development of the ESP, CP, OL, and COL applications. Because the TVA New Nuclear QAPD encompasses QA-related activities for DC and SDA applications and Part II, Section 1.5 of the TVA New Nuclear QAPD does specify that A/E Suppliers provides engineering services for the development of DC and SDA applications, an application for a DC or an SDA that references the TVA New Nuclear QAPD and intends to have A/E Suppliers for engineering services in support of the DC or SDA application must include a description of the management position that will oversee these A/E Suppliers. This is PSAI 4.4.

During the transition of a New Nuclear project from the design/construction phase to the operational phase, the Senior Vice President, New Nuclear Projects will interface with the Senior Vice President, Engineering and Operations Support to ensure that those positions required to support quality-related operations activities will retain their applicable responsibilities unit it is deemed that they are no longer necessary.

The General Manager, New Nuclear Projects Quality Assurance is the management position responsible for the quality aspects of New Nuclear Projects. The General Manager, New Nuclear Projects Quality Assurance reports to the Senior Vice President, New Nuclear Projects with direct access to the COO on quality issues. The General Manager, Nuclear Projects Quality Assurance is responsible for planning and performing activities to verify the development and effective implementation of the TVA New Nuclear QAPD TR. TVA states that the General Manager, New Nuclear Projects QA functions has sufficient independence from other TVA New Nuclear priorities to bring forward issues affecting safety and quality makes judgements regarding quality in all areas regarding TVA New Nuclear activities, as appropriate. The General Manager, New Nuclear Projects is responsible for assigning a QA supervisor to direct and manage the onsite New Nuclear Project QA.

As TVA stated in Part II, Section 1.3.2.1 of the TVA New Nuclear QAPD, the New Nuclear Projects QA function has sufficient independence from other TVA New Nuclear priorities to bring forward issues affecting safety and quality and makes judgements regarding quality in all areas regarding TVA New Nuclear activities as appropriate. The TVA New Nuclear Projects QA organization may make recommendations to management regarding improving the quality of work processes. If TVA New Nuclear Projects QA organization disagrees with any actions taken by the New Nuclear Projects group and is unable to obtain resolution, the TVA New Nuclear Projects QA organization shall inform QA management and bring the matter to the attention of the COO, who will determine the final disposition.

The Vice President, Site Projects is responsible for the Design Phase, Construction Phase and Operations Phase of a Project. This position is responsible for the oversight of design changes and configuration management. A Design Phase Management Team is responsible for engineering, fabrication, supply chain, document control, and support services. A Construction Phase Management Team is responsible for construction activities, including construction, engineering fabrication, supply chain, construction testing, document control, and other support services. An Operations Phase Management Team is responsible for plant operation activities, including operations, maintenance, engineering, supply chain, startup/preoperation testing, document control and other support services.

3.1.1.3 Authority to Stop Work and QA Organizational Independence

Part II, Section 1.6 of the TVA New Nuclear QAPD establishes the authority and responsibility for (QA and QC) personnel to stop work in progress which is not being done in accordance with

approved procedures or where safety or SSC integrity may be jeopardized. This authority extends to off-site work performed by a supplier that furnishes safety-related materials and service to TVA New Nuclear.

Part II, Section 1.7 of the TVA New Nuclear QAPD establishes the lines of independence between the organization(s) performing checking (QA and QC) functions and the organization performing the functions. This provision is not applicable to design review/verification. Design review/verification is described and evaluated in Section 3.1.3 of this safety evaluation.

3.1.1.4 Technical Evaluation

The NRC staff reviewed the descriptions of the roles and responsibilities of the various positions described in Part I, Section 1 of the TVA New Nuclear QAPD, as described in the preceding sections (Sections 3.1.1.1-3.1.1.3), and concludes that the QAPD adequately describes (1) the QA functions performed by these roles, (2) the positions that are responsible for the establishment and effective implementation of the TVA New Nuclear QA program, and (3) the authority, including the ability to stop work, and responsibilities of positions that perform verification of activities affecting safety-related functions have been correctly performed. The NRC staff also evaluated the authority and organizational independence of persons and organizations performing QA functions and concludes that these persons and organizations have access and report to an appropriate level of management and have the requisite authority and independence. The NRC inspection team verified that TVA New Nuclear will retain responsibility for the QA program should work be delegated to contractors, agents or consultants.

Based on the NRC staff's review of the above information and the commitment to NQA-1-2015, Requirement 1, and subject to the information requested in PSAIs 4.2, 4.3, and 4.4, the NRC staff determined that the TVA New Nuclear QAPD conforms to the guidance of SRP Section 17.5, Subsection II, Item A, "Organization." The NRC staff determined that upon the satisfaction of PSAIs 4.2, 4.3, and 4.4, the TVA New Nuclear Organization's controls comply with the requirements of Criterion I, "Organization," of Appendix B to 10 CFR Part 50.

3.1.2 Quality Assurance Program

3.1.2.1 Applicability and Establishment of the QA Program

Part II, Section 2, "Quality Assurance Program," of the TVA New Nuclear QAPD states that TVA New Nuclear has established the necessary measures and governing procedures to implement the QAP as described in the QAPD for design phase activities and will establish necessary measures and governing procedures for construction and operations phase activities prior to beginning those activities. TVA states that the TVA New Nuclear QAP ensures that activities affecting quality are accomplished under suitably controlled conditions. This section also states that a list or system that identifies SSCs and activities under the control of the New Nuclear QAPD shall be established and maintained at the appropriate facility. Design documents are used as the basis for this list because they include the applicable design standards that will be used to identify safety-related SSCs. Because the TVA New Nuclear QAPD does not provide the applicable standards or methodology for the selection and classification of SSCs, an application for a DC, an SDA, an ESP, a COL, a CP, an OL, or an LWA that references the TVA New Nuclear QAPD must provide this information. This is PSAI 4.5.

Part II, Section 2 of the TVA New Nuclear QAPD states that the objective of the QAP is to assure that TVA New Nuclear generating plants are designed, constructed, and operated in accordance with governing regulations and license requirements. The QAP applies to those quality-related activities that involve the functions of safety-related SSCs associated with the design, fabrication, construction, and testing of the SSCs of the facility and to the managerial and administrative controls to be used to assure safe operations. For the ESP, CP/OL, and/or COL applications, the TVA New Nuclear QAPD also applies to those activities that affect the safety-related site characteristics or analysis of those characteristics. For DC and SDA applications, the TVA New Nuclear QAPD applies to those activities that involve or affect safety-related functions. New Nuclear plant construction will be the responsibility of TVA New Nuclear Projects group. Detailed engineering specifications and construction procedures will be developed as needed to implement the TVA New Nuclear QAPD prior to commencement of pre-construction and/or construction activities.

TVA New Nuclear ensures through a systematic process described in the TVA New Nuclear QAPD that its suppliers of safety-related equipment or services will meet the applicable requirements of Appendix B to 10 CFR Part 50. Delegated responsibilities may be performed under a supplier's or principal contractor's QAP, provided that the supplier or principal contractor has been approved as a supplier in accordance with the TVA New Nuclear QAP or TVA Acceptable Suppliers List.

Part 2, Section 2.4 of the TVA New Nuclear QAPD states that management of those organizations implementing the QA, or portions thereof, will assess the adequacy of that part of the program for which they are responsible to assure its effective implementation, at least once each year or at least once during the life of the activity, whichever is shorter. This section of the QAPD states that for assessing the QAP during the operation phase, the period may be extended to once every two years.

Part II, Section 2.5 of the TVA New Nuclear QAPD states that administrative control of the TVA New Nuclear QAPD will be in accordance with 10 CFR 50.55(f) and 10 CFR 50.54(a).

3.1.2.2 Training Program

Part II, Section 2.6, "Personnel Training and Qualification," of the TVA New Nuclear QAPD, states that TVA New Nuclear establishes and maintains formal indoctrination, training, and qualification as necessary for personnel performing, verifying, or managing activities within the scope of the QAPD to achieve initial proficiency, maintain proficiency, and adapt to technology changes, method, or job responsibilities. Specific minimum qualification requirements are as delineated in the Unit Technical Specifications (TSs). Indoctrination and training include the administrative and technical objectives, requirements of the applicable codes and standards, and the New Nuclear QAPD element to be employed. Training for positions identified in 10 CFR 50.120 is accomplished according to programs accredited by the National Nuclear Accrediting Board of the National Academy of Nuclear Training. Records of personnel training and qualification are maintained. This section of the TVA New Nuclear QAPD also identifies the minimum qualifications for the (1) General Manager, New Nuclear Projects QA, (2) individuals responsible for supervising QA or QC personnel, and (3) individuals that are part of the New Nuclear Projects QA organization responsible for planning, implementing, and maintaining the programs for the New Nuclear QAPD.

Part II, Section 2.7 states that in establishing the qualification and training programs, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 2 and the applicable regulatory

position stated in RG 1.28, Revision 5, specifically Section C.1.a. for lead auditors with the following clarifications and exceptions:

- Section 303.3 Prospective lead auditors, with comparable industry experience, may satisfy the lead auditor qualification requirement of participating in a minimum of five QA audits within a period of 3 years prior to the date of qualification by alternatively demonstrating the ability to properly implement the audit process, effectively organize and report results, and participate in at least one nuclear audit within the year preceding the date of qualification, subject to review and acceptance by the responsible QA organization.

- Section 401(g) requires the date of certification expiration be included on the qualification record. TVA New Nuclear considers the certification expiration date to be the date from the certification or recertification date plus the certification interval time; therefore, the inclusion of a specific certification expiration date on the qualification record is optional.

3.1.2.3 Technical Evaluation

The NRC staff reviewed the descriptions of the measures and controls that are established for TVA New Nuclear QAP in Section 2 of the TVA New Nuclear QAPD, as discussed in Sections 3.1.2.1 and 3.2.2.2 of this safety evaluation. The NRC staff concludes that the QAPD adequately describes measures and controls for (1) ensuring that activities affecting quality are accomplished under suitably controlled conditions, (2) developing and maintaining a list of SSCs and activities under the control of the TVA New Nuclear QAPD in accordance with design documents, (3) identifying the scope of activities the QAPD is applicable to, (4) verifying the effective implementation of the QAP, and (5) establishing a training and qualification program for those personnel implementing elements of the TVA New Nuclear QAPD. Based on this review and subject to the information requested in PSAI 4.5, the NRC staff determined the TVA New Nuclear QAPD conforms to the guidance of SRP Section 17.5, Subsection II, Item B, “Quality Assurance Program,” and Item S, “Training and Qualification Criteria,” and Item T, “Training and Qualification – Inspection and Test.” The NRC staff evaluated the exception taken to compliance with NQA-1-2015, Requirement 2, with respect to lead auditors and determined this exception is acceptable because this exception conforms to the guidance in Section C.1.a of RG 1.28, Revision 5. The NRC staff evaluated the exception taken to compliance with NQA-1-2015, Requirement 2, with respect to date of expiration on the qualification record because the date of certification establishes the expiration date, when combined with the certification interval. The certification interval is normally a function of a code or standard and is identified in the organization’s procedure; therefore, because having both dates on the form is redundant, the NRC staff determined the exception to be acceptable. Therefore, the NRC staff determined that, upon satisfaction of PSAI 4.5, the TVA New Nuclear QAP controls, as described above, comply with the requirements of Criterion II, “Quality Assurance Program,” of Appendix B to 10 CFR Part 50.

3.1.3 Design Control

Part II, Section 3, “Design Control,” of the TVA New Nuclear QAPD states that TVA New Nuclear has established and implements a process to control the design, design changes, and temporary modifications of items that are subject to the provisions of the TVA New Nuclear QAPD. TVA New Nuclear prescribe and document the design activities to the level of detail

necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements. Design documents support the facility design, construction, and operation. The TVA New Nuclear QAPD states that appropriate quality standards and applicable design inputs are identified and documented, and their selection reviewed and approved. Use of existing data will be performed in accordance with NQA-1-2015, Part IV, Subpart 4.2.3, "Guidance on Qualification of Existing Data." The design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within TVA New Nuclear and with suppliers. These provisions assure that design inputs (such as design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions) so that the final design output contains or references appropriate acceptance criteria that can be related to the design input in sufficient detail to permit verification by inspection and test, as required.

Part II, Section 3 of the TVA New Nuclear QAPD states that changes to design inputs, final designs, and field changes, and temporary and permanent modifications are justified and subject to design control measures commensurate with those applied to the original design. Design changes and disposition of nonconformances are reviewed and approved by TVA New Nuclear engineering or by other organizations so authorized by TVA New Nuclear. Procedural control is established for reviewing and approving design documents. Design documents are reviewed[1] by individuals knowledgeable in QA to ensure documents contain the necessary QA requirements.

Part II, Section 3.1, "Design Verification," of the TVA New Nuclear QAPD describe the controls established for design verification to ensure that items, computer programs, and activities subject to the provisions of the TVA New Nuclear QAPD are suitable for their intended application, consistent with their effect on safety. Design verifications are performed by competent individuals or groups other than those who performed the original design but who may be from the same organization. The extent of the design verification required is a function of the importance to safety of the item or computer program under consideration, the complexity of the design, the degree of standardization, state-of-the-art, and the similarity with previously proven design. Testing used to verify the acceptability of a specific design feature demonstrates acceptable performance under conditions that simulate the most adverse design conditions expected for the item's intended use. In cases that TVA New Nuclear cannot complete design verification activities before the design outputs are used by another organization for design work or to support other activities, TVA New Nuclear will complete the requisite design verification activities prior to fuel load for a plant under construction, or before relying on the item to perform its intended design or safety function for an operating plant. Because the TVA New Nuclear QAPD does not specify whether the requisite design verification activities will be completed prior to relying on the design outputs to fulfill completion of ITAAC during construction, a COL application that references this TVA New Nuclear QAPD must provide this information. This is PSAI 4.6. Because the TVA New Nuclear QAPD does not specify whether the requisite design verification activities will be completed prior to relying on the design outputs in fulfilling the required information needed for OL issuance, an application for an OL must provide this information. This is PSAI 4.7. Part II, Section 3.2, "Design Records," state that TVA New Nuclear maintains records sufficient to provide evidence that the design was properly accomplished.

[1] This does not apply to ESP activities.

In establishing its program for design control and verification, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 3, Part II, Subpart 2.7, "Quality Assurance Requirements for Computer Software for Nuclear Facilities Applications," Part II, Subpart 2.14, "Quality Assurance Requirements for Commercial Grade Items and Services," and Part II, Subpart 2.20[2], "Quality Assurance Requirements for Subsurface Investigations for Nuclear Facilities."

The NRC staff evaluated the description of design control measures that TVA New Nuclear established and determined that the TVA New Nuclear QAPD conforms to the guidance within SRP Section 17.5, Subsection II, Item C, "Design Control." Based on this evaluation and TVA New Nuclear's commitment to comply with the Requirements of NQA-1-2015, Requirement 3, Part II, Subparts 2.7, 2.14, and 2.20,[3] the NRC staff determined that upon the satisfaction of PSAIs 4.6 and 4.7, the TVA New Nuclear QAPD complies with the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50.

3.1.4 Procurement Document Control

Part II, Section 4 of the TVA New Nuclear QAPD states that TVA New Nuclear has established the necessary measures and governing procedures to assure that purchased items, computer programs, and service are subject to appropriate quality and technical requirements. These controls include provisions for ensuring (1) applicable technical, regulatory, administrative, quality and reporting requirements are invoked for procurement of items and services, and (2) procurement documents require suppliers to have a documented QA program that meets Appendix B to 10 CFR Part 50, or the supplier may work under TVA New Nuclear approved QAP. In establishing the controls for procurement, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 4, with the following clarifications and exceptions:

- In lieu of requiring suppliers to work under their own QA program in accordance with Section 100 of NQA-1-2015, Requirement 4, the procurement documents may allow suppliers to work under the TVA New Nuclear QAP.

- Sections 300 and 400 of NQA-1-2015, Requirement 4, require the review of technical and QA Program requirements of procurement documents prior to award of a procurement contract and for procurement document changes. TVA states in Section 4.1 of Part I of the TVA New Nuclear QAPD that TVA may review the procurement specification when the specification contains the technical and QA requirements of the procurement contract.

- In lieu of having technical and quality requirements be specified in procurement documents in accordance with Sections 202 and 203 of NQA-1-2015, Requirement 4, for procurement of commercial grade items for use as safety-related items, the procurement document shall contain technical and quality requirements such that the item can be appropriately dedicated in accordance with the TVA New Nuclear QAPD.

The NRC staff reviewed the descriptions of the measures and controls that are established to assure that applicable regulatory requirements, design bases, and other requirements are included in procurement documents or referenced in the documents for procurement of material,

[2] Subpart 2.20 does not apply to Operations activities.
[3] NQA-1-2015 uses the term "Requirements" to refer to certain provisions within NQA-1-2015; when referring to the Requirements of NQA-1-2015, the NRC is using the term in that sense.

equipment, and services in Part II, Section 4 of the TVA New Nuclear QAPD, including a review of exceptions and clarifications taken to compliance with NQA-1-2015, Requirement 4. The NRC staff determined that:

- The exception to Section 100 of NQA-1-2015, Requirement 4 is acceptable because the procurement document will require that a supplier work under the TVA New Nuclear QAP, which based on the conclusions of this SE, meets the requirements of Appendix B to 10 CFR Part 50.

- The clarification to Section 300 and 400 of NQA-1-2015, Requirement 4 is acceptable because TVA New Nuclear may satisfy these sections of Requirement 4 through a review of the procurement specification when the specification contains the technical and QA requirements of the procurement.

- The exception to Sections 202 and 203 of NQA-1-2015, Requirement 4 is acceptable because TVA New Nuclear will include technical and quality requirements in procurement documents for the purchase of commercial grade items that will undergo the dedication process per Part 2, Section 7 of the TVA New Nuclear QAPD in order for TVA New Nuclear to use the commercial grade items as a safety-related item.

- The descriptions of the procurement document control measures conform to the guidance of SRP Section 17.5, Subsection II, Item D, “Procurement Document Control.”

Therefore, the NRC staff determined that the procurement document control measures in the TVA New Nuclear QAPD, as described above, comply with the requirements of Criterion IV, “Procurement Document Control,” of Appendix B to 10 CFR Part 50.

3.1.5 Instructions, Procedures, and Drawings

Part II, Section 5, “Instructions, Procedures, and Drawings” of the TVA New Nuclear QAPD states that TVA New Nuclear has established the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by and performed in accordance with instructions, procedures, or drawings, including, where applicable, qualitative or qualitative acceptance criteria to implement the TVA New Nuclear QAP. This section also establishes the policies that procedures are followed, and in cases when a procedure cannot be followed as written, provisions are established for making changes in accordance with Part II, Section 6 of the TVA New Nuclear QAPD. In addition, provisions are established for when personnel are authorized to depart from approved procedures in cases of emergency, when necessary to prevent injury to personnel or damage to the plant. TVA has established measures to address the applicable content of procedures as described in the “Introduction,” to Part II of NQA-1-2015. Procedures governing tests, inspections, operational activities, and maintenance will include as applicable, initial conditions and prerequisites for the performance of the activity. In establishing procedural controls, TVA New Nuclear commitments to compliance with NQA-1-2015, Requirement 5.

The NRC staff evaluated the description of measures established for ensuring that activities affecting quality are prescribed by and performed in accordance with written procedures in Part II, Section 5 of the TVA New Nuclear QAPD, and determined that these measures conform to the guidance of SRP Section 17.5, Subsection II, Item E, “Instructions, Procedures, and Drawings.” Based on this evaluation and TVA New Nuclear commitments to compliance with

NQA-1-2015, Requirement 5, the NRC staff determined that the TVA New Nuclear QAPD complies with the requirements of Criterion V, “Instructions, Procedures, and Drawings,” of Appendix B to 10 CFR Part 50.

3.1.6 Document Control

Part II, Section 6, “Document Control,” of the TVA New Nuclear QAPD states that TVA New Nuclear has established the necessary measures and governing procedures to control the preparation, issuance, and revision of documents that specify quality requirements or prescribe activities affecting quality to ensure that correct documents are used. This section specifies the controls that are applied to documents and the types of documents to which these controls apply to. Part II, Section 6.1 of the TVA New Nuclear QAPD specifies criteria for document review and approval. Part II, Section 6.2 of the TVA New Nuclear QAPD specifies criteria for revisions to documents, including the approval authority for changes. In establishing provisions for document control, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 6.

The NRC staff evaluated the descriptions of measures and controls that are applied to the issuance and revisions to documents and determined that these measures and controls conform to the guidance within SRP Section 17.5, Subsection II, Item F, “Document Control.” Based on this evaluation and TVA New Nuclear commitments to compliance with NQA-1-2015, Requirement 6, the NRC staff determined that the TVA New Nuclear QAPD complies with the requirements of Criterion VI, “Document Control,” of Appendix B to 10 CFR Part 50.

3.1.7 Control of Purchased Material, Equipment, and Services

Part II, Section 7, “Control of Purchased of Material, Equipment, and Services,” of the TVA New Nuclear QAPD states that TVA New Nuclear has established the necessary measures and governing procedures to control purchased items and services to assure conformance with specified requirements. Such control provides for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services. Part II, Section 7.1 of the TVA New Nuclear QAPD describes measures that will be used to assess the quality of purchased items and services, including evaluation of prospective safety-related items and service suppliers to assure only qualified suppliers are used, use of audits conducted by outside organizations (e.g., Nuclear Procurement Issues Corporation), review of documentation, performance of source verification, pre- and post-installation test, and acceptance inspections and testing of the item prior to relying upon it to perform its intended safety function. Controls are imposed for the selection, determination of suitability for intended use, evaluation, receipt, and acceptance of commercial grade services or items to assure they will perform satisfactorily in-service in safety-related applications. In establishing controls for purchased items and services, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 7 and the applicable regulatory position stated in RG 1.28, Revision 5 with the following clarifications and exceptions:

- TVA New Nuclear considers that other 10 CFR Part 50 and 52 licensees, Authorized Nuclear Inspection (ANI) Agencies, National Institute of Standards and Technology (NIST), or other State and Federal agencies which may provide items or services to the TVA New Nuclear plants are not required to be evaluated or audited. The NRC staff’s evaluation of these exceptions is provided in Section 3.1.7.1 of this safety evaluation.

- When purchasing commercial grade calibration or testing services from a laboratory holding accreditation by an accrediting body recognized by the international Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), TVA will implement the guidance from Nuclear Energy Institute (NEI) 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1 (Reference 10). The NRC staff's evaluation of this exception is provided in Section 3.1.7.2 of this safety evaluation.

- For Section 200 of NQA-1-2015, Requirement 7, during periods of exigent conditions, TVA New Nuclear may conduct remote audits/survey of suppliers in accordance with the guidance in EPRI TR-3002020796, "Remote Assessment Techniques: Planning and Conducting Audits and Surveys Using Remote Techniques During Exigent Conditions." The application of the guidance will be limited by the application of the EPRI TR's screening questions. The NRC staff's evaluation of this exception is provided in Section 3.1.7.2 of this safety evaluation.

- For Section 501 of NQA-1-2015, Requirement 7, TVA New Nuclear considers documents that may be stored in approved electronic media under TVA New Nuclear or vendor control, not physically located on the plant site, but accessible from the perspective nuclear facility site as meeting the requirement in NQA-1 for documents being available at the site. The NRC staff's evaluation of this clarification is provided in Section 3.1.7.2 of this safety evaluation.

- In establishing commercial grade item requirements, TVA New Nuclear commits to compliance with NQA-1-2015 Requirement 7, Section 700, and Part II, Subpart 2.14 with the clarification that (1) quality verification requirements are established and described in TVA New Nuclear documents, which also addresses determination of critical characteristics; and (2) TVA New Nuclear will assume 10 CFR Part 21 reporting responsibility for all items that TVA New Nuclear dedicates as safety-related. The NRC staff's evaluation of this clarification is provided in Section 3.1.7.2 of this safety evaluation.

In establishing the audit program for external suppliers, TVA New Nuclear commits to NQA-1-2015, Requirement 18 with the alternative to the audit interval specified in Section 202 of Requirement 18, in which TVA New Nuclear may apply an extension, not to exceed 25 percent of the audit interval, to contractor/supplier audits or surveys that are normally of a triennial frequency where performance of the audit or survey is not feasible. The end of the audit or survey will determine the date of the next triennial audit or survey. Application of the 25 percent extension is limited to extenuating circumstances, which include, but are not limited to, declaration of a national emergency; severe localized or national weather conditions or damage to TVA New Nuclear or TVA New Nuclear supplier's infrastructure; or Localized outbreak of a severe health concern to the public. Continued use of TVA New Nuclear suppliers that have exceeded the maximum allowed audit or survey time due to extenuating circumstances is allowed under the conditions specified in Part II, Section 18.2 of the TVA New Nuclear QAPD.

The NRC staff evaluated the descriptions of measures that are established by TVA New Nuclear to control purchased items and services to assure conformance with specified requirements, including measures for dedication of commercial grade items and services. For the reasons discussed above and in Sections 3.1.7.1 and 3.1.7.2 of this SE, the NRC staff has determined that these descriptions conform to the guidance in SRP Section 17.5, Subsection II,

Item G, “Control of Purchased Material, Equipment, and Services,” subject to the limitations identified below.

3.1.7.1 NRC Staff Evaluation of Proposed Exception to NQA-1-2015, Requirement 7 regarding Audits and Evaluation of Other 10 CFR Parts 50 and 52 licensees, Authorized Inspection Agencies (AIAs), NIST, or other State and Federal agencies

The NRC staff evaluated the proposed exception to NQA-1-2015, Requirement 7 regarding audits and evaluations of other 10 CFR Parts 50 and 52 licensees, AIAs,[4] NIST, or other State and Federal agencies, which may provide items or services to the applicant. Regarding the terms “audit” and “evaluation” as used for this proposed exception: The NRC staff considers audit to mean a planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation, consistent with the definition of “audit” in Part I, Section 400, “Terms and Definitions,” in NQA-1-2015. In the context of this proposed exception, the NRC staff considers evaluation to mean (1) prior to awarding a contract, the set of activities performed to evaluate the supplier’s capability to provide items or services in accordance with the requirements of the procurement documents as used in Section 200 “Supplier Evaluation and Selection” of NQA-1-2015; and (2) post award of a contract, the set of activities performed annually to review the supplier submittals of nonconformance notices and corrective actions, results of previous source verification and audits, operating experience of identical or similar products furnished by the same supplier and results of audits from other sources, as used in RG 1.28, Revision 6. The NRC staff’s evaluation for each of the entities identified in the applicant’s request for exception are discussed below.

Criterion VII of Appendix B requires measures to be established to assure that purchased material, equipment, and services conform to the procurement documents. Criterion VII further requires that these measures 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. Because of the “as appropriate” qualifier in this part of Criterion VII, TVA New Nuclear does not need to include all four provisions for each procurement. TVA New Nuclear instead selects and applies those provisions, “as appropriate” for verifying that purchased material, equipment, and services conform to the procurement documents. Therefore, the NRC staff evaluated whether the provisions described in the TVA New Nuclear QAPD, Part II, Section 7, meet the requirements of Criterion VII if the proposed exception for audit and evaluation is approved, recognizing that TVA New Nuclear is ultimately responsible for selecting measures in specific situations that are sufficient to verify that the purchased material, equipment, and services conform to the procurement documents. Finally, the last sentence of Criterion VII requires that the effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.

A. Other Parts 50 and 52 Licensees

[4] While TVA New Nuclear uses the term ANI Agencies, authorized nuclear inspectors are employed by AIAs. Therefore, ANI Agency refers to an AIA that employs the authorized nuclear inspectors.

Measures to Assure Conformity of Purchased Material, Equipment, and Services to the Procurement Documents

For 10 CFR Parts 50 and 52 licensees, the NRC staffed evaluated which of the measures specifically identified in the second sentence of Criterion VII of Appendix B would apply to the procurements from other Parts 50 or Part 52 licensees to assure that purchased material, equipment, and services conform to the procurement documents.

- *Source Evaluation and Selection*: If the proposed exception is approved as requested, TVA New Nuclear could procure materials, equipment, and services from other Parts 50 and 52 licensees without performing source evaluation and selection in accordance with the discussion above of "evaluation" activities prior to the award of contract. However, an application for a power reactor construction permit or operating license pursuant to 10 CFR 50.34, or for a combined license pursuant to 10 CFR 52.79, or for an ESP pursuant to 10 CFR 52.17, or for a manufacturing license pursuant to 10 CFR 52.157, is required to have a QAPD that meets the requirements of Appendix B to 10 CFR Part 50. Appendix B of 10 CFR Part 50 is directly applicable to these power reactor licensees. Each of these licensees' QAPDs is approved by the NRC staff, and subsequent changes to the QAPD can be made consistent with the requirements in 10 CFR 50.54(a) and 10 CFR 50.55(f), as applicable. Since this reasoning pertains to power reactor licensees, the NRC staff is limiting the proposed exception to other Parts 50 and 52 power reactor licensees.

- *Objective Evidence of Quality*: For objective evidence of quality furnished by the contractor, TVA New Nuclear stated in Part II, Section 7.1 of the TVA New Nuclear QAPD, that provisions are made for accepting purchased items and services, which include certificates of conformance and document reviews (e.g., Certified Material Test Report/Certificate). These provisions are applicable to procurements from other 10 CFR Parts 50 and 52 licensees. TVA New Nuclear committed to these provisions (e.g., Section 503) in Requirement 7 of NQA-1-2015 without exception.

- *Inspection at the Contractor or Subcontractor Source*: If the proposed exception is approved as requested, TVA New Nuclear would not perform source inspections of other Parts 50 and 52 licensees. Requirement 7 of NQA-1-2015 Section 504, "Source Verification," addresses the Criterion VII requirement regarding inspection at the contractor or subcontractor source, as appropriate. Source verification is typically used for procurements where the quality characteristics of the item are difficult to verify after delivery or when there is complexity in the design, manufacturing, and testing of the item. For procurements directly from other Parts 50 and Part 52 licensees, these licensees, excluding manufacturing licensees, are not designing, fabricating, manufacturing, or testing items that would necessitate source verification. For those items whose quality and technical requirements must be verified through source verification, the power reactor licensees that made the original procurement of these items are responsible for performing the source verification. Consistent with how the source verification provision is generally applied, TVA New Nuclear is not responsible for performing the source verification when procuring these items subsequently.

- *Examination of Products Upon Delivery*: For examination of products upon delivery for procurements from other Parts 50 and 52 licensees, Part II, Section 7.1 of the TVA New

Nuclear QAPD states that provisions are made for accepting purchased items and services, including receipt inspection and pre-and post-installation tests. These provisions are applicable to procurements from other 10 CFR Parts 50 and 52 licensees. TVA New Nuclear committed to these provisions (e.g., Section 505 and 506) in Requirement 7 of NQA-1-2015 without exception.

The NRC staff concludes that, except for source verification at a manufacturing licensee facility for those procurements whose quality can only be verified during the manufacturing process, the TVA New Nuclear QAPD includes appropriate provisions for establishing measures to assure that purchased material, equipment, and services from power reactor licensees conform to the procurement documents. The NRC staff concludes this because:

- Other Parts 50 and 52 power reactor licensees have an NRC-approved QAPD, and Appendix B is directly applicable as a requirement to these licensees;
- The TVA New Nuclear QAPD meets the requirements for establishing provisions for objective evidence of quality furnished by other Parts 50 and 52 licensees;
- With the exception of procurements from manufacturing licensees in which the inspections at the source must be conducted for those items whose quality could only be verified during the fabrication or manufacturing process, inspections at the source for procurements from other Parts 50 and 52 licensees is not necessary because these licensees do not manufacture or fabricate any material or equipment. The exception for procurements of items from manufacturing licensees where inspections during the fabrication or manufacturing process is required to assure quality is a limitation on the use of this TVA New Nuclear QAPD; and
- The TVA New Nuclear QAPD meets the requirements for establishing provisions for examination of products upon delivery for procurements from other Parts 50 and 52 licensees.

Assessing the Effectiveness of the Control of Quality by Contractors and Subcontractors

For assessment of effectiveness of control of quality of other power reactor Parts 50 and 52 licensees, these other licensees must perform periodic internal audits to verify compliance with all aspects of their QA program to determine the effectiveness of the program, per these licensees' QAPD. These internal audits encompass both the "audit" activities and the "annual evaluations" as described above. Therefore, the NRC staff finds that TVA New Nuclear QAPD meets the requirements for assessment of the control of quality by other Parts 50 and 52 licensees at intervals consistent with the importance, complexity, and quantity of the product or services as these other power reactor Parts 50 and 52 licensees are required to conduct an internal audit program to assess the effectiveness of the control of quality in accordance with Appendix B to 10 CFR Part 50. The other power reactor Parts 50 or 52 licensee effectively serves as the "designee" performing the assessment of the effectiveness of quality control that is required by the last sentence of Criterion VII. The NRC staff is allowing reliance in this manner on the internal audit program of these power reactor licensees because Appendix B is directly applicable as a requirement to these licensees.

B. Authorized Inspection Agencies (AIA)

10 CFR 50.55a, “Codes and Standards,” Paragraph (a)(1)(i) incorporates by reference Section III of the ASME Boiler and Pressure Vessel (BPV) Code, including the 2019 version of this code. Article NCA-5000, “Authorized Inspection” of Section III of the ASME BPV Code requires that an AIA be accredited by ASME in accordance with the provisions of ASME QAI-1 standard, “Qualifications for Authorized Inspection.” The AIA employs authorized nuclear inspectors that must be qualified in accordance with ASME QAI-1. TVA New Nuclear, as an owner, may procure inspection services from an AIA to verify that SSCs manufactured by an ASME certificate holder are constructed in accordance with Section III of the ASME BPV Code. In order for an SSC to be certified as constructed in accordance Section III of the ASME BPV Code and receive the ASME certification stamp, the AIA, and its employed ANIs, must perform the necessary inspection activities in accordance with Article NCA-5000.

As stated in the March 18, 1986, NRC letter, “NRC Endorsement of ASME’s Accreditation Program,” (ADAMS Accession No. ML19298D820), the NRC has determined that all prerequisites for NRC recognition and endorsement of the ASME Accreditation Program had been met. The prerequisites include submittal of the ASME Management Plan (ADAMS Accession No. ML19255E176), which included a provision to allow the NRC to audit AIA to verify conformance with applicable requirements of ASME Code, Section III and the ANSI/ASME N626, “Qualifications and Duties for Authorized Nuclear Inspection Agencies and Personnel” as part of NRC’s recognition of ASME’s Accreditation Program. Subsequently, the NRC issued IN 1986-021, “Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders,” which allowed licensees and construction permit holders to take credit for the ASME Accreditation Program.

Measures to Assure Conformity of Purchased Material, Equipment, and Services to the Procurement Documents

For procurements from AIA for inspection services, the NRC staffed evaluated which of the measures specifically identified in the second sentence of Criterion VII of Appendix B would apply to the procurements from AIA to assure that purchased inspection services conform to the procurement documents.

- *Source Evaluation and Selection*: If the proposed exception is approved as requested, TVA New Nuclear could procure from AIAs without performing source evaluation and selection for inspection services in accordance with the discussion above of “evaluation” prior to award of contract. Per IN 1986-021, TVA New Nuclear may take credit for ASME Accreditation Program for the source evaluation and selection of AIAs.

- *Objective Evidence of Quality*: For objective evidence of quality furnished by the contractor, TVA New Nuclear stated in Part II, Section 7.1 of the TVA New Nuclear QAPD, that provisions are made for accepting purchased items and services, which include certificates of conformance and document reviews. ASME issues a Certificate of Accreditation to each accredited AIA, which is included in the procurement documents. These provisions are applicable to procurements of inspection services from AIAs. TVA New Nuclear committed to these provisions (e.g., Section 503) in Requirement 7 of NQA-1-2015 without exception.

- *Inspection at the Contractor or Subcontractor Source*: For inspections of AIAs, Requirement 7 of NQA-1-2015, Section 504, “Source Verification,” addresses the Criterion VII requirement to inspect at the contractor or subcontractor source, as appropriate. Source verification is typically used for procurements where the quality characteristics of the item are difficult to verify after delivery or when there is complexity in the design, manufacturing, and testing of the item. TVA New Nuclear would only procure inspection services from AIAs, and source verification is not necessary for inspection services.

- *Examination of Products Upon Delivery*: For examination of products upon delivery for procurements of inspection services from AIAs, Part II, Section 7.1 of the TVA New Nuclear QAPD states that provisions are made for accepting purchased items and services, including receipt inspection and pre- and post-installation tests. These provisions are applicable to procurements of inspection services from AIAs. TVA New Nuclear committed to these provisions (e.g., Section 505 and 506) in Requirement 7 of NQA-1-2015 without exception.

The NRC staff concludes that the TVA New Nuclear QAPD includes appropriate provisions for establishing measures to assure that purchased services from AIAs conform to the procurement documents because:

- The NRC has recognized and endorsed the ASME Accreditation Program in IN 1986-021;
- The TVA New Nuclear QAPD meets the requirements for establishing provisions for objective evidence of quality furnished for procurements of inspection services from AIAs;
- Inspections at the source for procurements from AIAs is not necessary because AIAs only provide inspection services and do not manufacture or fabricate equipment; and
- The TVA New Nuclear QAPD meets the requirements for establishing provisions for examination of products upon delivery for procurements of inspection services from AIAs.

Assessing the Effectiveness of the Control of Quality by Contractors and Subcontractors

For assessment of effectiveness of control of quality by AIAs, ASME performs surveys at each AIA’s location(s) to evaluate the AIA’s Quality Program, including its implementation, as described in Section 4-4, “Evaluation for An AIA Certificate of Accreditation” in QAI-1, in order to certify or re-certify an AIA. The NRC staff finds that the TVA New Nuclear QAPD meets the requirements for assessment of the control of quality by AIAs at intervals consistent with the importance, complexity, and quantity of the product or services because ASME’s performance of these surveys assesses the effectiveness of the control of quality of inspection services provided by AIAs. ASME effectively serves as the “designee” performing the assessment of the effectiveness of quality control that is required by the last sentence of Criterion VII.

C. National Institute of Standards and Technology (NIST)

NIST is “a non-regulatory agency of the U.S. Department of Commerce. Its role as the National Metrology Institute (NMI) for the United States was established by Congress in 1901. As such,

NIST has the responsibility 'to develop, maintain, and retain custody of the national standards of measurement, and to provide the means and methods for making measurements consistent with those standards; to assure the compatibility of United States national measurement standards with those standards; and to assure the compatibility of United States national measurement standards with those of other nations' [15 U.S.C. 271]."[5] NIST may provide, for example, reference standard broadcast signals controlled or monitored by NIST (such as standard time and frequency signals), NIST Standard Reference Materials (SRMs), NIST-Traceable Reference Materials (NTRMs), or those NIST Standard Reference Instruments (SRIs) whose certificates include a statement of metrological traceability.

NIST has implemented a quality system for its measurement services. The NIST Quality System comprises policies and procedures that are documented in the NIST Quality Manual (NIST QM-I). Notably, "NIST documents the process by which it establishes traceability of its own measurement results as part of the NIST Quality System for Measurement Services. In accordance with the Quality System, NIST maintains current technical descriptions of (a) the measurement facility, system, or methods; (b) the procedures for conduct of the measurement(s); (c) the analysis of uncertainty of the measurement results; and (d) the procedures for statistical control of the measurement process. This documentation includes a description of how traceability is/was achieved."[6]

Measures to Assure Conformity of Purchased Material, Equipment, and Services to the Procurement Documents

For procurements from NIST, the NRC staff evaluated which of the measures specifically identified in the second sentence of Criterion VII of Appendix B would apply to the procurements from NIST to assure that purchased materials, equipment, and services conform to the procurement documents.

- *Source Evaluation and Selection*: If the proposed exception is approved as requested, TVA New Nuclear could procure from NIST without performing source evaluation and selection for procurement of materials, equipment and services from NIST in accordance with the discussion above of "evaluation" prior to award of contract. TVA New Nuclear may take credit of the fact that NIST is the U.S.-established NMI per 15 U.S.C. § 271.
- *Objective Evidence of Quality*: For objective evidence of quality furnished by the contractor, TVA New Nuclear stated in Part II, Section 7.1 of the TVA New Nuclear QAPD, that provisions are made for accepting purchased items and services, which include certificates of conformance and document reviews. NIST issues documents for certification (e.g., Certificates of Analysis, Certificates of Traceability). These provisions are applicable to procurements of standard reference material and services from NIST. TVA New Nuclear committed to these provisions (e.g., Section 503) in Requirement 7 of NQA-1-2015 without exception.
- *Inspection at the Contractor or Subcontractor Source*: For inspections of NIST, Requirement 7 of NQA-1-2015, Section 504, "Source Verification," addresses the Criterion VII requirement to inspect at the contractor or subcontractor source, as

[5] https://www.nist.gov/metrology/metrological-traceability
[6] https://www.nist.gov/metrology/metrological-traceability

appropriate. Source verification is typically used for procurements where the quality characteristics of the item are difficult to verify after delivery or when there is complexity in the design, manufacturing, and testing of the item. Although NIST manufactures its standard reference materials, NIST is the U.S.-established NMI per 15 U.S.C. § 271. Also, NIST is a part of the Federal government, and the Commission has held that there "is a presumption that governmental officials, acting in their official capacities, have properly discharged their duties. 'Clear evidence' is usually required to rebut this presumption."[7]

- *Examination of Products Upon Delivery*: For examination of products upon delivery for procurements of standard reference material and services from NIST, Part II, Section 7.1 of the TVA New Nuclear QAPD states that provisions are made for accepting purchased items and services, including receipt inspection and pre- and post-installation tests. These provisions are applicable to procurements of standard reference material and services from NIST. TVA New Nuclear committed to these provisions (e.g., Section 505 and 506) in Requirement 7 of NQA-1-2015 without exception.

The NRC staff concludes that the TVA New Nuclear QAPD includes appropriate provisions for establishing measures to assure that purchased materials, equipment, and services from NIST conform to the procurement documents because:

- NIST is the U.S.-established NMI per 15 U.S.C. § 271;
- The TVA New Nuclear QAPD meets the requirements for establishing provisions for objective evidence of quality furnished for procurements of standard reference material and services from NIST;
- NIST, as a part of the government, is presumed to have properly discharged its duties when acting in an official capacity; and
- The TVA New Nuclear QAPD meets the requirements for establishing provisions for examination of products upon delivery for procurements of standard reference material and services from NIST.

Assessing the Effectiveness of the Control of Quality by Contractors and Subcontractors

For assessment of effectiveness of control of quality by NIST, NIST documents the process by which it establishes traceability of its own measurement results as part of the NIST Quality System for Measurement Services. In accordance with the NIST Quality Manual, Section 8.8, NIST performs internal audits at planned intervals to provide information on whether the NIST Quality Management System meets the requirements specified in the manual. The NRC staff finds that the TVA New Nuclear QAPD meets the requirements for assessment of the control of quality by NIST at intervals consistent with the importance, complexity, and quantity of the product or services because NIST's internal audits assess the effectiveness of control of quality by NIST. NIST effectively serves as the "designee" performing the assessment of the effectiveness of quality control that is required by the last sentence of Criterion VII.

[7] *Louisiana Energy Services, L.P.* (National Enrichment Facility), CLI-06-22, 64 NRC 37, 51 n.48 (2006).

D. Federal Agencies

TVA New Nuclear indicates that it may procure items and services from Federal agencies. Examples might include United States Geological Survey (USGS), NRC, or Department of Defense (DOD). For example, the NRC allows distribution of reactor and radiation safety codes, tools to domestic organizations (utilities, vendors, academic institutions, commercial enterprises) and international organizations located in countries that participate in the Code Applications and Maintenance Program (CAMP), Cooperative Severe Accident Research Program (CSARP) or Radiation Protection Computer Code Analysis and Maintenance Program (RAMP) for a fee. USGS may supply survey data.

Measures to Assure Conformity of Purchased Material, Equipment, and Services to the Procurement Documents

For procurements from Federal agencies, the NRC staffed evaluated which of the measures specifically identified in the second sentence of Criterion VII of Appendix B would apply to the procurements from Federal agencies to assure that purchased material, equipment, and services conform to the procurement documents.

- *Source Evaluation and Selection*: If the proposed exception is approved as requested, TVA New Nuclear could procure materials, equipment and services from Federal agencies without performing source evaluation and selection in accordance with the discussion above of "evaluation" prior to award of contract. Federal agencies are created by the statutes in the U.S. Code. For example, the Energy Reorganization Act of 1974 established the NRC. Federal agencies are presumed to have properly discharged their duties when acting in an official capacity.

- *Objective Evidence of Quality*: For objective evidence of quality furnished by the contractor, procurements by TVA New Nuclear from Federal agencies, TVA New Nuclear stated in Part II, Section 7.1 of the TVA New Nuclear QAPD, that provisions are made for accepting purchased items and services, which may include certificates of conformance and document reviews. These provisions are applicable to procurements of materials, equipment, and services from Federal agencies. TVA New Nuclear committed to these provisions (e.g., Section 503) in Requirement 7 of NQA-1-2015 without exception.

- *Inspection at the Contractor or Subcontractor Source*: For inspections of Federal agencies, Requirement 7 of NQA-1-2015, Section 504, "Source Verification," addresses the Criterion VII requirement to inspect at the contractor or subcontractor source, as appropriate. Source verification is typically used for procurements where the quality characteristics of the item are difficult to verify after delivery or when there is complexity in the design, manufacturing, and testing of the item. Although TVA New Nuclear may procure manufactured or fabricated equipment from Federal agencies, Federal agencies are presumed to have properly discharged their duties when acting in an official capacity.

- *Examination of Products Upon Delivery*: For examination of products upon delivery for procurements from Federal agencies, Part II, Section 7.1 of the TVA New Nuclear QAPD states that provisions are made for accepting purchased items and services, including

receipt inspection and pre- and post-installation tests. These provisions are applicable to procurements from Federal agencies. TVA New Nuclear committed to these provisions (e.g., Section 505 and 506) in Requirement 7 of NQA-1-2015 without exception.

The NRC staff concludes that the TVA New Nuclear QAPD includes appropriate provisions for establishing measures to assure that purchased materials, equipment, and services from Federal agencies conform to the procurement documents because:

- Federal agencies are presumed to have properly discharged their duties when acting in an official capacity;

- The TVA New Nuclear QAPD meets the requirements for establishing provisions for objective evidence of quality furnished for procurements of materials, equipment and services from Federal agencies; and

- The TVA New Nuclear QAPD meets the requirements for establishing provisions for examination of products upon delivery for procurements of material, equipment, and services from Federal agencies.

Assessing the Effectiveness of the Control of Quality by Contractors and Subcontractors

For assessing the control of quality by Federal agencies, Section 7.1 of the TVA New Nuclear QAPD states that measures are established and implemented to assess the quality of purchased items and services at intervals and to a depth consistent with the item or service importance to safety, complexity, quantity, and the frequency of procurement. Verification actions include testing, as appropriate, during design, fabrication, construction, and operation activities. The NRC staff finds that the TVA New Nuclear QAPD meets the requirements for assessment of the control of quality by Federal agencies at intervals consistent with the importance, complexity, and quantity of the product or services because TVA New Nuclear established and implemented measures to perform verification actions of procured items and services from Federal agencies. With the exception of procurements in accordance with the Regulatory Position 4.b(1) of RG 1.28, Revision 5,[8] the NRC staff considers reliance solely on verification actions after procurement as a means for assessing the effectiveness of the supplier's QA program to be acceptable only in the case of Federal or State agencies (see Section E below for State agencies) because Federal and State agencies are presumed to have properly discharged their duties when acting in an official capacity.

E. State Agencies

TVA New Nuclear may procure items and services from State agencies. These might include a State's Department of Agriculture for standard reference material or calibration services, a State's Department of Natural Resources for surveys (e.g., geological, archaeological) in

[8] RG 1.28, Revision 5, Regulatory Position 4.b(1) states, "After award of a contract, the applicant or licensee may determine, based on the evaluation conducted in accordance with Regulatory Position 4.b.(4) below, that external audits are not necessary for procuring items (a) that are relatively simple and standard in design, manufacturing, and testing and (b) that are adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery. For other procurement actions not covered by the above exceptions, audits should be conducted as described below."

support of site characterization activities, or State agency certifications to meet Environmental Protection Agency (EPA) requirements. For calibration services or standard reference material, a State's metrology laboratory is issued a Certificate of Metrological Traceability by NIST,[9] which includes the scope of calibration or standard references (e.g., 25 kg to 1 mg) that the State metrology laboratory is certified to provide. NIST assesses and maintains the list of certified State metrology laboratories in accordance with NIST Handbook 143 – Program Handbook for State Weights and Measures Laboratories and ISO/IEC 17025:2017. For procurement of surveys, permits, or certifications from a State agency, the State establishes any authorities for conducting surveys, and issuing permits or certifications.

Measures to Assure Conformity of Purchased Material, Equipment, and Services to the Procurement Documents

For procurements from State agencies, the NRC staffed evaluated which of the measures specifically identified in the second sentence of Criterion VII of Appendix B would apply to the procurements from State agencies to assure that purchased material, equipment, and services conform to the procurement documents.

- *Source Evaluation and Selection*: If the proposed exception is approved as requested, TVA New Nuclear could procure materials, equipment and services from State agencies without performing source evaluation and selection in accordance with the discussion above of "evaluation" prior to award of contract. State agencies are created by the statutes in each State's laws and regulations. For example, Maryland State Law, Chapter 342, Acts of 1972 created the Maryland Department of Agriculture. Maryland Department of Agriculture supplies weight and measures as one of its functions.[10] State agencies are presumed to have properly discharged their duties when acting in an official capacity.

- *Objective Evidence of Quality*: For objective evidence of quality furnished by the contractor, procurements by TVA New Nuclear from State agencies, TVA New Nuclear stated in Part II, Section 7.1 of the TVA New Nuclear QAPD, that provisions are made for accepting purchased items and services, which may include certificates of conformance and document reviews. For example, a State's metrology laboratory issues documents for certification (e.g., Certificates of Traceability, Certificate of Calibration). These provisions are applicable to procurements of materials, equipment, and services from State agencies. TVA New Nuclear committed to these provisions (e.g., Section 503) in Requirement 7 of NQA-1-2015 without exception.

- *Inspection at the Contractor or Subcontractor Source*: For inspections of State agencies, Requirement 7 of NQA-1-2015, Section 504, "Source Verification," addresses the Criterion VII requirement to inspect at the contractor or subcontractor source, as appropriate. Source verification is used for procurements where the quality of the item could only be verified during the fabrication or manufacturing process. Although TVA New Nuclear may procure manufactured or fabricated equipment from State agencies,

[9] https://www.nist.gov/pml/owm/external-resources-weights-and-measures/state-metrology-laboratories
[10] https://mda.maryland.gov/weights_measures/Pages/weights_measures.aspx

State agencies are presumed to have properly discharged their duties when acting in an official capacity.

- *Examination of Products Upon Delivery*: For examination of products upon delivery for procurements from State agencies, Part II, Section 7.1 of the TVA New Nuclear QAPD states that provisions are made for accepting purchased items and services, including receipt inspection and pre-and post-installation tests. These provisions are applicable to procurements from State agencies. TVA New Nuclear committed to these provisions (e.g., Section 505 and 506) in Requirement 7 of NQA-1-2015 without exception.

The NRC staff concludes that the TVA New Nuclear QAPD includes appropriate provisions for establishing measures to assure that purchased materials, equipment, and services from State agencies conform to the procurement documents because:

- State agencies are presumed to have properly discharged their duties when acting in an official capacity;

- The TVA New Nuclear QAPD meets the requirements for establishing provisions for objective evidence of quality furnished for procurements of materials, equipment, and services from State agencies; and

- The TVA New Nuclear QAPD meets the requirements for establishing provisions for examination of products upon delivery for procurements of material, equipment, and services from State agencies.

Assessing the Effectiveness of the Control of Quality by Contractors and Subcontractors

For assessing the control of quality by State agencies, Section 7.1 of the TVA New Nuclear QAPD states that measures are established and implemented to assess the quality of purchased items and services at intervals and to a depth consistent with the item or service importance to safety, complexity, quantity, and the frequency of procurement. Verification actions include testing, as appropriate, during design, fabrication, construction, and operation activities. The NRC staff finds that the TVA New Nuclear QAPD meets the requirements for assessment of the control of quality by State agencies at intervals consistent with the importance, complexity, and quantity of the product or services because TVA New Nuclear established and implemented measures to perform verification actions of procured items and services from State agencies. With the exception of procurements in accordance with the Regulatory Position 4.b(1) of RG 1.28, Revision 5,[11] the NRC staff considers reliance solely on verification actions after procurement as a means for assessing the effectiveness of the supplier's QA program to be acceptable only in the case of Federal and State agencies because

[11] RG 1.28, Revision 5, Regulatory Position 4.b(1) states, "After award of a contract, the applicant or licensee may determine, based on the evaluation conducted in accordance with Regulatory Position 4.b.(4) below, that external audits are not necessary for procuring items (a) that are relatively simple and standard in design, manufacturing, and testing and (b) that are adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery. For other procurement actions not covered by the above exceptions, audits should be conducted as described below."

Federal and State agencies are presumed to have properly discharged their duties when acting in an official capacity.

For the reasons stated above, the NRC staff concludes that the requested exception regarding audit and evaluation is acceptable subject to the limitations stated above. TVA New Nuclear is still responsible for ensuring that the items and services procured conform to the applicable criteria in Appendix B to 10 CFR Part 50, ASME Boiling and Pressure Vessel Code requirements, and other regulatory requirements and commitments. TVA New Nuclear is also responsible for ensuring that procured items or services are suitable for the intended application, as well as for documenting the associated evaluation.

3.1.7.2 NRC Staff Evaluation of Other Clarifications and Exceptions to TVA New Nuclear's Commitment to Compliance with NQA-1-2015, Requirement 7

The NRC evaluated the other clarifications and exceptions to TVA New Nuclear's commitment to compliance with NQA-1-2015, Requirement 7 and determined that:

- TVA New Nuclear's implementation of guidance in NEI 14-05A, Revision 1 for using the ILAC accreditation process in lieu of performing a commercial grade survey is acceptable because this is consistent with the NRC staff's current regulatory position regarding the acceptability of procuring commercial grade calibration and testing services from laboratories accredited by ILAC, as documented in the NRC staff's SE, dated November 23, 2020 (Reference 11) for NEI-14-05A, Revision 1.

- TVA New Nuclear's performance of remote audits/survey of suppliers during exigent conditions in accordance with EPRI TR-3002020796 as an alternative to Section 200 of NQA-1-2015, Requirement 7, is acceptable on the basis that this alternative has been approved previously in the NRC staff's SE for Columbia Generating Station SE report (ML20160A411).

- The NRC staff concludes that TVA New Nuclear's position that documents stored in approved electronic media under TVA New Nuclear or vendor control is an acceptable alternative to Section 501 of NQA-1-2015, Requirement 7 based on the NRC staff's evaluation of TVA New Nuclear's use of electronic records as documented in Section 3.1.17 of this SE.

- Establishment of quality verification requirements and processes for identification of critical characteristics of TVA New Nuclear documents as part of the commercial grade dedication process is acceptable because this is consistent with the guidance in SRP Section 17.5, Subsection II, Item G, and is therefore acceptable.

The NRC also evaluated TVA New Nuclear's commitment to complying with NQA-1-2015, Requirement 18 for external supplier audits, including the proposed alternative to Section 202 of Requirement 18 for extension of the external audit interval during exigent conditions and determined that the proposed alternative to Section 202 of Requirement 18 is acceptable for the following reasons: (1) this alternative has been approved previously in the NRC staff's SE for the Callaway Plant Unit 1 QA Manual, Revision 34b, for exigent conditions, dated August 6, 2020 (ML20216A681), (2) the bases for the NRC staff's conclusion approving the alternative in the QA Manual Revision 34b for Callaway Plant Unit 1 apply to the alternative requested in the TVA New Nuclear QAPD with the exception of the maturity of the QA program, and (3) although

TVA New Nuclear does not have a mature QA program, the NRC staff determined that the experience TVA has implementing a QA program for its existing fleet reduces the risk of approving this alternative for TVA New Nuclear. The NRC staff notes that the COVID-19 related public health emergency expired on May 11, 2023; therefore, the provisions for audit extension and remote source verification under exigent conditions, as described above, can no longer be used unless new exigent conditions exists.

3.1.7.3 Conclusion

Based on the above evaluation and subject to the limitations stated in Section 4.0 of this safety evaluation, the NRC staff determined that the TVA New Nuclear QAPD complies with the requirements of Criterion VII, "Control of Purchased Materials, Equipment, and Services" of Appendix B to 10 CFR Part 50.

3.1.8 Identification and Control of Materials, Parts, and Components

Part II, Section 8, "Identification and Control of Materials, Parts, and Components," of the TVA New Nuclear QAPD states that TVA New Nuclear has established the necessary measures and governing procedures to identify and control items to prevent the use of incorrect or defective items. This includes controls for consumable materials and items with limited shelf-life. The identification of items is maintained throughout fabrication, erection, installation, and use so that the item can be traced to its documentation, consistent with the item's effect on safety. Identification locations and methods are selected so as not affect the function or quality of the item. In establishing the provision for identification and control of items, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 8.

The NRC staff evaluated the description of measures that are established to ensure identification and control of items to prevent use of incorrect or defective items and determined that this description conforms to the guidance in SRP Section 17.5, Subsection II, Item H, "Identification and Control of Materials, Parts, and Components." Based on this evaluation and TVA's commitment to comply with the requirements of NQA-1-2015, Requirement 8, the NRC staff determined that the TVA New Nuclear QAPD complies with the requirements of Criterion VIII, "Identification and Control of Materials, Parts, and Components" of Appendix B to 10 CFR Part 50.

3.1.9 Control of Special Processes

Part II, Section 9, "Control of Special Processes," of the TVA New Nuclear QAPD states that TVA New Nuclear has established the necessary measures and governing procedures to assure that special processes that require interim process controls to assure quality, such as welding, heat treating, and nondestructive examination, are controlled. These provisions include assuring that special processes are accomplished by qualified personnel using qualified procedures and equipment. Instructions or procedures for special processes include or reference procedures, personnel, and equipment requirements. Records are maintained as appropriate for currently qualified personnel, process and equipment for each special process. In establishing measures for the control of special processes, TVA New Nuclear commits to compliance with NQA-2015, Requirement 9.

The NRC staff evaluated the description of measures that are established to assure special processes are controlled in accordance with procedures and instructions by qualified personnel and determined that this description conforms to the guidance in SRP Section 17.5, Subsection

II, Item I, “Control of Special Processes.” Based on this evaluation and TVA’s commitment to comply with NQA-1-2015, Requirement 9, the NRC staff determined that that the TVA New Nuclear QAPD comply with the requirements of Criterion IX, “Control of Special Processes” of Appendix B to 10 CFR Part 50.

3.1.10 Inspection

Part II, Section 10, “Inspection,” of the TVA New Nuclear QAPD states that TVA New Nuclear has established the necessary measures and governing procedures to implement inspections that assure items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. Inspection may also be applied to items, services, and activities affecting plant reliability and integrity. Types of inspections may include those verifications related to procurement, such as source, in-process, final, and receipt inspection, as well as construction, installation, maintenance, modification, in-service, and operations activities. Inspections are carried out by qualified persons independent of those who performed or directly supervised the work. The inspection program establishes inspections as necessary to verify quality at the (1) source of supplied items or services, (2) in-process during fabrication at a supplier’s facility or at TVA New Nuclear facilities, (3) for final acceptance of fabricated and/or installed items during construction, (4) upon receipt of items for a facility, and (5) during maintenance, modification, in-service, and operating activities. Inspection records identify the item inspected, the date of inspection, the inspector’s identity, the type of observation, the inspection results and acceptability, and reference to information on action taken in connection with nonconformances. Inspection results are reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results. TVA New Nuclear has established a qualification program for personnel performing quality inspections. In establishing inspection requirements, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 10 and Part II, Subparts 2.5 and 2.8.

The NRC staff evaluated the description of measures that are established to verify activities affecting quality conform with documented instructions, procedures, and drawings for accomplishing the activity and determined that this description conforms to the guidance in SRP Section 17.5, Subsection II, Item J, “Inspection.” Based on this evaluation and TVA New Nuclear’s commitment to compliance with NQA-1-2015, Requirement 10 and Part II, Subparts 2.5 and 2.8, the NRC staff determined that the TVA New Nuclear QAPD complies with the requirements of Criterion X, “Inspection” of Appendix B to 10 CFR Part 50.

3.1.11 Test Control

Part II, Section 11, “Test Control,” of the TVA New Nuclear QAPD states that TVA New Nuclear shall establish the necessary measures and governing procedures to demonstrate that items subject to the provisions of the QAPD will perform satisfactorily in-service, that the plant can be operated safely and as designed, and that the coordinated operation of the plant is satisfactory. These programs include criteria for determining when testing is required, such as proof tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, in-service tests, and operational tests (such as surveillance tests required by Plant TSs), to demonstrate that performance of plant systems is in accordance with design. Tests are performed to applicable procedures that include: instructions and prerequisites to perform the test, use of proper test equipment, acceptance criteria, and mandatory verification points as necessary to confirm satisfactory test completion. Test programs ensure appropriate retention of test data in accordance with the records requirements of the QAPD. The initial startup test

program is planned and scheduled to permit safe fuel loading and startup; to increase power in safe increments; and to perform major testing at specified power levels. Tests are performed, and results documented in accordance with applicable technical and regulatory requirements, including those described in the TSs and safety analysis report. Test records, at a minimum shall identify the item tested, date of test, tester or data recorder, type of observation, results and acceptability, action taken in connection with any deviation noted, and the person evaluating test results.

Part II, Section 11.1, "NQA-1 Commitment for Computer Program Testing," of the TVA New Nuclear QAPD states that TVA New Nuclear establishes and implements provisions to assure that computer software used in applications affecting safety is prepared, documented, verified, and tested, and used such that the expected output is obtained, and configuration control maintained.

In establishing provision for testing, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 11. In addition, TVA New Nuclear commits to compliance with applicable provisions in NQA-1-2015, Part II, Subpart 2.7 for establishing provisions for computer program testing.

The NRC staff evaluated the description of the test program that TVA New Nuclear will establish to assure all testing required to demonstrate SSCs will perform satisfactorily in-service and determined that this description conforms to the guidance in SRP Section 17.5, Subsection II, Item K, "Test Control." Based on this evaluation and TVA New Nuclear's commitment to comply with NQA-1-2015, Requirement 11, and applicable provisions of Part II, Subpart 2.7 in establishing a test control program, the NRC staff determined that the TVA New Nuclear QAPD complies with the requirements of Criterion XI, "Test Control" of Appendix B to 10 CFR Part 50.

3.1.12 Control of Measuring and Test Equipment

Part II, Section 12, "Control of Measuring and Test Equipment," of the TVA New Nuclear QAPD states that TVA New Nuclear shall establish the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment (M&TE) that provides data to verify acceptance criteria are met or information important to safe plant operation. The provisions of such procedures cover equipment such as indicating and actuating instruments and gauges, tools, reference and transfer standards, and nondestructive examination equipment. Part II, Section 12.1 of the TVA New Nuclear QAPD describes the controls for calibration and adjustment of instrument and control devices installed in the facility during the operational phase of the facility. M&TE are calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards if such standards exists or to a documented basis otherwise. Provisions are established for control of M&TE found out of calibration. In establishing the provisions for control of M&TE, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 12.

The NRC staff evaluated the description of the provisions that TVA New Nuclear will establish to control M&TE used in activities affecting quality, including calibration at specified intervals to maintain accuracy within necessary limits and determined that this description conforms to the guidance in SRP Section 17.5, Subsection II, Item L, "Control of Measuring and Test Equipment." Based on this evaluation and TVA New Nuclear's commitment to comply with NQA-1-2015, Requirement 12, the NRC staff determined that the TVA New Nuclear QAPD

complies with the requirements of Criterion XII, “Control of Measuring and Test Equipment,” of Appendix B to 10 CFR Part 50.

3.1.13 Handling, Storage, and Shipping

Part II, Section 13, “Handling, Storage, and Shipping,” of the TVA New Nuclear QAPD states that TVA New Nuclear has established the necessary measures and governing procedures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss, and to minimize deterioration. These provisions include specific procedures, when required to maintain acceptable quality of the items important to the safe operations of the plant. Items are appropriately marked and labeled during packaging, shipping, handling, and storage to identify, maintain, and preserve the item’s integrity and indicate the need for special controls. Special controls are provided when required to maintain acceptable quality. This section also describes controls for special handling tools and equipment and specific controls for hoisting, rigging, and transport activities during the operational phase of the facility. Section 13.1, “Housekeeping,” describes the housekeeping practices and requirements that will be established within the plant, including controls for cleanliness of facilities and materials, fire prevention and protection, disposal of combustible material and debris, control of access to work areas, and protection of equipment, as well as radioactive contamination control, and storage of solid radioactive waste.

In establishing provisions for handling, storage, and shipping, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 13. During the construction and operational phase of the plant, TVA New Nuclear commits to compliance with the Requirements of NQA-1-2015, Part II, Subpart 2.1, Subpart 2.2, Subpart 2.3, and Part III, Subpart 3.2-2.1, with the following clarifications and exceptions:

- In lieu of the cleanness level system of NQA-1-2015, Part II, Subpart 2.1, TVA New Nuclear may establish cleanness requirements on a case-by-case basis, consistent with other provisions of Subpart 2.1.

- In lieu of classifying items into protection levels during the operational phase, as specified in NQA-1-2015, Part II, Subpart 2.2, Section 201, TVA New Nuclear may establish packaging, shipping, handling, and storage of such items on a case-by-case basis with due regard for the item’s complexity, use, and sensitivity to damage.

- In lieu of the requirements for written records containing information on personnel access, as specified in NQA-1-2015, Part II, Subpart 2.2, Section 606, TVA New Nuclear documents establish controls for storage areas that describe those authorized to access areas and requirements for recording access of personnel. These records are not considered quality records and will be retained in accordance with the administrative controls of the applicable plant.

- In lieu of the requirements for establishing a five-zone designation for housekeeping cleanliness controls, as specified in NQA-1-2015, Part II, Subpart 2.3, Section 202, TVA New Nuclear bases its control over housekeeping activities on a consideration of what is necessary and appropriate for the activity involved. The controls are implemented through procedures or instructions, which, in the case of maintenance or modification work, are developed on a case-by-case basis.

The NRC staff evaluated the description of the measures TVA New Nuclear has established to control the handling, storage, shipping, cleaning and preservation of material and equipment to prevent damage or deterioration and determined that this description conform to the guidance of SRP Section 17.5, Subsection II, Item M, “Handling, Storage and Shipping.” The NRC staff evaluated TVA New Nuclear’s clarifications and exceptions to its commitment to compliance with NQA-1-2015, Part II, Subparts 2.1, 2.2, 2.3, and 3.2-2.1 and determined that:

- The proposed alternative to Subpart 2.1, Section 301 is acceptable on the basis that this alternative is consistent with the NRC staff guidance provided in SRP Section 17.5 and was approved previously in the NRC staff’s SE for the Nuclear Management Company (NMC) QA TR, dated March 24, 2005 (ADAMS Accession No. ML050700416).
- The proposed alternative to Subpart 2.2, Section 201 is acceptable on the basis that this alternative is consistent with the NRC staff guidance provided in SRP Section 17.5 and was approved previously in the NRC staff’s SE for the NMC QA TR dated March 24, 2005.
- The proposed exception to Subpart 2.2, Section 606 is acceptable on the basis that these records do not meet the classification of a quality record as defined in NQA-1-2015, Requirement 17.
- The proposed alternative to Subpart 2.3, Section 202 is acceptable, on the basis that this alternative is consistent with the NRC staff guidance provided in SRP Section 17.5 and was approved previously in the NRC staff’s SE for the NMC QA TR dated March 24, 2005.

Therefore, based on the NRC staff’s evaluations above, including the evaluation of TVA New Nuclear’s commitments to NQA-1-2015, Requirement 13, and Part II, Subparts 2.1, 2.2, and 2.3 with clarifications and exceptions, the NRC staff determined that that the TVA New Nuclear QAPD complies with the requirements of Criterion XIII, “Handling, Storage and Shipping,” of Appendix B to 10 CFR Part 50.

3.1.14 Inspection, Test, and Operating Status

Part II, Section 14, “Inspection, Test, and Operating Status,” of the TVA New Nuclear QAPD states that TVA New Nuclear has established the necessary measures and governing procedures to identify the inspection, test, and operating status of items and components subject to the provisions of the TVA New Nuclear QAPD in order to maintain personnel and reactor safety and avoid inadvertent operation of equipment. Where necessary to preclude inadvertent bypassing of inspections or tests, or to preclude inadvertent operation, these measures require the inspection, test, or operating status be verified before release, fabrication, receipt, installation, test, or use. The status verification and tracking of temporary design changes or modifications are controlled. Administrative procedures describe the controls applied to altering the sequence of required tests, inspections, and other operations. In establishing measures for control of inspection, test, and operating status, TVA New Nuclear commits to complying with NQA-1-2015, Requirement 14.

The NRC staff evaluated the description of the measures that TVA New Nuclear has established to (1) indicate the status of inspections and tests performed of items and components, (2) control temporary changes or modifications, and (3) indicate operating status of SSCs to prevent inadvertent operation and determined that this description conform to the

guidance of SRP Section 17.5, Subsection II, Item N, “Inspection, Test, and Operating Status.” Based on this evaluation, and TVA New Nuclear’s commitment to comply with NQA-1-2015, Requirement 14, the NRC staff determined that the TVA New Nuclear QAPD complies with the requirements of Criterion XIV, “Inspection, Test, and Operating Status,” of Appendix B to 10 CFR Part 50.

3.1.15 Nonconforming Materials, Parts, or Components

Part II, Section 15, “Control of Nonconforming Items,” of the TVA New Nuclear QAPD states that TVA New Nuclear has established the necessary measures and governing procedures to control items, including services, that do not conform to specified requirements to prevent inadvertent installation or use. Instructions require that the individual discovering a nonconformance identify, describe, and document the nonconformance in accordance with the requirements of Part II, Section 16, of the TVA New Nuclear QAPD. Controls are established to identify, document, evaluate, segregate, and dispose of nonconforming items. Controls are provided for conditional release of nonconforming items that for use of nonconforming items on an at-risk basis prior to resolution and disposition of nonconformance, with requirements for documenting basis for conditional release. Item disposition, such as use-as-is, reject, repair, or rework shall be identified and documented. The technical justification for accepting a nonconforming item, or dispositioning it through repair or use-as-is, shall be documented. Reworked, repaired, and replacement items shall be inspected and tested in accordance with the original inspection and test requirements or specified alternatives. Nonconformance dispositions are reviewed for adequacy and analysis of quality trends, and to verify that reports are provided to the designated management, as required. Significant trends are reported to management in accordance with TVA New Nuclear procedures, regulatory requirements, and industry standards.

Part II, Section 15.1, “Interface with the Reporting Program,” of the TVA New Nuclear QAPD states that TVA New Nuclear has appropriate interfaces with the reporting program for identification and control of nonconforming materials, parts, or components to satisfy the requirements of:

- 10 CFR Part 52, and 10 CFR Part 21 during design certification and standard design approval,
- 10 CFR Part 52, 10 CFR 50.55, and 10 CFR Part 21 during ESP, CP, and COL design and construction, and
- 10 CFR Part 21 during operations.

In establishing the measures for control of nonconforming materials, parts, or components, TVA New Nuclear commits to complying with NQA-1-2015, Requirement 15.

The NRC staff evaluated the description of the measures that TVA New Nuclear has established to (1) control materials, parts, or components that do not conform to requirements in order to prevent their inadvertent use, and (2) disposition nonconforming items for acceptance, rejection, repair, or rework, and determined that this description conforms to the guidance of SRP Section 17.5, Subsection II, Item O, “Nonconforming Materials, Parts, or Components.” Based on this evaluation, and TVA New Nuclear’s commitment to comply with NQA-1-2015, Requirement 15, the NRC staff determined that the TVA New Nuclear QAPD complies with the

requirements of Criterion XV, “Nonconforming Materials, Parts, or Components,” of Appendix B to 10 CFR Part 50.

3.1.16 Corrective Action

Part II, Section 16, “Corrective Action,” of the TVA New Nuclear QAPD states that TVA New Nuclear has established the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality. TVA New Nuclear procedures assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of a significant condition adverse to quality, the cause is determined and actions to preclude recurrence are taken. In the case of suppliers working on safety-related activities, or other similar situations, TVA New Nuclear may delegate specific responsibilities for corrective actions, but TVA New Nuclear maintains responsibility for the effectiveness of corrective action measures.

Part II, Section 16.1, “Interface with the Reporting Program,” of the TVA New Nuclear QAPD states that TVA New Nuclear has appropriate interfaces with the corrective action program to satisfy the reporting requirements of:

- 10 CFR Part 52, and 10 CFR Part 21 during design certification and standard design approval,
- 10 CFR Part 52, 10 CFR 50.55, and 10 CFR Part 21 during ESP, CP, and COL design and construction, and
- 10 CFR Part 21 during operations.

In establishing the provisions for the corrective actions program, TVA New Nuclear commits to complying with NQA-1-2015, Requirement 16.

The NRC staff evaluated the description of the measures that TVA New Nuclear has established to assure that (1) conditions adverse to quality are promptly identified and corrected, and (2) the cause of significant conditions adverse to quality is determined and corrective actions to preclude repetition are implemented. The NRC staff determined that this QAPD description conforms to the guidance of SRP Section 17.5, Subsection II, Item P, “Corrective Action.” Based on this evaluation, and TVA New Nuclear’s commitment to comply with NQA-1-2015, Requirement 16, the NRC staff determined that the TVA New Nuclear QAPD complies with the requirements of Criterion XVI, “Corrective Action,” of Appendix B to 10 CFR Part 50.

3.1.17 Quality Assurance Records

Part II, Section 17, “Quality Assurance Records,” of the TVA New Nuclear QAPD states that TVA New Nuclear has established the necessary measures and governing procedures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. The provisions of such procedures establish the scope of the records retention program. The TVA New Nuclear records programs provides provisions for the administration, receipt, preservation, retention, storage,

safekeeping, retrieval, access controls, user privileges, and disposition of all records. All records are retrievable, maintained in a readable format, and safeguarded against equipment malfunction or human error. Document access controls, user privileges, and other appropriate security controls are established.

Section 17.1, “Record Retention,” of the TVA New Nuclear QAPD describes the measures that are established to ensure that sufficient records of completed items and activities affecting quality are appropriately stored. Records of activities for design, engineering, procurement, construction, inspection and test, installation, pre-operation, startup, operations, maintenance, modification, and audits and their retention times are defined in appropriate procedures. The records include at least operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. Records and retention are identifiable and retrievable. Records and retention times are based on RG 1.28, Revision 5, Regulatory Positions C.3.a.(1) and (2), for design, construction, and initial startup, and RG 1.33 for the operational phase.

Section 17.2, “Electronics Records,” of the TVA New Nuclear QAPD states that TV New Nuclear commits to complying with Generic Letter 88-18, “Plant Record Storage on Optical Disks,” when using optical disks for electronic records storage and retrieval systems. In addition, TVA New Nuclear will manage the storage of QA Records in electronic media consistent with the intent of RIS 2000-18, “Guidance on Managing Quality Assurance Records in Electronic Media,” and the associated Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guidelines (TG), including TG 11-2011, “Authentication of Records and Media,” TG 15-2011, “Management of Electronic Records,” TG 16-2011, “Software Configuration Management and Quality Assurance,” and TG 21-2011, “Electronic Records Protection and Restoration.”

In establishing the provisions for control of quality records, TVA New Nuclear commits to complying with NQA-1-2015, Requirement 17 and Regulatory Position C.3.a(1) and C.3.a(2) in RG 1.28, Revision 5.

The NRC staff evaluated the description of the measures that TVA New Nuclear has established to assure that sufficient records are maintained to furnish evidence of activities affecting quality and determined that this description conforms to the guidance of SRP Section 17.5, Subsection II, Item Q, “Quality Assurance Records.” Based on this evaluation, and TVA New Nuclear’s commitment to comply with NQA-1-2015, Requirement 17 and with Regulatory Positions C.3.a(1) and C.3.a(2) in RG 1.28, Revision 5, the NRC staff determined that the TVA New Nuclear QAPD complies with the requirements of Criterion XVII, “Quality Assurance Records,” of Appendix B to 10 CFR Part 50.

3.1.18 Audits

Part II, Section 18, “Audits,” of the TVA New Nuclear QAPD states that TVA New Nuclear has established the necessary measures and governing procedures to verify that activities covered by the QAP are performed in conformance with the established requirements and performance criteria are met. Part II, Section 18.1 of the TVA New Nuclear QAPD states that internal audits of selected aspects of design, construction, and operating 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. During the early portions of TVA New Nuclear activities, audits will focus on areas including but not limited to, site investigation, design, procurement, and corrective action. TVA New Nuclear is responsible for conducting periodic internal audits to determine the adequacy of programs and procedures (by representative sampling), and to

determine if they are meaningful and comply with the TVA New Nuclear QAPD. Audits of suppliers of safety-related components and/or services are conducted as described in Part II, Subsection 7.1.

Part II, Section 18.2 of the TVA New Nuclear QAPD states that internal audits of organization and facility activities, conducted prior to placing the facility in operation, are performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter. Internal audits of activities, conducted after placing the facility in operation, are performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area within a period of two years. Internal audit frequencies of well-established activities, conducted after placing the facility in operation, may be extended one year at a time beyond the above two-year interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. The internal audit frequency interval cannot exceed a maximum of four years.

Part II, Section 18.2 of the TVA New Nuclear QAPD states that internal audits may also be used to meet the periodic review requirements of the code for Security, Emergency Preparedness, Fire Protection, Independent Spent Fuel Storage Installations, and Radiological Protection programs within the provisions of, and at frequencies required by, the applicable code. An inspection and audit of fire protection equipment and program implementation are conducted utilizing either a qualified off-site licensed fire protection engineer or an outside qualified fire protection consultant. Because the TVA New Nuclear QAPD does not specify the qualification requirements for an outside qualified fire protection consultant, an application for a COL, a CP, or an OL that references the TVA New Nuclear QAPD must describe the qualification requirements for the outside fire protection consultant. This is PSAI 4.8.

Part II, Section 2 of the TVA New Nuclear QAPD states that a grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis, unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90-day grace period could be applied. The grace period does not allow the “clock” for a particular activity to be reset forward. The “clock” for an activity is reset backward by performing the activity early. Audit schedules are based on the month in which the audit starts.

In establishing the independent audit program, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 18 and the applicable regulatory positions stated in RG 1.28, Revision 5 with the following exception:

- For Section 201 of NQA-1-2015, Requirement 18, TVA New Nuclear may apply an extension, not to exceed 25 percent, for internal audit intervals for each audit area. Schedules are based on the month in which the audit starts. This extension does not apply to scheduled audits of Emergency Preparedness, Security, Cybersecurity, or Access Authorization. When an audit interval extension is greater than one month, the next audit for that particular audit will be scheduled from the original anniversary month rather than from the month of the extended audit.

The NRC staff evaluated the description of the measures that TVA New Nuclear has established to assure that a comprehensive system of planned and periodic audits are carried out to verify compliance with all aspects of the QAP and to determine the effectiveness of the program and determined that this description conforms to the guidance in SRP Section 17.5,

Subsection II, Item R, “Audits.” The NRC staff evaluated TVA New Nuclear’s proposed exception to its commitment to compliance with NQA-1-2015, Part II, Requirement 18, Section 201 and determined that the exception is acceptable on the basis that:

- The 25 percent extension to the internal audit frequency has been approved in the NRC staff’s SE for Southern Nuclear Company QA Program, dated June 17, 2005 (ADAMS Accession No. ML051570349).
- The 25 percent extension as applied to NQA-1-2015, Requirement 18, Section 201 for well-established activities will allow a maximum internal audit interval of 48 months, which is within the maximum audit frequency of 4 years (i.e., 48 months) specified in Section 201 of Requirement 18. The maximum internal audit interval of 48 months is calculated from a two-year audit frequency during operations, with one year extension for well-established activities, a 25 percent extension (i.e., 9 months), and a 90-day grace period (i.e., 3 months).

Therefore, based on the NRC staff’s evaluations above, including the evaluation of TVA New Nuclear’s commitments to NQA-1-2015, Requirement 18 with exception, the NRC staff determined that, upon satisfactory completion of PSAI 4.8, the TVA New Nuclear QAPD complies with the requirements of Criterion XVIII, “Audits,” of Appendix B to 10 CFR Part 50.

3.2 Quality Control for SSCs that are Not Safety-Related

SSCs that Are Not Safety-Related But With Significant Contribution to Plant Safety

Part III, Section 1, “NonSafety-Related with Special Treatment,” of the TVA New Nuclear QAPD describes program controls that are applied to SSCs that are not safety-related but have special treatment. These SSCs are not required to meet 10 CFR Part 50, Appendix B; however, since these SSCs are relied upon to perform safety-significant functions, QA program controls are applied to these SSCs. The specific program controls consistent with applicable sections of the TVA New Nuclear QAPD are applied to those SSCs in a selective manner, targeted at those characteristics or critical attributes with safety-significant functions that render the SSC a significant contributor to plant safety.

SSCs that Are Not Safety-Related – Credited for Regulatory Events

Part III, Section 2, “NonSafety-Related Structures, Systems, and Components Credited for Regulatory Events,” of the TVA New Nuclear QAPD states that for those SSCs that are not safety-related but are credited to meet the regulations in:

- 10 CFR 50.48 for fire protection, TVA New Nuclear implements quality requirements in accordance with RG 1.189, “Fire Protection for Nuclear Power Plants,” Revision 4.
- 10 CFR 50.62 for anticipated transients without scram (ATWS), TVA New Nuclear implements quality requirements in accordance with Part III, Section 1 of the TVA New Nuclear QAPD, based on assessment of the reactor technology’s requirement for ATWS equipment.

- 10 CFR 50.63, the station blackout (SBO) rule, TVA New Nuclear implements quality requirements in accordance with Part III, Section 1 of the TVA New Nuclear QAPD, based on an assessment of the reactor technology's requirement for SBO equipment.

The NRC staff evaluated the descriptions in Part III, Sections 1 and 2 of the TVA New Nuclear QAPD for QCs that are applied to (1) safety-significant, but not safety-related SSCs, and (2) SSCs that are not safety-related but are credited for certain regulatory events, respectively, and determined that these descriptions conform to the guidance in SRP Section 17.5, Subsection II, Item U, "Nonsafety-Related SSC Quality Controls."

3.3 Quality Assurance and Administrative Controls for the Plant Operational Phase

Part V, "Additional Quality Assurance and Administrative Controls for the Plant Operational Phase," of the TVA New Nuclear QAPD describes requirements that are applicable when establishing the necessary measures and governing procedures for the operational phase of the plant. Implementation of the additional controls described in Part V of the TVA New Nuclear QAPD are applied 30 days prior to initial fuel load for COL holders in accordance with 10 CFR 50.54(a)(1) and 90 days prior to initial fuel load for CP holders.

Part V, Section 2.1 of the TVA New Nuclear QAPD states that the TVA New Nuclear onsite organization will conduct reviews, both periodic and as situations demand, to evaluate plant operations and plan future activities. The important elements of the reviews will be documented, and subjects of potential concern will be brought to the attention of Operations Phase Management for independent review. The reviews are part of the normal duties of plant supervisory personnel in order to provide timely and continuing monitoring of operating activities in order to assist the manager responsible for Operations Phase Management. TVA New Nuclear commits to compliance with RG 1.33, Revision 3, including the conditions on use of ANSI/ANS 3.2-2012 specified in Section C of RG 1.33.

Part V, Section 2.2 of the TVA New Nuclear QAPD states that activities during the operational phase will be independently reviewed on a periodic basis. The independent review program will be functional prior to initial core loading. This section describes the independent review function. This section also describes the roles and responsibilities of an Independent Review Committee, including qualification requirements for this function.

Part V, Section 3, "Operational Phase Procedures," of the TVA New Nuclear QAPD describes the various types of procedures that TVA New Nuclear will use to govern design, operation, and maintenance of its nuclear generating plants. This section states that the guidance of RG 1.33 is used to identify the types of activities that should have procedures or instructions to control the activity. In addition, this section identifies requirements for the format and content of operational phase procedures.

Part V, Section 4, "Control of Systems and Equipment in the Operational Phase," of the TVA New Nuclear QAPD describes the controls that will be established to release systems and equipment for maintenance or modification to ensure personnel and equipment safety. Administrative procedures govern the length of time the equipment may be out of service.

Part V, Section 5, "Plant Maintenance," of the TVA New Nuclear QAPD states that controls will be established for the maintenance or modification of items and equipment subject to the TVA New Nuclear QAPD to ensure quality at least equivalent to that specified in the original design bases and requirements, such that safety-related SSCs are maintained in a manner that

assures their ability to perform their intended safety function(s). In establishing controls for plant maintenance, TVA New Nuclear commits to compliance with NQA-1-2015, Subpart 2.18, with the following clarifications:

- Where Subpart 2.18 refers to the requirements of ANS-3.2, it means the applicable standards and requirements established within the TVA New Nuclear QAPD. The QAPD includes a commitment to conform to RG 1.33, which endorses ANS 3.2-2012 with a condition. This commitment is discussed and found acceptable in Section 3.4 of this safety evaluation.

- Section 203 of Subpart 2.18 requires cleanliness during maintenance to be in accordance with Subpart 2.1. TVA New Nuclear's commitment to compliance with Subpart 2.1 of NQA-1-2015 with alternatives is described in Part II, Section 13.2 of the TVA New Nuclear QAPD. TVA's commitment to Subpart 2.1 of NQA-1-2015 with this alternative is evaluated and found acceptable in Section 3.1.13 of this safety evaluation.

The NRC staff evaluated the description of managerial and administrative controls that will be applied to during the operational phase of the TVA New Nuclear plants and determined that this description conforms to the applicable guidance for operational phase activities in SRP Section 17.5, Subsection II:

- Item B, "Quality Assurance Program"
- Item E, "Instructions, Procedures, and Drawings"
- Item F, "Document Control"

Based on this evaluation and TVA New Nuclear's commitment to compliance with RG 1.33, Revision 3 and ANSI/ANS 3.2-2012, as endorsed by RG 1.33 with conditions, the NRC staff determined that the managerial and operational controls described in TVA New Nuclear QAPD is consistent with the requirements in 10 CFR 50.34(b)(6)(ii) and 10 CFR 52.79(a)(27).

3.4 Regulatory Commitments

Part IV of the TVA New Nuclear QAPD states that TVA New Nuclear identifies the extent of conformance with the following NRC RGs and QA standards or within applicable license application documents, with certain clarifications and exceptions, as described below:

- RG 1.8, "Qualification and Training of Personnel for Nuclear Power Plants," Revision 4

  TVA New Nuclear states that it will address conformance to and exceptions from the applicable regulatory position guidance provided in this RG in applicable license applications (e.g., safety analysis reports (SAR)).

- RG 1.26, "Quality Group Classifications and Standards for Water, Steam, and Radioactive-Waste-Containing Components of Nuclear Power Plants," Revision 6

  TVA New Nuclear states that it will address conformance to and exceptions from the applicable regulatory position guidance provided in this RG in applicable license applications (e.g., the SAR).

- RG 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5

TVA New Nuclear states that it will address conformance to and exceptions from the applicable regulatory position guidance provided in this RG in applicable license applications (e.g., the SAR).

Because TVA has stated a commitment to compliance with RG 1.28, Revision 5, in other sections of the TVA New Nuclear QAPD, the NRC staff understands that the preceding statement from TVA to mean that any departures from the commitments stated in these other sections of the TVA New Nuclear QAPD will be provided in applicable license applications.

- RG 1.29, “Seismic Design Classification,” Revision 6

  TVA New Nuclear states that it will address conformance to and exceptions from the applicable regulatory position guidance provided in this RG in applicable license applications (e.g., the SAR).

- RG 1.33, “Quality Assurance Program Requirements (Operations),” Revision 3

  TVA New Nuclear will conform with RG 1.33, Revision 3 and comply with the NRC staff regulatory guidance for the conditions described on the use of ANSI/ANS 3.2-2012.

- RG 1.54, “Service Level I, II, III, and In-Scope License Renewal Protective Coatings Applied to Nuclear Power Plants,” Revision 3

  TVA New Nuclear states that it will address conformance to and exceptions from the applicable regulatory position guidance provided in this RG in applicable license applications (e.g., the SAR).

- RG 1.164, “Dedication of Commercial-Grade Items for Use in Nuclear Power Plant,” Revision 0

  TVA New Nuclear states that it will address conformance to and exceptions from the applicable regulatory position guidance provided in this RG in applicable license applications.

- RG 1.189, “Fire Protection for Nuclear Power Plants,” Revision 4

  TVA New Nuclear states that it will address conformance to and exceptions from the applicable regulatory position guidance provided in this RG in applicable license applications based on an assessment of the reactor technology’s requirements.

- RG 1.231, “Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants,” Revision 0

  TVA New Nuclear states that it will address conformance to and exceptions from the applicable regulatory position guidance provided in this RG in applicable license applications.

- RG 1.234, “Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21,” Revision 0

  TVA New Nuclear states that it will address conformance to and exceptions from the applicable regulatory position guidance provided in this RG in applicable license applications.

- ASME NQA-1-2015 – Quality Assurance Requirements for Nuclear Facility Applications

  TVA New Nuclear commits to NQA-1-2015, Parts I and II, as described in Parts II and V of the TVA New Nuclear QAPD, with specific identification of exceptions or clarification. TVA New Nuclear commits to NQA-1-2015, Parts III and IV only as specifically noted in Parts II and V of the TVA New Nuclear QAPD.

- NEI 14-05A, “Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,” Revision 1

  In establishing controls for purchased items and services, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 7, as described in Part II, Section 7.2 of the TVA New Nuclear QAPD.

- NIRMA TGs

  TVA New Nuclear commits to NIRMA TGs as described in Part II, Section 17.2 of the TVA New Nuclear QAPD.

The NRC staff evaluated TVA Nuclear’s commitments to RGs and QA standards in Part IV of the TVA New Nuclear QAPD and determined that TVA New Nuclear’s commitment to:

- RG 1.33, Revision 3 and the endorsed ANSI/ANS 3.2-2012, is acceptable for complying with the Commission’s regulation for an overall QAP for the operation phase of nuclear power plants.

- NQA-1-2015, Parts I and II, as described in Parts II and V of the TVA New Nuclear QAPD, with specific identification of exceptions or clarification is acceptable based on the NRC staff’s evaluations in Section 3.1 and 3.3 of this SE.

- NQA-1-2015, Parts III and IV, only as specifically noted in Parts II and V of the TVA New Nuclear QAPD, is acceptable based on the NRC staff’s evaluations in Section 3.1 and 3.3 of this SE.

- NEI 14-05A, as described in Part II, Section 7 of the TVA New Nuclear QAPD, is acceptable based on the NRC staff’s evaluations in Section 3.1.7 of this SE.

- NIRMA TGs, as identified in Part II, Section 17, of the TVA New Nuclear QAPD, is acceptable based on the NRC staff’s evaluations in Section 3.1.17 of this SE.

Because TVA New Nuclear states that conformances and exceptions to RG 1.8, Revision 4; RG 1.26, Revision 6; RG 1.28, Revision 5; RG 1.29, Revision 6; RG 1.54, Revision 3; RG

1.164, Revision 0; RG 1.189, Revision 4; RG 1.231, Revision 0; and RG 1.234, Revision 0 will be identified in applicable license applications, an application for an SDA, a DC, an ESP, a COL, a CP, or an OL, or if applicable, an LWA that references the TVA New Nuclear QAPD must provide information on conformance with and exceptions to these RGs. This is PSAI 4.9.

4.0 LIMITATIONS AND CONDITIONS

An application for an ESP, a COL, a CP, an OL, a DC, an SDA, or an LWA may reference the approved TVA New Nuclear QAPD provided that the application satisfies the following conditions and limitations, as applicable. The conditions and limitations are intended to address plant-specific aspects of TVA New Nuclear QA program that have not been described in the TVA New Nuclear QAPD. The TVA New Nuclear QAPD and the NRC staff's SE provides context and basis for the required additional information.

The following PSAIs must be satisfied by applications referencing the TVA New Nuclear QAPD:

- PSAI 4.1: An application for an SDA, a DC, an ESP, a COL, a CP, an OL, or an LWA (as applicable) that intends to credit the approved version of the TVA New Nuclear QAPD for activities where the regulations other than 10 CFR Part 50 and Part 52 establish QA requirements must include an analysis that demonstrates the QA requirements set forth in these other regulations are met by the TVA New Nuclear QAPD.

- PSAI 4.2: An application for an SDA, a DC, an ESP, a COL, a CP, an OL, or an LWA that references the TVA New Nuclear QAPD must include an organizational diagram that aligns with the description of the roles and responsibilities of the Senior Vice President, Engineering Operations Support in Part II, Sections 1.2.1 and 1.3.2.2.3 of the TVA New Nuclear QAPD.

- PSAI 4.3: An application for a COL or an OL that references the TVA New Nuclear QAPD must include (1) a description of site-specific positions required for operations, and (2) an organizational diagram that depicts these site-specific positions in the organizational structure.

- PSAI 4.4: An application for a DC or an SDA that references the TVA New Nuclear QAPD and intends to have A/E Suppliers for engineering services in support of the DC or SDA application must include a description of the management position that will oversee these A/E Suppliers.

- PSAI 4.5: An application a DC, an SDA, an ESP, a COL, a CP, an OL, or an LWA referencing the TVA New Nuclear QAPD must provide the applicable standards or methodology for the selection and classification of SSCs.

- PSAI 4.6: An application for a COL that references the TVA Nuclear QAPD must specify that requisite design verification activities will be completed prior to relying on the design outputs to fulfill completion of ITAAC during construction.

- PSAI 4.7: An application for an OL that references the TVA New Nuclear QAPD must specify that requisite design verification activities will be completed prior to relying on the design outputs in fulfilling the required information needed for OL issuance.

- PSAI 4.8: An application for a COL, a CP, or an OL that references the TVA New Nuclear QAPD must describe the qualification requirements for outside fire protection consultants who will be relied upon to conduct fire protection equipment and program inspections.

- PSAI 4.9: An application for an SDA, a DC, an ESP, a COL, a CP, an OL, or if applicable, an LWA that references the TVA New Nuclear QAPD must provide information on conformance with and exceptions to RG 1.8; RG 1.26; RG 1.28; RG 1.29; RG 1.54; RG 1.164; RG 1.189; RG 1.231; and RG 1.234.

The following limitations on the use of this TVA New Nuclear QAPD applies:

- The exception to not perform audit or evaluation for procurements from other Parts 50 and 52 licensees only applies when TVA New Nuclear procures from other Parts 50 and 52 *power reactor* licensees.

- When TVA New Nuclear procures from manufacturing licensees where inspections during the fabrication or manufacturing process are required to assure quality, TVA New Nuclear must establish measures for source verification for these procurements, as required by Criterion VII of Appendix B to 10 CFR Part 50.

5.0 CONCLUSIONS

The TVA New Nuclear QAPD delineates the policies, processes, and controls established by TVA New Nuclear and associated implementing documents relative to U.S. domestic quality assurance requirements for licensing nuclear power plants. Subject to the satisfaction of PSAIs 4.1 – 4.9, the QAP documents defined in the TVA New Nuclear QAPD provide for control of TVA New Nuclear activities that affect the quality of safety-related nuclear plant SSCs and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in-service.

The TVA New Nuclear QAPD may also be applied to certain equipment and activities, discussed above, that are not safety-related, but support safe plant operations, or where other NRC regulations and policies establish programmatic controls.

The NRC staff used the acceptance criteria in SRP Section 17.5 as the basis for evaluating the compliance of the TVA New Nuclear QAPD with the provisions of Appendix B to 10 CFR Part 50 and concludes that the TVA New Nuclear QAPD satisfies the acceptance criteria within SRP Section 17.5. The NRC staff concludes that upon the satisfaction of PSAIs 4.1 – 4.9, the TVA New Nuclear QAPD meets the requirements in Appendix B to 10 CFR Part 50, and is therefore, acceptable.

6.0 REFERENCES

1. Tennessee Valley Authority Letter to the US NRC, “Topical Report Quality Assurance Program Description for the Tennessee Valley Authority New Nuclear Program,” dated August 25, 2022 (ADAMS Accession No. ML22238A101)

2. American Society of Mechanical Engineers (ASME) NQA-1-2015, “Quality Assurance Program Requirements for Nuclear Facilities,” New York, NY dated February 20, 2015

3. Regulatory Guide 1.28, “Quality Assurance Program Criteria (Design and Construction),” Revision 5, dated October 2017 (ADAMS Accession No. ML17207A293)

4. US NRC Letter to the Tennessee Valley Authority, “Request for Additional Information (RAI) on Tennessee Valley Authority Topical Report (TR) NNP-TR-001-NP, Revision 0, Quality Assurance Program Description for TVA New Nuclear Program, eRAI-386” dated January 27, 2023 (ADAMS Accession No. ML23027A132)

5. Tennessee Valley Authority Letter to the US NRC, “Response to Request for Additional Information eRAI-386 and Revised Quality Assurance Program Description for TVA New Nuclear Program Topical Report NNP-TR-001-NP, Revision 1,” dated February 22, 2023. (ADAMS Accession No. ML23054A158)

6. US NRC Staff Feedback Questions on Tennessee Valley Authority Responses to eRAI-386, dated May 4, 2023. (ADAMS Accession No. ML23124A036)

7. US NRC Staff Additional Feedback on Tennessee Valley Authority Responses to eRAI-386, dated June 8, 2023 (ADAMS Accession No. ML23159A103)

8. Tennessee Valley Authority Letter to the US NRC, “Supplemental to Response to NRC Feedback Questions on TVA’s Response to eRAI-386,” dated July 7, 2023 (ADAMS Accession No. ML23188A150)

9. NUREG-0800, “Standard Review Plan for Review of Safety Analysis Reports for Nuclear Power Plants,” Section 17.5, “Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants,” Revision 1, dated August 2015 (ADAMS Accession No. ML 15037A441)

10. Revision 1 of Nuclear Energy Institute (NEI) 14-05A, “Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,” dated September 2020 (ADAMS Accession No. ML20259B731)

11. Final Safety Evaluation by the Office of Nuclear Reactor Regulation for the NEI Technical Report NEI 14-05A, “Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,” Revision 1, dated February 19, 2021 (ADAMS Accession No. ML20322A019)

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