TENNESSEE VALLEY AUTHORITY

1101 Market Street, Chattanooga, Tennessee 37402

NNP-23-001

February 22, 2023

10 CFR 50, Appendix B

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

Clinch River Project
Project No. 99902056

Subject: **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**

References:

1. Topical Report Quality Assurance Program Description for The Tennessee Valley Authority New Nuclear Program, August 25, 2022 (ML22238A101)

2. Request for Additional Information (RAI) on Tennessee Valley Authority Topical Report (TR) NNP-TR-001-NP, Revision 0, "Quality Assurance Program Description [(QAPD)] for TVA New Nuclear Program" (eRAI-386), January 27, 2023 (ML23027A132)

This letter transmits the Tennessee Valley Authority's (TVA) response to Request for Additional Information (RAI) eRAI-386. In addition, this letter submits a revised Quality Assurance Program Description for TVA New Nuclear Program, Topical Report NNP-TR-001-NP, Revision 1, for Nuclear Regulatory Commission (NRC) staff review. TVA originally submitted the subject Topical Report for staff review on August 25, 2022 (Reference 1).

Enclosure 1 contains TVA's response to the RAIs submitted on January 27, 2023 (Reference 2). The RAI responses incorporate insights provided by the clarification discussions between the NRC staff and TVA conducted on December 19, 2022 and January 17, 2023.

As a result of the RAI responses, changes were made to Topical Report NNP-TR-001-NP. Enclosure 2 contains a mark-up of the Topical Report, showing the RAI changes. Enclosure 3 provides a clean copy of the Topical Report with all changes incorporated. The Topical Report provided in Enclosure 3 supersedes the version submitted by Reference 1 in its entirety. TVA requests that the NRC staff review and approve this document.

If you have any questions or need any additional information, please contact Ray Schiele at 423-751-8628.

Respectfully,

Scott W. Hunnewell,
Vice President, New Nuclear Program

Enclosures:

1. TVA Response to NRC Request for Additional Information dated January 27, 2023 (eRAI-386).
2. NNP-TR-001-NP, Revision 0 - Markup, Quality Assurance Program Description for TVA New Nuclear
3. NNP-TR-001-NP, Revision 1, Quality Assurance Program Description for TVA New Nuclear

cc (with Enclosure):

Michelle Hayes, Chief, New Reactor Licensing Branch
Allen H. Fetter, NRC Project Manager, Clinch River Nuclear Site
Kerri Kavanagh, Chief, Quality Assurance and Vendor Inspection Branch

Enclosure 1

TVA Response to NRC Request for Additional Information dated January 27, 2023
(eRAI-386)

January 27, 2023

Request for Additional Information (RAI) on Tennessee Valley Authority Topical Report (TR) NNP-TR-001-NP, Revision 0, "Quality Assurance Program Description [(QAPD)] for TVA New Nuclear Program"

eRAI-386

By letter dated August 25, 2022 (Agencywide Document Access and Management System (ADAMS) Accession No. ML22238A101), 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 Program QAPD TR) to the U.S. Nuclear Regulatory Commission (NRC). In this letter, TVA requested the NRC staff's review and approval of this TR to be used to satisfy the quality assurance 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)*
- *Standard Design Approval (SDA)) Applications pursuant to 10 CFR 52.137(a)(19)*

The applicant specified that the TVA New Nuclear Program QAPD TR 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," as endorsed by NRC Regulatory Guide (RG) 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5.

The NRC staff reviewed the information presented in the TVA New Nuclear Program QAPD TR, Revision 0 against the quality assurance (QA) requirements in Appendix B to 10 CFR Part 50, in accordance with the review guidance in NUREG-0800, "Standard Review Plan (SRP)," Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants," Revision 1. Based on this review, the NRC staff requests additional information, as documented below, to complete its review.

RAI 1

Criterion I, "Organization," of Appendix B to 10 CFR Part 50 requires, in part, that "the applicant shall be responsible for the establishment and execution of the Quality Assurance Program (QAP). The authority and duties of person and organizations performing activities affecting the safety-related functions of SSCs shall be clearly established and delineated in writing. The persons and organizations performing QA functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. The persons organizations performing quality assurance functions shall report to a management level so that the required authority and

organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided." SRP Section 17.5, Subsection II, "SRP Acceptance Criteria," Item A specifies acceptance criteria to meet the requirements of Criterion I of Appendix B to 10 CFR Part 50. Item A.13 within this SRP section, states, "The person responsible for directing and managing the onsite QA program is identified and has appropriate organizational position, responsibility, and authority to exercise proper control over the QA program. This individual is free from non-QA duties and can thus give full attention to ensuring that the QA program at the plant site is being effectively implemented."

Part II. Section I, "Organization" of the TVA New Nuclear Program QAPD TR describes the TVA New Nuclear Program organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. This section states that the TVA New Nuclear organization is responsible for all aspects of design, construction, and operation of TVA's New Nuclear plants. In addition, this section specifies that several organizations within the TVA New Nuclear Program implement and support the QAPD, which include engineering, operations support, and quality assurance. This section also states that the TVA New Nuclear Program oversees multiple sites and projects and Figure II.1-1 is provided to illustrate the TVA New Nuclear Program organization.

Part II, Section 1.5.1 of the TVA New Nuclear Program QAPD TR, Revision 0, states, in part, that "The Senior Vice President, New Nuclear Projects is responsible for all aspects of design, construction, and operations for Site Projects…Transition from design phase to construction and operations phases occurs such that those positions required to support quality-related activities will retain their applicable responsibilities until it is deemed that they are no longer necessary. During all phases, QA management has access to the Senior Vice President, New Nuclear Projects as the executive with overall responsibilities for QA." Part II, Section 1.5.2, "General Manager New Nuclear Quality Assurance," of the QAPD TR, states, in part, that "The General Manager, New Nuclear Quality Assurance reports to the TVA Senior Vice President, New Nuclear Projects with direct access to Chief Operating Officer [(COO)]. The General Manager is responsible for planning and performing activities to verify the development and effective implementation of the QAPD…The QA function has sufficient independence from other TVA New Nuclear Program priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas regarding TVA New Nuclear Program design activities as appropriate." In Part II, Section 1.10, "NQA-1 Commitment," of the QAPD TR, in establishing its organizational structure, the applicant commits to compliance with NQA-1-2015, Requirement 1.

The NRC staff finds that the descriptions of the TVA New Nuclear Program Organization, including the responsibilities for aspects of the design, construction, and operation phase, in Part 2, Section 1 of the TVA New Nuclear Program QAPD TR, is not sufficient to clearly delineate the roles and responsibilities of personnel for onsite and offsite activities affecting quality to meet the requirements of Criterion I to Appendix B. Specifically, the NRC staff did not find a clear mapping of the responsibilities for quality related activities during each of the phases, as identified in the table provided in Part 2, Section 1 of the TVA New Nuclear Program QAPD TR, to the descriptions of positions within Part 1, Sections 1.1 thru 1.7 of the QAPD TR or the organizational structure depicted in Figure II.1-1. The NRC staff requests the applicant to provide a mapping of the responsibilities identified in the table to the descriptions in Sections 1.1 thru 1.7 and verify alignment with Figure II.1-1. In addition, the NRC staff requests the applicant to clarify whether the role of President/Chief Executive Officer (CEO), Executive Vice President

(EVP)/Chief Nuclear Officer (CNO), and EVP/COO will oversee the design, construction, and operation phase for all new nuclear projects.

The NRC staff also reviewed the role of the Senior Vice President, New Nuclear Projects and the General Manager New Nuclear Quality Assurance, as described in Sections 1.5.1 and 1.5.2 of the TVA New Nuclear Program QAPD TR, Revision 0 and requests the applicant to clarify whether there is a specific QA person assigned to each new nuclear plant site during the operational phase who will be responsible for directing and managing the onsite QA program, to address the acceptance criteria in in Section 17.5, Subsection II, Item A.13.

RAI 1, Part 1:

The NRC staff finds that the descriptions of the TVA New Nuclear Program Organization, including the responsibilities for aspects of the design, construction, and operation phase, in Part 2, Section 1 of the TVA New Nuclear Program QAPD TR, is not sufficient to clearly delineate the roles and responsibilities of personnel for onsite and offsite activities affecting quality to meet the requirements of Criterion I to Appendix B. Specifically, the NRC staff did not find a clear mapping of the responsibilities for quality related activities during each of the phases, as identified in the table provided in Part 2, Section 1 of the TVA New Nuclear Program QAPD TR, to the descriptions of positions within Part 1, Sections 1.1 thru 1.7 of the QAPD TR or the organizational structure depicted in Figure II.1-1. The NRC staff requests the applicant to provide a mapping of the responsibilities identified in the table to the descriptions in Sections 1.1 thru 1.7 and verify alignment with Figure II.1-1.

TVA Response:

TVA has provided a mapping of responsibilities identified in the table in Part II, Section 1 Organization to the position descriptions defined in Section 1. As a result, Sections 1.1 – 1.7 have been reformatted as Section 1.1 through 1.4 to clearly delineate organizational roles and responsibilities. Additionally, the organization defined in Figure II.1-1 “TVA New Nuclear Organization” has been revised to reflect the organizational clarifications provided in Sections 1.1 through 1.3. Specifically, the following underlined changes have been made to the position descriptions in Section 1.1 – 1.3.

1.1. President/Chief Executive Officer

<u>The President/Chief Executive Officer (CEO) is responsible for all aspects of design, construction, and operation of TVA’s nuclear plants, including new nuclear projects developed under TVA New Nuclear.</u> The President/CEO is also responsible for all technical and administrative support activities provided by TVA and contractors. The President/CEO directs the Chief Nuclear Officer and the Chief Operating Officer in the fulfillment of their responsibilities. The President/CEO reports to the TVA Board of Directors with respect to all matters.

1.2. Executive Vice President/Chief Nuclear Officer

The Chief Nuclear Officer (CNO) is responsible for the safe, reliable, and efficient operation of the TVA Nuclear Plants. The CNO also has the overall responsibility for the establishment, implementation, and administration of TVA’s Fleet NQAP and the evaluation of its effectiveness. This responsibility is implemented through the General

Manager, Quality Assurance. The CNO also supports the New Nuclear Program activities through the Senior Vice President, Engineering and Operations Support.

1.2.1.1. Vice President, New Nuclear Program

Vice President, New Nuclear Program reports to the Senior Vice President, Nuclear Engineering and Operations Support. This position is responsible for nuclear site development, fabrication, supply chain, site characterization, document control and advanced design engineering. The Vice President, New Nuclear Program is also responsible for developing strategies for workforce development, training, and transition planning for the New Nuclear Program. The Vice President, New Nuclear Program is responsible for technical, administrative, and corporate support services provided by the New Nuclear Program and contractors. The Vice President, New Nuclear Program is also responsible for establishing and managing the NSSS contract for the development of new nuclear generation.

The Vice President, New Nuclear Program is responsible for licensing activities related to the New Nuclear Program and New Nuclear Project Sites. These include, Early Site Permits (ESPs), Limited Work Authorizations (LWA), Construction Permits (CPs), Operating Licenses (OLs), Combined Operating Licenses (COLs), Design Certifications (DCs) and Standard Design Approval Applications (SDAs). Roles and responsibilities for these activities are contained in New Nuclear Program procedures and guidelines.

The Vice President, New Nuclear Program interfaces with the Vice President, Site Projects for project-related advanced nuclear technology development, Licensing, Supply Chain, and Safety during the design phase and for corporate support during construction and operations in fulfillment of their responsibilities.

1.3. Executive Vice President/Chief Operating Officer

The Chief Operating Officer (COO) is responsible for TVA's transmission and power supply, power operations, resource management and operations services, and generation projects and fleet services. The Chief Operating Officer supports TVA Nuclear through the Senior Vice President, Resource Management and Operations Support. Organizations that report through the Senior Vice President, Resource Management and Operations Support include Supply Chain, Nuclear Materials, Central Labs and Services, and Inspection Services. The COO also supports the New Nuclear Projects activities through the Senior Vice President, New Nuclear Projects.

The COO will interface with the CNO regarding QA decisions affecting the New Nuclear Program. The COO does not have the authority to disposition quality assurance issues affecting the New Nuclear Program organization.

1.3.2 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. The Senior Vice President, New Nuclear Projects is also responsible for all technical and administrative support activities provided by the Site Project and its contractors.

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. During the transition of a New Nuclear project from design/construction phase to operational phase as defined by programs and procedures, 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 until it is deemed that they are no longer necessary.

During all phases, QA management has access to the Senior Vice President, New Nuclear Projects as the executive with overall responsibilities for QA. General Manager, New Nuclear Projects Quality Assurance shall have the freedom and authority to raise issues, that cannot be resolved at lower levels, to the Chief Operating Officer for final decision.

1.3.2.1 General Manager, New Nuclear Projects Quality Assurance

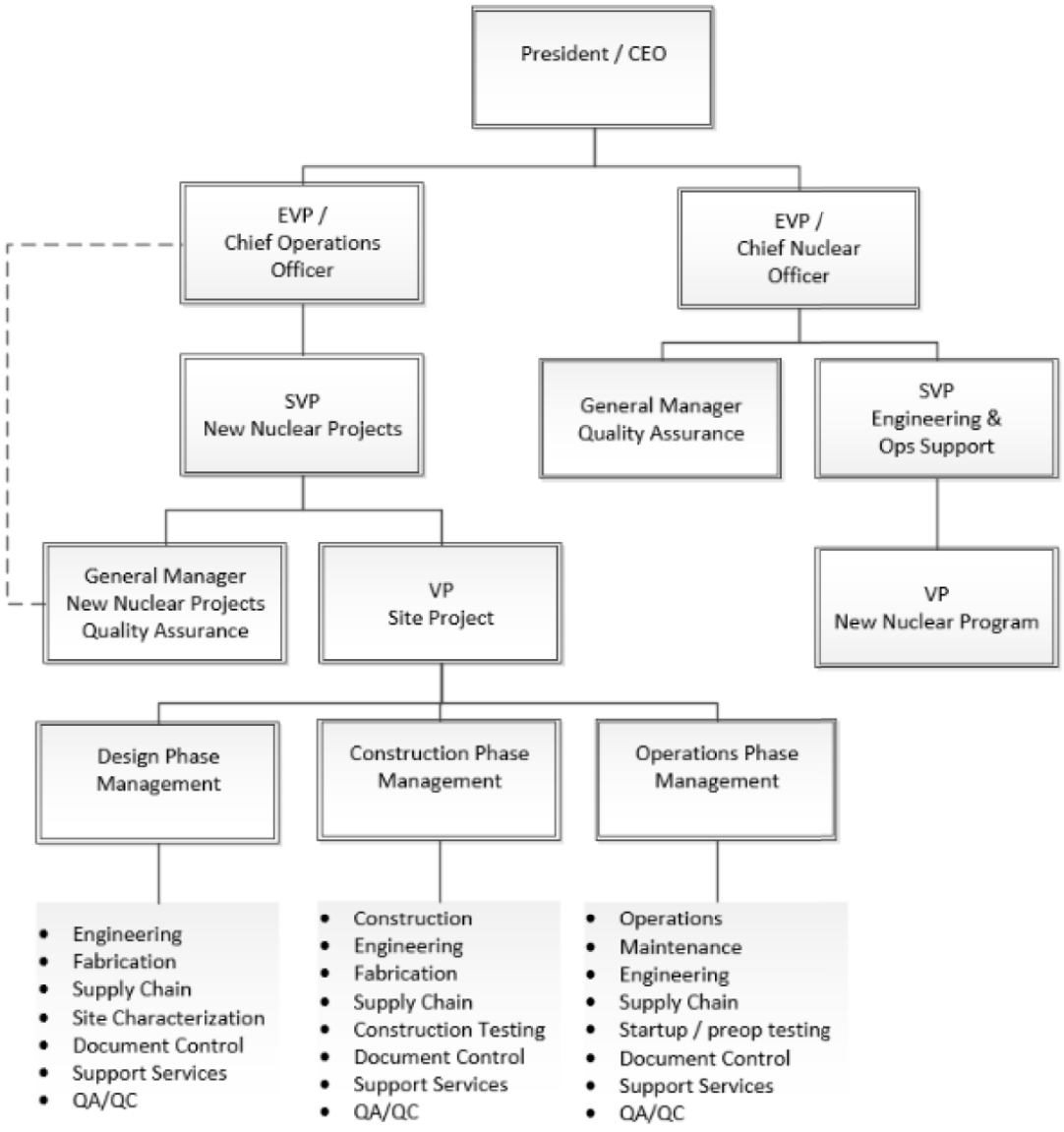
The General Manager, New Nuclear Projects Quality Assurance (QA) is the management position responsible for the quality aspects of New Nuclear Projects. The General Manager, New Nuclear Projects QA reports to the Senior Vice President, New Nuclear Projects with direct access to Chief Operating Officer on quality issues. The General Manager, New Nuclear Projects QA administers quality assurance responsibilities through the management positions responsible for New Nuclear Project Site QA.

The General Manager, New Nuclear Projects QA is responsible for assigning an individual to direct and manage the onsite New Nuclear Project QA. This individual has appropriate organizational position, responsibility, and authority to exercise proper control over the QAP at the project site. This individual is free from non-QA duties and can thus give full attention to ensuring that the QAP at the project site is effectively implemented. The General Manager, New Nuclear Projects QA is also responsible through the management position at the new nuclear project site for quality control and quality assurance activities during the design, construction, and operations phases of the project.

The General Manager, New Nuclear Projects QA is responsible for planning and performing activities to verify the development and effective implementation of the New Nuclear QAPD. Effective implementation includes but is not limited to developing and maintaining the New Nuclear QAPD, evaluating compliance to QAP requirements, assuring compliance with regulatory requirements and procedures through audits and technical reviews, monitoring organizational processes to ensure conformance to commitments and licensing document requirements, and ensuring that vendors providing quality services, parts, and materials to site projects are meeting the requirements of 10 CFR 50, Appendix B through NUPIC, joint utility, or TVA vendor audits.

Figure II.1-1 has been revised to reflect the General Manager Quality Assurance for the TVA Nuclear Fleet, and the New Nuclear Programs and Projects reporting alignments as follows.

FIGURE II.1-1 TVA NEW NUCLEAR ORGANIZATION



RAI 1, Part 2:

In addition, the NRC staff requests the applicant to clarify whether the role of President/Chief Executive Officer (CEO), Executive Vice President (EVP)/Chief Nuclear Officer (CNO), and EVP/COO will oversee the design, construction, and operation phase for all new nuclear projects.

TVA Response:

As noted in response to part 1 of this RAI, clarification for President/Chief Executive Officer, Executive Vice President/Chief Nuclear Officer, and Executive Vice President/Chief Operating Officer responsibilities for overseeing all phases of New Nuclear Programs and Projects has been added to Part II, Section 1 Organization, Sections 1.1, 1.2, and 1.3 respectively.

RAI 1, Part 3:

The NRC staff also reviewed the role of the Senior Vice President, New Nuclear Projects and the General Manager New Nuclear Quality Assurance, as described in Sections 1.5.1 and 1.5.2 of the TVA New Nuclear Program QAPD TR, Revision 0 and requests the applicant to clarify whether there is a specific QA person assigned to each new nuclear plant site during the operational phase who will be responsible for directing and managing the onsite QA program, to address the acceptance criteria in in Section 17.5, Subsection II, Item A.13.

TVA Response:

TVA has revised, in part, the position description for the General Manager, New Nuclear Projects QA (Section 1.3.2.1) to state the following:

> The General Manager, New Nuclear Projects Quality Assurance (QA) is the management position responsible for New Nuclear Projects. The General Manager, New Nuclear Projects QA reports to the Senior Vice President, New Nuclear Projects with direct access to Chief Operating Officer on quality issues. The General Manager, New Nuclear Projects QA administers quality assurance responsibilities through the management positions responsible for New Nuclear Project Site QA.
>
> The General Manager, New Nuclear Projects QA is responsible for assigning an individual to direct and manage the onsite New Nuclear Project QA. This individual has appropriate organizational position, responsibility, and authority to exercise proper control over the QAP at the project site. This individual is free from non-QA duties and can thus give full attention to ensuring that the QAP at the project site is effectively implemented. The General Manager, New Nuclear Projects QA is also responsible through the management position at the new nuclear project site for quality control and quality assurance activities during the design, construction, and operations phases of the project.
>
> The General Manager, New Nuclear Projects QA is responsible for planning and performing activities to verify the development and effective implementation of the New Nuclear QAPD. Effective implementation includes but is not limited to developing and maintaining the New Nuclear QAPD, evaluating compliance to QAP requirements, assuring compliance with regulatory requirements and procedures through audits and technical reviews, monitoring organizational processes to ensure conformance to

commitments and licensing document requirements, and ensuring that vendors providing quality services, parts, and materials to site projects are meeting the requirements of 10 CFR 50, Appendix B through NUPIC, joint utility, or TVA vendor audits.

RAI 2

Criterion I of Appendix B to 10 CFR Part 50 requires, in part, that "the applicant shall be responsible for the establishment and execution of the QAP. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility for the quality assurance program."

Part II. Section I, "Organization," states "Design, engineering, environmental, and construction services may be provided to the TVA New Nuclear Program organization by contractors in accordance with their QAPDs." Section 1.4, "New Nuclear Program" within Part II. Section I, states, "TVA New Nuclear Program is responsible for all aspects of licensing, nuclear site development, and advanced design engineering." Section 1.5, "New Nuclear Projects," states "New Nuclear Projects is responsible for the site preparation and infrastructure, developing the standard plant design, establishing the construction plan applying innovation in engineering, design and construction activities and executing the projects."

Based on the description of Part I, Section I regarding use of contractors and the role of the TVA New Nuclear Program, the NRC staff requests the following clarifications:

1) *Clarify whether design, engineering, environmental, and construction services associated with safety-related activities performed "by contractors in accordance with their QAPDs" is limited to those contractors that perform these services through a QAPD that is compliant with Appendix B to 10 CFR Part 50.*

2) *Clarify the relationship between TVA New Nuclear Program and New Nuclear Projects.*

3) *Clarify the role of TVA New Nuclear Program in terms of licensing activities. Specifically, will this program be responsible for design certification/standard design approval related activities and any site-specific licensing activities (e.g., COL, ESP, CP, etc.). If this program is responsible for all these activities, will there be any separation of roles and responsibilities within the organization for each type of application to resolve any interface issues between these types of applications.*

RAI 2, Part 1:

1) *Clarify whether design, engineering, environmental, and construction services associated with safety-related activities performed "by contractors in accordance with their QAPDs" is limited to those contractors that perform these services through a QAPD that is compliant with Appendix B to 10 CFR Part 50.*

TVA Response:

Part II, Section I, "Organization" of the New Nuclear QAPD has been clarified to require that contractor/supplier QAPDs are either in compliance with 10 CFR 50 App B or the affected

contractor/suppliers will be required to perform work under the TVA Fleet QAPD or the New Nuclear QAPD. The following text has been added to Part II, Section 1.

> Design, engineering, environmental, and construction services may be provided to the TVA New Nuclear organization by contractors in accordance with their QAPDs compliant with 10 CFR 50, Appendix B, or shall be required to meet the requirements of the TVA New Nuclear QAPD or TVA Fleet QAPD.

RAI 2, Part 2:

2) *Clarify the relationship between TVA New Nuclear Program and New Nuclear Projects.*

TVA Response:

TVA New Nuclear Program activities are performed under the oversight of the General Manager, Quality Assurance in accordance with the TVA Fleet QAPD. TVA New Nuclear Projects activities are performed under the oversight of the General Manager, New Nuclear Projects Quality Assurance in accordance with the TVA New Nuclear QAPD.

The following language has been included in a new paragraph two to Part II, Section I, "Organization" of the New Nuclear QAPD to clarify the relationship between New Nuclear Program and New Nuclear Projects:

> The TVA New Nuclear organization is divided into two parts: New Nuclear Program and New Nuclear Projects. The New Nuclear Program addresses global infrastructure and programmatic matters with siting, licensing, and planning for multiple new nuclear projects across multiple sites. The New Nuclear Projects organization supports the engineering, procurement, construction, startup, and operational development activities of specific projects at designated sites.

RAI 2, Part 3:

3) *Clarify the role of TVA New Nuclear Program in terms of licensing activities. Specifically, will this program be responsible for design certification/standard design approval related activities and any site-specific licensing activities (e.g., COL, ESP, CP, etc.). If this program is responsible for all these activities, will there be any separation of roles and responsibilities within the organization for each type of application to resolve any interface issues between these types of applications.*

TVA Response:

TVA has clarified the role of the Vice President, New Nuclear Programs, in Part II, Section I, "Organization" as provided below, to include licensing responsibilities for the New Nuclear. Language was added to state that these activities and roles/responsibilities will be controlled by procedures/guidelines.

> 1.2.1.1. Vice President, New Nuclear Program
>
> Vice President, New Nuclear Program reports to the Senior Vice President, Nuclear Engineering and Operations Support. This position is responsible for nuclear site development, fabrication, supply chain, site characterization, document control and advanced design engineering. The Vice President, New

Nuclear Program is also responsible for developing strategies for workforce development, training, and transition planning for TVA New Nuclear. The Vice President, New Nuclear Program is responsible for technical and administrative support activities provided by New Nuclear and contractors. The Vice President, New Nuclear Program is responsible for establishing and managing the NSSS contract for the development of new nuclear generation.

The Vice President, New Nuclear Program is responsible for licensing activities related to the TVA New Nuclear Sites. These include, Early Site Permits (ESPs), Limited Work Authorizations (LWA), Construction Permits (CPs), Operating Licenses (OLs), Combined Operating Licenses (COLs), Design Certifications (DCs) and Standard Design Approval Applications (SDAs). Roles and responsibilities for these activities are contained in New Nuclear procedures and guidelines.

The Vice President, New Nuclear Program interfaces with the Vice President, Site Projects for project-related advanced nuclear technology development, Licensing, Supply Chain, and Safety during the design phase and for corporate support during construction and operations in fulfillment of their responsibilities.

RAI 3

Criterion I of Appendix B to 10 CFR Part 50 requires, in part, that "The persons and organizations performing QA functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. The persons organizations performing quality assurance functions shall report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided."

Part II, Section 1.5.2, "General Manager, New Nuclear Quality Assurance," of the TVA New Nuclear Program QAPD TR, Revision 0, states, in part, "The General Manager, New Nuclear Quality Assurance reports to the TVA Senior Vice President, New Nuclear Projects with direct access to Chief Operating Officer. The General Manager is responsible for planning and performing activities to verify the development and effective implementation of the QAPD. The QA function has sufficient independence from other TVA New Nuclear Program priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas regarding TVA New Nuclear Program design activities as appropriate. QA may make recommendations to management regarding improving the quality of work processes. If QA disagrees with any actions taken by the organization and is unable to obtain resolution, QA shall inform quality assurance management and bring the matter to the attention of the COO, who will determine the final disposition." Figure II.1 depicts the organizational relationship of the General Manager New Nuclear Quality Assurance under the EVP/COO and separately, the VP New Nuclear Programs falls under EVP/CNO. Part II, Section 2.1, "Responsibilities," of the QAPD states that personnel who work directly or indirectly for TVA New Nuclear Program are responsible for achieving acceptable quality in the work covered by the QAPD. This includes the activities delineated in Part I, Section 1.1.

The NRC staff reviewed Part II, Sections 1.5.2 and 2.1 of the TVA New Nuclear Program QAPD TR and finds that this section does not clearly describe the personnel and organization that will be performing QA function as required by Criterion I of Appendix B to 10 CFR Part 50. The NRC

staff requests the applicant to specify whether a QA organization will be established for design, construction, and operations phases, to which the General Manger, New Nuclear Quality Assurance, will oversee. In addition, given that the EVP/CNO and EVP/COO both reporting to the President/CEO, the NRC staff requests the applicant to explain the authority of EVP/COO to make appropriate QA decisions for the TVA New Nuclear Program.

RAI 3, Part 1:

The NRC staff reviewed Part II, Sections 1.5.2 and 2.1 of the TVA New Nuclear Program QAPD TR and finds that this section does not clearly describe the personnel and organization that will be performing QA function as required by Criterion I of Appendix B to 10 CFR Part 50. The NRC staff requests the applicant to specify whether a QA organization will be established for design, construction, and operations phases, to which the General Manger, New Nuclear Quality Assurance, will oversee.

TVA Response:

TVA has revised Part II, Section 1.3.2.1 to specify that the General Manager, New Nuclear Projects Quality Assurance is responsible to clearly describe the personnel and organization that will be performing QA functions. This revision states:

> 1.3.2.1 General Manager, New Nuclear Projects Quality Assurance
>
> The General Manager, New Nuclear Projects Quality Assurance (QA) is the management position responsible for New Nuclear Projects. The General Manager, New Nuclear Projects QA reports to the Senior Vice President, New Nuclear Projects with direct access to Chief Operating Officer on quality issues. The General Manager, New Nuclear Projects QA administers quality assurance responsibilities through the management positions responsible for New Nuclear Project Site QA.
>
> The General Manager, New Nuclear Projects QA is responsible for assigning an individual to direct and manage the onsite New Nuclear Project QA. This individual has appropriate organizational position, responsibility, and authority to exercise proper control over the QAP at the project site. This individual is free from non-QA duties and can thus give full attention to ensuring that the QAP at the project site is effectively implemented. The General Manager, New Nuclear Projects QA is also responsible through the management position at the new nuclear project site for quality control and quality assurance activities during the design, construction, and operations phases of the project.

RAI 3, Part 2:

In addition, given that the EVP/CNO and EVP/COO both reporting to the President/CEO, the NRC staff requests the applicant to explain the authority of EVP/COO to make appropriate QA decisions for the TVA New Nuclear Program.

TVA Response:

The COO will not disposition quality assurance issues affecting the New Nuclear Program organization. Issues affecting the New Nuclear Program organization will be dispositioned by the General Manager, Quality Assurance who reports to the CNO. The following new

paragraph has been added to Part II, Section 1.3, Executive Vice President/Chief Operating Officer.

> The COO will interface with the CNO regarding QA decisions affecting the New Nuclear Program. The COO does not have the authority to disposition quality assurance issues affecting the New Nuclear Program organization.

RAI 4

Criterion II, "Quality Assurance Program," of Appendix to 10 CFR Part 50 requires the applicant to establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this appendix. This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout plant life in accordance with those policies, procedures, or instructions. The applicant shall identify the structures, systems, and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations." SRP Section 17.5, Subsection II, Item B specifies acceptance criteria to meet the requirements of Criterion II of Appendix B to 10 CFR Part 50. Item B.5 within this SRP section specifies that, "The QAPD includes the criteria used to identify the items and activities to which the QA program applies. A list of the SSCs and/or activities under the control of the QA program is required to be established and maintained at the applicant's or holder's facility. This does not apply to ESP applicant QA programs." In addition, Item B.6 within this SRP section states, "The QA program ensures that activities affecting quality will be accomplished under suitable controlled conditions, including (1) the use of appropriate equipment, (2) a suitable environment for accomplishing the activity, e.g., adequate cleanliness, and (3) compliance with necessary prerequisites for the given activity."

Part II, Section 2, "Quality Assurance Program," of the TVA New Nuclear Program QAPD TR, Revision 0, states, in part, that "The objective of the QAP is to assure that TVA New Nuclear Program's 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 structures, systems, and components (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. Examples of ESP, CP/OL, or COL program safety-related activities include, but are not limited to, site-specific engineering related to safety-related SSCs, site geotechnical investigations, site engineering analysis, seismic analysis, and meteorological analysis. A list or system that identifies SSCs and activities to which this program applies is maintained at the appropriate facility."

Part II, Section 2 also states "New nuclear plant construction will be the responsibility of TVA New Nuclear Program 's construction organization. Detailed engineering specifications and construction procedures will be developed to implement the QAPD prior to commencement of pre-construction and/or construction activities. In general, the program requirements specified herein are detailed in implementing procedures that are either TVA New Nuclear Program implementing procedures, or supplier implementing procedures governed by a supplier quality assurance program."

The NRC staff reviewed Part II, Section 2 of the TVA New Nuclear Program QAPD TR, Revision 0, and finds that additional information is required to demonstrate compliance with the

requirements of Criterion II of Appendix B to 10 CFR Part 50. Specifically, the NRC staff requests the applicant to:

1) *Clarify the applicability of this QAPD to quality related activities that involve the functions of safety-related activities for DC and SDA applications;*

2) *Demonstrate how the acceptance criteria within SRP Section 17.5, Subsection II, Item B.5 for criteria that will be used to identify SSCs and/or activities to which the QAP applies and Item B.6 for the QAP to ensure that activities affecting quality will be accomplished under suitable controlled conditions, have been addressed in the QAPD TR; and*

3) *Clarify whether New Nuclear Projects will be using the TVA New Nuclear Program implementing procedures or will separate implementing procedures be developed and used by New Nuclear Projects.*

RAI 4, Part 1:

1) *Clarify the applicability of this QAPD to quality related activities that involve the functions of safety-related activities for DC and SDA applications;*

TVA Response:

TVA confirms that the QAPD applies to quality related activities that involve the functions of safety-related activities for DC and SDA applications. Part I Section 1.1, “Scope and Applicability” states in part, “The QAPD applies to design phase, construction phase and operations phase activities, including those in support of Standard Design Approval (SDA), Design Certification (DC), Early Site Permit (ESP), Limited Work Authorization (LWA), Construction Permit (CP), construction/pre-operation, Operating License (OL), Combined Operating License (COL), and operation activities affecting the quality and performance of safety-related structures, systems, and components, …”

TVA has revised the fifth paragraph of QAPD Part II Section 2, “Quality Assurance Program” by adding the following text:

> For the ESP, CP/OL, and/or COL applications, the QAPD applies to those activities that can affect either directly or indirectly the safety-related site characteristics or analysis of those characteristics. <u>For DC and SDA applications, the QAPD applies to those activities that involve or affect safety-related functions. In addition, the QAPD applies to engineering activities that are used to characterize the site or analyze that characterization.</u>

RAI 4, Part 2:

2) *Demonstrate how the acceptance criteria within SRP Section 17.5, Subsection II, Item B.5 for criteria that will be used to identify SSCs and/or activities to which the QAP applies and Item B.6 for the QAP to ensure that activities affecting quality will be accomplished under suitable controlled conditions, have been addressed in the QAPD TR;*

TVA Response:

TVA has revised Part II, Section 2, Quality Assurance Program to provide compliance with SRP Section 17.5, Subsection II. Paragraphs 1 and 2 of Part II, Section 2, Quality Assurance Program have been revised. Paragraph 1 has been revised to read:

> TVA New Nuclear QA program ensures that activities affecting quality shall be accomplished under suitably controlled conditions, including (1) the use of appropriate equipment, (2) a suitable environment for accomplishing the activity, e.g., adequate cleanliness, and (3) compliance with necessary prerequisites for the given activity. 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 New Nuclear is committed to implementing the QAP in all aspects of work that are important to the safety of the nuclear plants as described and to the extent delineated in the QAPD. The QAP shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities important to safety are performed satisfactorily. Further, TVA New Nuclear ensures through the systematic process described herein that its suppliers of safety-related equipment or services meet the applicable requirements of 10 CFR 50, Appendix B. Senior management is regularly apprised of the adequacy of implementation of the QAP through the audit functions described in Part II, Section 18.

Paragraph 2 has been revised to read:

> The objective of the QAP is to assure that the TVA New Nuclear generating plants are designed, constructed, and operated in accordance with governing regulations and license requirements. The program is based on the requirements of ASME NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," as endorsed by Regulatory Guide 1.28, Revision 5 and as described in this document. The QAP applies to those quality-related activities that involve the functions of safety-related structures, systems, and components (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. Examples of ESP, CP/OL, or COL program safety-related activities include, but are not limited to, site-specific engineering related to safety-related SSCs, site geotechnical investigations, site engineering analysis, seismic analysis, and meteorological analysis. 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. Cost and scheduling challenges must be addressed; however, they do not prevent proper implementation of the QAP.

RAI 4, Part 3:

3) *Clarify whether New Nuclear Projects will be using the TVA New Nuclear Program implementing procedures or will separate implementing procedures be developed and used by New Nuclear Projects.*

TVA Response:

To the extent practical existing TVA Nuclear implementing procedures will apply to both New Nuclear Programs and New Nuclear Projects. Where TVA Nuclear implementing procedures cannot be applied to New Nuclear Projects, new procedures will be developed for use by New Nuclear Projects. No change was made to the New Nuclear QAPD.

RAI 5

Criterion II of Appendix to 10 CFR Part 50 states, in part, that "The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained." RG 1.28, Revision 5, endorses NQA-1-2015 with specific clarifications, as one method for meeting the requirements of Appendix B to 10 CFR Part 50. NQA-1-2015, Part 1, Requirement 2, provides specific training and qualification requirements for personnel performing nondestructive examination, inspection and test, and audits. RG 1.28, Section C.1.a provides clarifications on audit participation requirements in NQA-1-2015, Part 1, Requirement 2.

Part II, Section 2.6, "Personnel Training and Qualification" of the TVA New Nuclear Program QAPD TR, Revision 0, states, in part, "TVA New Nuclear Program 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." The NRC staff reviewed this section and found that no specific training or qualification requirements were provided for personnel performing nondestructive examination, inspection and test, and audits, as specified in NQA-1-2015, Part 1, Requirement 2 and clarified in RG 1.28, Section C.1.a. As such, the NRC staff requests the applicant to provide additional information in TVA New Nuclear Program QAPD TR to address training and qualification requirements for these positions.

TVA Response:

TVA is committed to NQA-1-2015 Requirement 2. Sections 301 and 302 of Requirement 2 satisfy requirements for NDE and Test and Inspection personnel.

For audit personnel, the regulatory guidance in RG 1.28 Revision 5, Section C.1.a allows for prospective lead auditors to satisfy the audit participation requirements by participating in at least one nuclear audit within the year preceding qualification and demonstrating ability to properly implement the audit process. As the Staff noted, TVA New Nuclear QAPD Revision 0, did not implement this alternative.

TVA has revised New Nuclear QAPD Part II Section 2.7 NQA-1 Commitment/Exceptions to incorporate the alternate method of qualification of prospective lead auditors as follows:

2.7.1 NQA-1 Commitment / Exceptions

In establishing qualification and training programs, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 2 and the applicable regulatory position stated in Regulatory Guide 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 three (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.

RAI 6

Criterion III, "Design Control," of Appendix B to 10 CFR Part 50 requires, in part, that measures to be established to assure that applicable regulatory requirements and the design basis, as defined in § 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems, and components.

NQA-1-2015, Part I, Requirement 3, as endorsed in RG 1.28, Revision 5, provides criteria on establishing design control measures. Section 200 within Requirement 3 states, "Applicable design inputs shall be identified and documented, and their selection reviewed and approved. The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes." Section 300 within Requirement 3 specifies criteria for the design process.

Part II, Section 3, "Design Control" of the TVA New Nuclear Program QAPD TR, Revision 0 states, in part, that "TVA New Nuclear Program has established and implements a process to control the design, design changes, and temporary modifications (e.g., temporary bypass lines, electrical jumpers, and lifted wires, and temporary setpoints) of items that are subject to the provisions of the QAPD. The design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within TVA New Nuclear Program 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 3.5, "NQA-1 Commitment," of the TVA New Nuclear Program QAPD TR, Revision 0, states that "In establishing its program for design control and verification, TVA New Nuclear Program commits to compliance with NQA-1-2015 Part II, Subpart 2.7 Quality Assurance Requirements for Computer Software for nuclear facilities applications, NQA-1-2015, Part II, Subpart 2.14 for Quality Assurance Requirements for Commercial Grade Items and Services, and Part II, Subpart 2.20 for Quality Assurance Requirements for Subsurface Investigations for Nuclear Facilities (Subpart 2.20 does not apply to Operations activities)."

The NRC staff reviewed Part II, Section 3.1 of the TVA New Nuclear Program QAPD TR, Revision 0, and finds that this section does not specify that design inputs will be identified and documented, and the selection of these design inputs are reviewed and approved, to address the guidance in Section 200 within Requirement 3 of NQA-1-2015. In addition, the NRC staff finds this section of the QAPD does not address the guidance in Section 300 within Requirement 3 of NQA-1-2015 for the design process. Further, Part II, Section 3.5 of the QAPD TR only commits to NQA-2015, Part II, Subparts 2.7, 2.14, and 2.20, and does not commit to compliance with NQA-1-2015, Part I, Requirement 3. The staff requests the applicant to clarify whether it commitments to compliance NQA-1-2015, Part I, Requirement 3, and if so, how the guidance in Section 200 and 300 of the NQA-1-2015, Part I, Section 3 are addressed in the TVA New Nuclear Program QAPD, TR, in order to meet the requirements in Criterion III of Appendix B to 10 CFR Part 50.

RAI 6, Part 1

Further, Part II, Section 3.5 of the QAPD TR only commits to NQA-2015, Part II, Subparts 2.7, 2.14, and 2.20, and does not commit to compliance with NQA-1-2015, Part I, Requirement 3.

TVA Response:

TVA acknowledges the inadvertent omission of a statement of commitment to NQA-1 Part I Requirement 3 in QAPD Part II, Section 3. TVA commits to NQA-1-2015 Part I Requirement 3, including the requirements established in Sections 200 and 300.

QAPD Part II, Section 3.5 has been amended to read as follows:

> In establishing its program for design control and verification, TVA New Nuclear commits to compliance with NQA-1-2015 Part I Requirement 3, NQA-1-2015 Part II, Subpart 2.7 Quality Assurance Requirements for Computer Software for nuclear facilities applications, NQA-1-2015, Part II, Subpart 2.14 Quality Assurance Requirements for Commercial Grade Items and Services, and Part II, Subpart 2.20 Quality Assurance Requirements for Subsurface Investigations for Nuclear Facilities (Subpart 2.20 does not apply to Operations activities).

RAI 6, Part 2

The staff requests the applicant to clarify whether it commitments to compliance NQA-1-2015, Part I, Requirement 3, and if so, how the guidance in Section 200 and 300 of the NQA-1-2015, Part I, Section 3 are addressed in the TVA New Nuclear Program QAPD, TR, in order to meet the requirements in Criterion III of Appendix B to 10 CFR Part 50.

TVA Response:

TVA has revised, in part, the first paragraph of Part II, Section 3 “Design Control” to clarify our commitment to the guidance of NQA-1-2015, section 200 and 300 as follows:

> TVA New Nuclear shall 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 shall support the facility design, construction, and operation. Appropriate quality standards shall be

identified and documented, and their selection reviewed and approved. TVA New Nuclear has established and implements a process to control the design, design changes, and temporary modifications (e.g., temporary bypass lines, electrical jumpers, and lifted wires, and temporary setpoints) of items that are subject to the provisions of the QAPD. Applicable design inputs shall be identified and documented, and their selection reviewed and approved. The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a controlled manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. The design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within TVA New Nuclear and with suppliers. 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. 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. Design change processes and the division of responsibilities for design-related activities are detailed in TVA New Nuclear and supplier procedures. Changes to design inputs, final designs, and field changes, and temporary and permanent modifications ~~to operating facilities~~ are justified and subject to design control measures commensurate with those applied to the original design. The design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution, and revision of design inputs and outputs. Design changes and disposition of nonconforming items as "use as is" or "repair" are reviewed and approved by the New Nuclear engineering or by other organizations so authorized by TVA New Nuclear.

RAI 7

Criterion III of Appendix B to 10 CFR Part 50 requires, in part, that design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.

Part II, Section 3 of the TVA New Nuclear Program QAPD TR, Revision 0 states, in part, that "Design change processes and the division of responsibilities for design-related activities are detailed in TVA New Nuclear Program and supplier procedures. Changes to design inputs, final designs, and field changes, and temporary and permanent modifications to operating facilities are justified and subject to design control measures commensurate with those applied to the original design… Design changes and disposition of nonconforming items as "use as is" or "repair" are reviewed and approved by the New Nuclear Program, Project Engineering or by other organizations so authorized by TVA New Nuclear Program."

The NRC staff reviewed this section and requests the applicant to clarify:

1) *whether the design change processes and the division of responsibilities for design-related activities will remain with the TVA New Nuclear Program procedures during the operation phase of a site; and*

2) *whether the statement: "Changes to design inputs, final designs, and field changes, and temporary and permanent modifications to operating facilities are justified and subject to design control measures commensurate with those applied to the original design," applies only to the facilities in operation or would this statement also apply to changes during the design and construction phase.*

RAI 7, Part 1:

1) *The NRC staff reviewed this section and requests the applicant to clarify whether the design change processes and the division of responsibilities for design-related activities will remain with the TVA New Nuclear Program procedures during the operation phase of a site;*

TVA Response:

Following transition from the construction phase to the operating phase, the design change process, procedures, and division of responsibilities will remain with the TVA New Nuclear organization.

The TVA New Nuclear Quality Assurance Plan Part II, Section 1 "Organization" Section 1.3.2, paragraph two has been revised to read as follows:

> 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. <u>During the transition of a New Nuclear project from design/construction phase to operational phase as defined by programs and procedures, 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 activities will retain their applicable responsibilities until it is deemed that they are no longer necessary.</u>

RAI 7, Part 2:

The NRC staff reviewed this section and requests the applicant to clarify whether the statement: "Changes to design inputs, final designs, and field changes, and temporary and permanent modifications to operating facilities are justified and subject to design control measures commensurate with those applied to the original design," applies only to the facilities in operation or would this statement also apply to changes during the design and construction phase.

TVA Response:

Controls are applied to design changes during the design, construction, and operations phases. The first paragraph in Part II, Section 3 "Design Control" has been revised to delete the phrase "to operating facilities".

> <u>TVA New Nuclear organization shall 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 shall support the facility design, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and</u>

approved. TVA New Nuclear has established and implements a process to control the design, design changes, and temporary modifications (e.g., temporary bypass lines, electrical jumpers, and lifted wires, and temporary setpoints) of items that are subject to the provisions of the QAPD. Applicable design inputs shall be identified and documented, and their selection reviewed and approved. The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a controlled manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. The design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within TVA New Nuclear and with suppliers. 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. 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. Design change processes and the division of responsibilities for design-related activities are detailed in TVA New Nuclear and supplier procedures. Changes to design inputs, final designs, and field changes, and temporary and permanent modifications ~~to operating facilities~~ are justified and subject to design control measures commensurate with those applied to the original design. The design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution, and revision of design inputs and outputs. Design changes and disposition of nonconforming items as "use as is" or "repair" are reviewed and approved by the New Nuclear, Project Engineering or by other organizations so authorized by TVA New Nuclear.

RAI 8

Criterion III of Appendix B to 10 CFR Part 50 requires, in part, that "design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization." SRP Section 17.5, Subsection II, Item C specifies acceptance criteria to meet the requirements of Criterion III of Appendix B to 10 CFR Part 50. Item C.19.b within this SRP section states, in part, that "Construction site activities associated with a design or design change should not proceed without verification past the point where the installation would become irreversible (i.e., require extensive demolition and rework). In all cases, the design verification should be complete prior to fuel load for a plant under construction, or in the case of an operating plant, prior to relying upon the component, system, or structure to perform its function." In addition, Item C.19.c within this SRP section states, in part, that "Procedural control is established for design documents; this control differentiates between documents that receive formal design verification by interdisciplinary or multi-organizational teams and those which can be reviewed by a single individual (a signature and date is acceptable documentation for personnel certification)."

Part II, Section 3.1, "Design Verification," of the TVA New Nuclear Program QAPD TR, Revision 0 states, in part, that, "TVA New Nuclear Program design processes provide for design verification to ensure that items, computer programs, and activities subject to the provisions of the QAPD are suitable for their intended application, consistent with their effect on safety… Design verification procedures are established and implemented to assure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria are identified, and the verification is satisfactorily accomplished and documented…TVA New Nuclear Program normally completes design verification activities before the design outputs are used by other organizations for design work, and before they are used to support other activities such as procurement, or construction. When such timing cannot be achieved, the design verification is completed before relying on the item to perform its intended design or safety function."

Based on the review Part II, Section 3.1 of the QAPD TR, the NRC staff requests the applicant to demonstrate how the guidance within SRP, Section 17.5, Subsection II, Item C.19.b related to construction activities design change verification and completion of design verification prior to fuel load for a plant under construction, are addressed in the TVA New Nuclear Program QAPD TR. In addition, the NRC staff requests the applicant to demonstrate how the guidance SRP, Section 17.5, Subsection II, Item C.19.c related to establishing controls to differentiates between documents that receive formal design verification by interdisciplinary or multi-organizational teams and those which can be reviewed by a single individual, are addressed in in the TVA New Nuclear Program QAPD TR.

RAI 8, Part 1:

Based on the review Part II, Section 3.1 of the QAPD TR, the NRC staff requests the applicant to demonstrate how the guidance within SRP, Section 17.5, Subsection II, Item C.19.b related to construction activities design change verification and completion of design verification prior to fuel load for a plant under construction, are addressed in the TVA New Nuclear Program QAPD TR.

TVA Response:

TVA has revised the last paragraph of Section 3.1 "Design Verification" to provide the following guidance**.**

> TVA New Nuclear normally completes design verification activities before the design outputs are used by other organizations for design work, and before they are used to support other activities such as procurement, or construction. When such timing cannot be achieved, <u>the design verification is completed 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.</u>

RAI 8, Part 2:

The NRC staff requests the applicant to demonstrate how the guidance SRP, Section 17.5, Subsection II, Item C.19.c related to establishing controls to differentiates between documents that receive formal design verification by interdisciplinary or multi-organizational teams and those which can be reviewed by a single individual, are addressed in in the TVA New Nuclear Program QAPD TR.

TVA Response:

TVA has added a new second paragraph of QAPD Part II, Section 3 “Design Control” to clarify how procedural controls will be established for design documents as follows:

> Procedural control is established for design documents; this control differentiates between documents that receive formal design verification by interdisciplinary or multi-organizational teams and those which can be reviewed by a single individual (a signature and date is acceptable documentation for personnel certification). Design documents subject to procedural control include, but are not limited to, specifications, calculations, computer programs, system descriptions, Safety Analysis Report when used as a design document, and drawings including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams structural systems for major facilities, site arrangements, and equipment locations. Specialized reviews should be used when uniqueness or special design considerations warrant.

RAI 9

Criterion III of Appendix B to 10 CFR Part 50 states, in part, that “Measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in § 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions.”

Part II, Section 3.4, “Setpoint Control,” of the TVA New Nuclear Program QAPD TR, Revision 0, states that instrument and equipment setpoints that could affect nuclear safety shall be controlled in accordance with written instructions. This section provides criteria that should be included, as a minimum, in these written instructions. The NRC staff requests the applicant to clarify whether the criteria written instructions used for setpoint control apply to only the operational phase or to the design and construction phases as well.

TVA Response:

TVA New Nuclear has developed instructions and requirements necessary for preparing, revising, controlling, issuing, and maintaining setpoint documents. The purpose of these setpoint documents is to serve as a design output document to transmit requirements to New Nuclear project site organizations to ensure values/conditions assessed in the safety analyses or other design documents relative to instrument setpoints are incorporated in the plant as assessed in the relevant design documents. Setpoint Control is established at system turnover to the operations phase. Procedures have also been developed to apply to the process of controlling setpoints and with installation and calibration of process instruments.

As such, TVA has revised Section 3.4, “Setpoint Control” to clarify the sources of setpoint design output as follows:

> Instrument and equipment setpoints that could affect nuclear safety shall be controlled in accordance with written instructions. As a minimum, these written instructions shall:
>
> - Identify responsibilities and processes for reviewing, approving, and revising

setpoints and setpoint changes supplied by a supplier, Design Certification holder, or the plant's technical staff.

- Ensure that setpoints and setpoint changes are consistent with design and accident analysis requirements and assumptions.
- Provide for documentation of setpoints, including those determined operationally.
- Provide for access to necessary setpoint information for personnel who write or revise plant procedures, operate, or maintain plant equipment, develop, or revise design documents, or develop or revise accident analyses.

This subsection does not apply to ESP activities.

RAI 10

Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50, states, "Measures shall be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements." SRP Section 17.5, Subsection II, Item I specifies acceptance criteria to meet the requirements of Criterion IX of Appendix B to 10 CFR Part 50. Items I.3 and I.4 within this SRP section state, "Each special process instruction includes or references procedure(s), personnel, and equipment qualification requirements," and "Records are maintained as appropriate for the currently qualified personnel, processes, and equipment for each special process," respectively.

The NRC staff reviewed Part II, Section 9, "Control of Special Processes," and Section 17, "Quality Assurance Record," of the TVA New Nuclear Program QAPD TR, Revision 0, and did not identify how the applicant has addressed the guidance in SRP, Section 17.5, Subsection II, Item I.3 and I.4 states. As such the NRC staff requests the applicant to address the guidance in SRP, Section 17.5, Subsection II, Item I.3 and I.4.

TVA Response:

TVA has revised Section 9 "Control of Special Processes to clarify its commitment to NQA-1-2015 to include instruction or procedures for special process requirements and to specify records maintenance as follows:

> 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 includes or references procedures, personnel, and equipment qualification requirements. Personnel are qualified and special processes are performed in accordance with applicable codes, standards, specifications, criteria, or other specially established requirements. Records are maintained as appropriate for the currently qualified personnel, processes, and equipment for each special process. Special processes are those where the results are highly dependent on the control of the

process or the skill of the operator, or both, and for which the specified quality cannot be fully and readily determined by inspection or test of the final product.

RAI 11

Criterion X, "Inspection," of Appendix B to 10 CFR Part 50, states, in part, that "A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity." SRP Section 17.5, Subsection II, Item J specifies acceptance criteria to meet the requirements of Criterion X of Appendix B to 10 CFR Part 50. Item J.9 within this SRP section, states "Inspection records identify item inspected, date of inspection, the inspector's identity, type of observation, results, or acceptability, and reference to information on action taken in connection with nonconformances."

Part II, Section 10, "Inspection," of the TVA New Nuclear Program QAPD TR, Revision 0, states, in part, that "Inspection results are documented." Part II, Section 10.1, "Inspection Program," of the QAPD TR states, in part, that, "Inspection program documents establish requirements for performing the planned inspections, and documenting required inspection information such as rejection, acceptance, and re-inspection results, and the person(s) performing the inspection. Inspection results are documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings."

The NRC staff reviewed Part II, Sections 10 and 10.1 of the TVA New Nuclear Program QAPD TR, Revision 0, and finds that these sections did not address the guidance in SRP Section 17.5, Subsection II, Item J.9 for the type of observation and references to information on action taken in connection with nonconformances. As such, the NRC staff requests the applicant to address this portion of the guidance in SRP Section 17.5, Subsection II, Item J.9.

TVA Response:

TVA has revised the fourth paragraph of Section 10.1 "Inspection Program" to clearly identify the content of inspection records as follows:

> Inspection records identify item inspected, date of inspection, the inspector's identity, type of observation, inspection results and acceptability, and reference to information on action taken in connection with nonconformances. Inspection results are documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings.

RAI 12

Criterion XI, "Test Control" of Appendix B to 10 CFR Part 50, states, in part, that "A test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents…Test results shall be documented and evaluated to assure that test requirements have been satisfied." SRP Section 17.5, Subsection II, Item K specifies acceptance criteria to meet the requirements of Criterion XI of Appendix B to 10 CFR Part 50. Item K.6 within this SRP section states, "Test records, at a minimum, identify the item

tested, date of test, tester or data recorder, type of observation, results and acceptability, action taken in connection with any deviations noted, and the person evaluating test results."

Part II, Section 11, "Test Control," of the TVA New Nuclear Program QAPD TR, Revision 0, states, in part, that "Test programs ensure appropriate retention of test data in accordance with the records requirements of the QAPD."

The NRC staff reviewed Part II, Section 17 of the TVA New Nuclear Program QAPD TR, Revision 0, and did not identify specific records requirements for retention of test data. In addition, the NRC staff finds that the guidance in SRP Section17.5, Subsection II, Item K.6, specific to test records requirements, has not been addressed by the applicant. As such, the NRC staff requests the applicant to address the guidance in SRP Section 17.5, Subsection II, Item K.6.

TVA Response:

TVA has revised the last sentence of the first paragraph of Section 11 Test Control to add clarity for the requirements for test records:

> 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 as a whole 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 Technical Specifications), to demonstrate that performance of plant systems is in accordance with design. Programs also include provisions to establish and adjust test schedules, and to maintain status for periodic or recurring tests. Tests are performed according to applicable procedures that include, consistent with the effect on safety: (1) instructions and prerequisites to perform the tests, (2) use of proper test equipment, (3) acceptance criteria, and (4) mandatory verification points as necessary to confirm satisfactory test completion. Test results are documented and evaluated by the organization performing the test and reviewed by a responsible authority to assure that the test requirements have been satisfied. If acceptance criteria are not met, re-testing is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure. <u>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 deviations noted, and the person evaluating test results.</u>

RAI 13

Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50, states "Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits." SRP Section 17.5, Subsection II, Item L specifies acceptance criteria to meet the requirements of Criterion XII of Appendix B to 10 CFR Part 50. Item L.4 within this SRP section states that maintenance and test equipment (M&TE) should be calibrated, adjusted, and maintained at

prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration should be documented. Item L.5 within this SRP section states that M&TE that are found to be out of calibration should be tagged or segregated and not used until it is recalibrated. When M&TE is found out of calibration, an evaluation should be made and the validity of previous inspection or test results and of the acceptability of items previously inspected or tested should be documented. If any measuring or test equipment is consistently found out of calibration, it should be repaired or replaced. A calibration should be performed when the accuracy of the equipment is suspect.

Part II, Section 12, "Control of Measuring and Test Equipment," of the TVA New Nuclear Program QAPD TR, Revision 0, states, in part, that the TVA New Nuclear Program has established the necessary measures and governing procedures to control the calibration, maintenance, and use of M&TE that provides data to verify acceptance criteria are met or information important to safe plant operation. Section 12.1 of the QAPD TR describes the controls for calibration and adjustment of instrument and control devices installed in the facility during the operational phase of the facility.

The NRC staff reviewed Part II, Sections 12 and 12.1 of the TVA New Nuclear Program QAPD TR, Revision 0, and finds that these sections did not contain information to address the guidance in SRP Section 17.5, Subsection II, Items L.4 and L.5. As such, the NRC staff requests the applicant to demonstrate how the guidance in Items L.4 and L.5 of this SRP section has been addressed in the QAPD TR.

TVA Response:

TVA has revised Section 12.1 Installed Instrument and Control Devices to address the Staff's questions regarding Measuring and Test Equipment. This paragraph now reads:

12.1 Installed Instrument and Control Devices

For the operational phase of the facilities, TVA New Nuclear shall establish and implement procedures for the calibration and adjustment of instrument and control devices installed in the facility. The calibration and adjustment of these devices is accomplished through the facility maintenance programs to ensure the facility is operated within design and technical requirements. 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 no nationally recognized standards exist, the bases for calibration are documented. M&TE found out of calibration is tagged or segregated and not used until it is recalibrated. When M&TE is found out of calibration, an evaluation is made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested using the suspect M&TE. Any measuring or test equipment consistently found out of calibration is repaired or replaced. A calibration is performed when the accuracy of the equipment is suspect. Appropriate documentation will be maintained for these devices to indicate the control status, when the next calibration is due, and identify any limitations on use of the device. This paragraph does not apply to ESP activities.

RAI 14

Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50, states "Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. Nonconforming items shall be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures." SRP Section 17.5, Subsection II, Item O specifies acceptance criteria to meet the requirements of Criterion XV of Appendix B to 10 CFR Part 50. Item O.5 within this SRP section states that the disposition, such as use as-is, reject, repair, or rework, of nonconforming items should be identified and documented. Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use as-is should be documented. Item O.6 within this SRP section states that reworked, repaired, and replacement items should be inspected and tested in accordance with the original inspection and test requirements or specified alternatives.

Part II, Section 15, "Control of Nonconforming Items," of the TVA New Nuclear Program QAPD TR, Revision 0, states, in part, that "TVA New Nuclear Program 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."

The NRC staff reviewed Part II, Section 15, of the TVA New Nuclear Program QAPD TR, Revision 0 and finds that these sections did not contain information to address the guidance SRP Section 17.5, Subsection II, Items O.5 and O.6. As such, the NRC staff requests the applicant the applicant to demonstrate how the guidance in Items O.5 and O.6 of this SRP section has been addressed in the QAPD TR.

TVA Response:

TVA has revised Section 15 Control of Nonconforming Items to ensure the disposition of use-as-is, reject, repair or rework is identified and documented. Additionally, guidance has been added to ensure that items that are reworked, repaired, and replaced are inspected and tested in accordance with the original inspection and test requirements or specified alternatives. The paragraph now reads:

> 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, "Corrective Action". Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. Controls are provided to address conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release. <u>Item disposition, such as use-as-is, reject, repair, or rework shall be identified and documented.</u> Conditional release of nonconforming items for installation requires the approval of the designated management. Nonconformances are corrected or resolved prior to depending on the item to perform its intended safety function. Nonconformances are evaluated for impact on operability of quality structures, systems, and components to assure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements

dispositioned repair or use-as-is are subject to design control measures commensurate with those applied to the original design and the technical justification for acceptability of a nonconforming item, dispositioned 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, analysis of quality trends, and reports provided to the designated management. Significant trends are reported to management in accordance with TVA New Nuclear procedures, regulatory requirements, and industry standards.

RAI 15

Criterion XV of Appendix B to 10 CFR Part 50, states, in part, "Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation." 10 CFR Part 21.2(a)(3) and (a)(4) identify applicability of 10 CFR Part 21 for each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, applying for a design certification rule under 10 CFR Part 52, and applying for or holding a standard design approval under 10 CFR Part 52, respectively.

Part II, Section 15.1, "Interface with the Reporting Program," of the QAPD TR, Revision 0, describes the interfaces between the QAP for identification and control of nonconforming materials, parts, or components and the non-QA Reporting Program to satisfy the requirements of 10 CFR 52, 10 CFR 50.55, and 10 CFR 21 during ESP/CP/COL design and construction, and 10 CFR 21 during operations.

The NRC staff requests the applicant to clarify whether there will be appropriate interfaces between the QAP for identification and control of non-conforming materials, parts or components and the non-QA Reporting Program to satisfy the requirements of interface requirements of 10 CFR Part 52 and 10 CFR Part 21 for design certification and standard design approval applicants and holders.

TVA Response:

TVA agrees that a reference to design certification (DC) and standard design approval (SDA) applicants and holders should be added to Section 15.1, "Interface with the Reporting Program" of the New Nuclear QAPD. As a result, Section 15.1 has been revised to add the underlined text as follows:

15.1 Interface with Reporting Program

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

RAI 16

Criterion XVI, "Corrective Action" of Appendix B to 10 CFR Part 50, states, in part, "Criterion XV of Appendix B to 10 CFR Part 50, states, in part, "Measures shall be established to control

materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation." 10 CFR Part 21.2(a)(3) and (a)(4) identify applicability of 10 CFR Part 21 for each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, applying for a design certification rule 10 CFR Part 52, and applying for or holding a standard design approval under 10 CFR Part 52, respectively.

Part II, Section 16.1, "Interface with the Reporting Program," of the QAPD TR, Revision 0, describes the interfaces between the QAP for corrective actions and the non-QA Reporting Program to satisfy the requirements of 10 CFR 52, 10 CFR 50.55, and 10 CFR 21 during ESP/CP/COL design and construction, and 10 CFR 21 during operations.

The NRC staff requests the applicant to clarify whether there will be appropriate interfaces between the QAP for corrective action and the non-QA Reporting Program to satisfy the requirements of interface requirements of 10 CFR Part 52 and 10 CFR Part 21 for design certification and standard design approval applicants and holders.

TVA Response:

TVA agrees that a reference to design certification (DC) and standard design approval (SDA) applicants and holders should be added to Section 16.1, "Interface with the Reporting Program" of the New Nuclear QAPD. As a result, Section 16.1 has been revised to add the underlined text as follows:

16.1 Interface with the Reporting Program

TVA New Nuclear has appropriate interfaces with the corrective action program to satisfy the reporting requirements of 10 CFR 52 and 10 CFR 21 during design certification and standard design approval, 10 CFR 52, 10 CFR 50.55, and 10 CFR 21 during ESP/CP/COL design and construction, and 10 CFR 21 during operations.

RAI 17

Criterion XVII, "Quality Assurance Records" of Appendix B to 10 CFR Part 50, states, in part, that "Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted."

SRP Section 17.5, Subsection II, Item Q specifies acceptance criteria to meet the requirements of Criterion XVII of Appendix B to 10 CFR Part 50. Item Q.8 within this SRP section states that all records should be retrievable, maintained in a readable format, and safeguarded against equipment malfunction or human error. Document access controls, user privileges, and other appropriate security controls should be established. RG 1.28, Revision 5, Section C.3 provides the staff's position on QA records in addition to NQA-1-2015, Requirement 17.

Part II, Section 17 of the TVA New Nuclear Program QAPD TR, Revision 0, states, in part, that "TVA New Nuclear Program has 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." Section 17.1, "Record Retention," of QAPD TR, states, in part, that "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 and retention times are based on Regulatory Position C.3.a.(1) and C.3.a.(2) of Regulatory Guide 1.28, Revision 5 for design, construction, and initial start-up. Retention times for operational phase records are based on construction records that are similar in nature."

The NRC staff reviewed Part II, Sections 17 and 17.1 of the TVA New Nuclear Program QAPD TR, Revision 0 and finds that information was not included to demonstrate how the requirement for inclusion of operating logs and the results of reviews, monitoring of work performance, and materials analyses in records in Criterion XVII of Appendix B to 10 CFR Part 50 are met. In addition, the NRC staff did not identify how the guidance in SRP 17.5, Subsection II, Item Q.8 with respect to ensuring records are safeguarded against equipment malfunction or human error, and establishing access controls, user privileges, and other appropriate security controls, has been addressed in the QAPD TR, Revision 0. As such, the NRC staff requests the applicant to demonstrate how the requirements in Criterion XVII of Appendix B to 10 CFR Part 50 for the types of records that must be maintained are met. In addition, the NRC staff requests that the applicant address the guidance in Section 17.5, Subsection II, Items Q.8. Further, NRC staff requests the applicant to clarify whether RG 1.28, Revision 5, Regulatory Position C.3.a.(1), with respect to maintaining a lifetime record for the life of the particular item for the life while it is installed in the plant or stored for future use, and Regulatory Position C.3.a(2) with respect to documenting nonpermanent record retention periods and maintaining of these records for their retention period, are applied to permanent and nonpermanent records, respectively, during plant operational phase.

RAI 17, Part 1:

The NRC staff requests the applicant to demonstrate how the requirements in Criterion XVII of Appendix B to 10 CFR Part 50 for the types of records that must be maintained are met.

TVA Response:

TVA has revised Section 17.1, "Record Retention" to more clearly align with the guidance found in 10 CFR Part 50, Appendix B, criterion XVII, as stated below:

> Sufficient records shall be maintained to furnish evidence of activities affecting quality. 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 shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall meet the requirements of NQA-1-2015, Section 11.
>
> Records shall be identifiable and retrievable. The records and retention times are based on Regulatory Position C.3.a.(1) for Lifetime Records and C.3.a.(2) for Non-permanent

> Records of Regulatory Guide 1.28, Revision 5 for design, construction, and initial start-up, and Regulatory Guide 1.33, Revision 3 for operational phase. Retention times for permanent and nonpermanent operational phase records are based on construction records that are similar in nature. In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met.

RAI 17, Part 2:

The NRC staff requests that the applicant address the guidance in Section 17.5, Subsection II, Items Q.8.

TVA Response:

TVA has revised Section 17 Quality Assurance Records to include guidance regarding the records program as follows:

> TVA New Nuclear has 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 program provides provisions for the administration, receipt, storage, preservation, safekeeping, retrieval, and disposition of all records. All records must be retrievable, maintained in a readable format, and safeguarded against equipment malfunction or human error. Document access controls, user privileges, and other appropriate security controls must be established (ANSI/ANS 3.2).

RAI 17, Part 3:

NRC staff requests the applicant to clarify whether RG 1.28, Revision 5, Regulatory Position C.3.a.(1), with respect to maintaining a lifetime record for the life of the particular item for the life while it is installed in the plant or stored for future use, and Regulatory Position C.3.a(2) with respect to documenting nonpermanent record retention periods and maintaining of these records for their retention period, are applied to permanent and nonpermanent records, respectively, during plant operational phase.

TVA Response:

TVA has revised Section 17.1 Record Retention to reflect that permanent and nonpermanent records will be maintained during the plant operational phase as follows:

> Sufficient records shall be maintained to furnish evidence of activities affecting quality. 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 shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall meet the requirements of NQA-1-2015, Section 11.

Records shall be identifiable and retrievable. The records and retention times are based on Regulatory Position C.3.a.(1) for Lifetime Records and C.3.a.(2) for Non-permanent Records of Regulatory Guide 1.28, Revision 5 for design, construction, and initial start-up, and Regulatory Guide 1.33, Revision 3 for operational phase. Retention times for permanent and nonpermanent operational phase records are based on construction records that are similar in nature. In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met.

TVA has also revised Section 17.3 NQA-1 Commitment to reflect the commitment to Regulatory Guide 1.2.8, Revision 5, Regulatory Positions C.3.a.(1) and C.3.a.(2). The NQA-1 Commitment now states:

17.3 NQA-1 Commitments

In establishing provisions for records, TVA New Nuclear commits to compliance with NQA-1-2015 Requirement 17 as endorsed by Regulatory Guide 1.28, Revision 5, including Regulatory Positions C.3.a.(1) and C.3.a.(2).

RAI 18

Part III, Section 2, "Non-Safety-Related Structures, Systems, and Components Credited for Regulatory Events," of the TVA New Nuclear Program QAPD TR, Revision 0, states that for fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), the station blackout (SBO) (10 CFR 50.63) SSCs that are not safety-related, TVA New Nuclear program implements quality requirements for:

- *Fire protection systems in accordance with Regulatory Position 1.7, "Quality Assurance," in RG 1.189, "Fire Protection for Nuclear Power Plants," Revision 3;*
- *Safety Significant, but not safety-related, ATWS equipment in accordance with Part III, Section 1 of the TVA New Nuclear Program QAPD TR, Revision 0;*
- *Safety Significant, but not safety-related, SBO equipment in accordance with Part III, Section 1 of the TVA New Nuclear Program QAPD TR, Revision 0.*

The NRC staff reviewed the criteria that are applied to SSCs that are not safety-related but are credited for regulatory events in Part III, Section 2 of the TVA New Nuclear Program QAPD TR, Revision 0, and has the following questions regarding the quality requirements that are applied to fire protection systems. Specifically, the TVA New Nuclear Program QAPD TR, Revision 0, references RG 1.189, Revision 3. However, RG 1.189, Revision 4 is the most up-to-date version of this RG. The staff requests the applicant to clarify why Revision 3 was referenced in the QAPD TR instead of Revision 4. In addition, in Part IV, "Regulatory Commitments," of the QAPD TR, the applicant did not specify it conform to the guidance in RG 1.189. Therefore, the staff requests the applicant to clarify whether it commitments to conformance with RG 1.189, Revision 4.

In addition, the NRC staff requests the applicant to clarify whether applicability of Part III, Section 1 to ATWS and SBO equipment is consistent with the applicants planned applications with respect to different reactor technologies.

RAI 18, Part 1:

The staff requests the applicant to clarify why Revision 3 was referenced in the QAPD TR instead of Revision 4.

TVA Response:

The reference to RG 1.189, Revision 3, Part III, Section 2, was made in error. The first bullet should have referred to RG 1.189, Revision 4 and has been corrected in Part III, Section 2, "Nonsafety-Related Structures, Systems, and Components Credited for Regulatory Events" and reads as follows:

> The following criteria apply to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), the station blackout (SBO) (10 CFR 50.63) SSCs that are not safety-related:
>
> - TVA New Nuclear implements quality requirements for the fire protection system in accordance with Regulatory Guide 1.189, Fire Protection for Nuclear Power Plants, Revision 4.

RAI 18, Part 2:

The staff requests the applicant to clarify whether it commits to conformance with RG 1.189, Revision 4.

TVA Response:

As noted in response to Part 1 above, the existing text in Part III, Section 2, first bullet, has been revised as follows:

> TVA New Nuclear Program implements quality requirements for the fire protection system in accordance with Regulatory Guide 1.189, Fire Protection for Nuclear Power Plants, Revision 4.

Additionally, Part IV, Regulatory Commitments has been revised to include Regulatory Guide 1.189 as follows:

> **Regulatory Guide 1.189,** Fire Protection for Nuclear Power Plants, Revision 4.
>
> Regulatory Guide 1.189 provides an approach that is acceptable to meet the regulatory requirements of Title 10 of the Code of Federal Regulations (10 CFR) section 50.48(a). The standards of record related to the design and installation of fire protection systems and features required to satisfy NRC requirements in all new reactor designs are those NFPA codes and standards in effect 180 days before the submittal of the application under 10 CFR Part 50 or 10 CFR Part 52. TVA New Nuclear identifies conformance with and exceptions/clarifications for the applicable regulatory position guidance in this regulatory guide in applicable license applications based on an assessment of the reactor technology's requirements.

RAI 18, Part 3:

The NRC staff requests the applicant to clarify whether applicability of Part III, Section 1 to ATWS and SBO equipment is consistent with the applicant's planned applications with respect to different reactor technologies.

TVA Response:

The extent that different technologies require non-safety-related, safety-significant ATWS and/or SBO equipment will be assessed for each reactor technology selected for deployment at TVA. TVA has changed the following bullet points to Part III, Section 2, to reflect this requirement:

- TVA New Nuclear implements the quality requirements for nonsafety-related, safety significant ATWS equipment in accordance with Part III, Section 1, based on an assessment of the reactor technology's requirement for such equipment.

- TVA New Nuclear implements quality requirements for nonsafety-related, safety significant SBO equipment in accordance with Part III, Section 1, based on an assessment of the reactor technology's requirement for such equipment.

RAI 19

Criterion III, Criterion IV, "Procurement Document Control," and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50 establish the underlying regulatory requirements for dedication of commercial grade items for use as basic components at nuclear power plants. 10 CFR Part 21, "Reporting of Defects and Noncompliance," establish regulatory requirements to determine whether a basic component contains a defect or whether there is a failure to comply with Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards.

RG 1.164, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plant," Revision 0, describes methods acceptable to the NRC staff for complying with the regulatory requirements for dedication of commercial-grade items and services used in nuclear power plants. RG 1.231, "Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants," Revision 0, describes methods acceptable to the NRC staff for complying with the regulatory requirements for acceptance and dedication of commercial-grade design and analysis computer programs used in safety-related applications for nuclear power plants. RG 1.234, "Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21," Revision 0, describes methods acceptable to the NRC staff for complying with the provisions of 10 CFR Part 21.

Part IV of the TVA New Nuclear Program QAPD TR, Revision 0, identifies the NRC RGs and other QA standards which have been selected to supplement and support the QAPD. This section identifies the extent of conformance to these RGs and QA standards, including cases when conformance to these documents will be addressed within applicable license application documents submitted in accordance with 10 CFR Part 50 and 10 CFR Part 52. A list of RGs and standards is included in this section with descriptions of the applicant's commitment to conforming with the guidance.

The NRC staff reviewed the information on commitments to RGs and QA standards in this section and finds that Part IV of the TVA New Nuclear Program QAPD TR, Revision 0, did not include commitments to RG 1.164, Revision 0, RG 1.231, Revision 0, and RG 1.234, Revision 0. Given that these RGs provide guidance on acceptable methods to comply with regulatory requirements for commercial-grade dedication, and evaluation and reporting requirements in 10 CFR Part 21, the NRC staff requests the applicant to clarify whether it intends to conform to the guidance in these RGs or whether alternative methods will be used to comply with the applicable regulatory requirements.

TVA Response:

TVA has revised Part IV, "Regulatory Commitments" of the TVA New Nuclear Quality Assurance Program Description by adding the referenced regulatory guides as follows:

> **Regulatory Guide 1.164**, Dedication of Commercial-Grade Items for Use in Nuclear Power Plant, Revision 0, June 2017
>
> Regulatory Guide 1.164, Rev.0, provides guidance for dedication of commercial-grade items and services used in nuclear power plants. This RG endorses, in part, the Electric Power Research Institute (EPRI) 3002002982, Revision 1 to EPRI NP-5652 and TR-102260, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications", with respect to acceptance of commercial-grade dedication of items and services to be used as basic components for nuclear power plants. TVA New Nuclear identifies conformance and exceptions/clarifications for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications.
>
> **Regulatory Guide 1.231**, Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants, Revision 0, January 2017
>
> Regulatory Guide 1.231, Rev.0, provides guidance for the use of Revision 1 of EPRI Technical Report 1025243, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications", with respect to acceptance of commercial-grade design and analysis computer programs associated with basic components for nuclear power plants. TVA New Nuclear identifies conformance and conditions for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications.
>
> **Regulatory Guide 1.234**, Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21, Revision 0, April 2018.
>
> Regulatory Guide 1.234, Rev 0 provides guidance on an acceptable method of evaluating and reporting defects under 10 CFR Part 21. This guidance will aid in minimizing compliance challenges to licensees and vendors that have been identified through inspection activities. This new guide endorses Nuclear Energy Institute (NEI) 14-09, "Guidelines for Implementations of 10 CFR Part 21 Reporting of Defects and Noncompliance," Revision 1. TVA New Nuclear identifies conformance and clarifications for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications.

RAI 20

10 CFR 50.34(b)(6)(ii) requires that each application for an operating license includes a final safety analysis report (FSAR) that contain information on managerial and administrative controls to be used to assure safe operation. 10 CFR 52.79(a)(27) requires that an application for a COL includes a that contain information on managerial and administrative controls to be used to assure safe operation. Both these 10 CFR sections requires that the information on the controls to be used for a nuclear power plant must include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 is satisfied.

RG 1.33, "Quality Assurance Program Requirements (Operation)," Revision 3, describes methods that the NRC staff considers actable for complying with the provisions of regulations in 10 CFR 50.34(b)(6)(ii) and 10 CFR 52.79(a)(27). RG 1.33 endorses ANSI/ANS 3.2-2012, "Managerial, Administrative, and Quality Assurance Controls for Operational Phase of Nuclear Power Plants."

Part IV of the TVA New Nuclear Program QAPD TR, Revision 0, provides a list and descriptions of RGs and quality assurance standards that the applicant commitments to conformance with. The NRC staff reviewed this list and finds that the list does not include commitment to ANSI/ANS 3.2-2012. The NRC staff requests the applicant to clarify whether it will conform to the guidance in ANSI/ANS 3.2-2012, as endorsed by RG 1.33, Revision 3.

TVA Response:

TVA has added clarification to its commitment to Regulatory Guide 1.33 in Part IV, "Regulatory Commitments" of the New Nuclear QAPD to clarify that it will conform to the guidance in ANSI/ANS 3.2-2012, as endorsed by RG 1.33, Revision 3. The following revision has been made**:**

> Regulatory Guide 1.33, Rev. 3 June 2013, Quality Assurance Program Requirements (Operation)
>
> Regulatory Guide 1.33, Rev.3, describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to overall quality assurance program requirements for the operation phase of nuclear power plants. Revision 3 of the Regulatory Guide endorses ANSI/ANS 3.2 – 2012, Managerial, Administrative, and Quality Assurance Controls for the Operational Phase of Nuclear Power Plants. TVA New Nuclear will conform with Regulatory Guide 1.33, Rev. 3 and comply with the Staff Regulatory Guidance for meeting the conditions described on the use of ANSI/ANS 3.2 – 2012.

Enclosure 2

NNP-TR-001-NP, Revision 0 - Markup, Quality Assurance Program Description for TVA New Nuclear

NNP-TR-001-NP
Mark-up
Document Date: February 2023

Quality Assurance Program Description for TVA New Nuclear

Topical Report

Non-Proprietary

REVISION LOG

Revision	Date	Description of Revision
0	August 2022	Initial Issuance
Mark-up	February 2023	Updated to address final RAIs (eRAI-386). Changed title to New Nuclear versus New Nuclear Program QAP to further eliminate confusion. Also, changed references, where applicable, from New Nuclear Programs and New Nuclear Projects to New Nuclear.

EXECUTIVE SUMMARY

This topical report provides a description of the TVA New Nuclear Quality Assurance Program (QAP) for the site-selection, design, construction, and operation of nuclear plant(s) at multiple sites and projects. The QAP has been prepared in accordance with the requirements of Title 10, Part 50 of the Code of Federal Regulations (10 CFR 50), "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" and ASME NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications" as endorsed by Regulatory Guide (RG) 1.28, Revision 5, "Quality Assurance Program Criteria (Design and Construction)." This topical report considered the guidance in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 17.5, and is based on the Nuclear Energy Institute (NEI) 11-04A, "Nuclear Generation Quality Assurance Program Description" template. Departures from the NEI 11-04A template were necessary in some instances to conform to the Nuclear Regulatory Commission endorsement of NQA-1-2015 in RG 1.28, Revision 5.

The early site permit (ESP) for the Clinch River Small Modular Reactor (SMR) Project was produced under the TVA Nuclear Quality Assurance Plan (NQAP), TVA-NQA-PLN89-A, Revision 39, and is excluded from compliance with this QAP. ESPs for future SMR projects will comply with this QAP. Consistent with common licensing practice, text is written in the present tense, active voice, including discussions of activities and processes associated with a phased implementation of design, construction, and operation.

The topical report is divided into five parts:

- Introduction and Scope
- Quality Assurance Program Description (QAPD) Details
- Non-safety-Related Structures, Systems, and Components (SSC) Quality Control
- Regulatory Commitments, and
- Additional QA and Administrative Controls for the Plant Operational Phase

TVA New Nuclear requests NRC review and approval of this topical report to be used to satisfy quality assurance requirements for use by nuclear power plant applications submitted in accordance with 10 CFR 50 and 10 CFR 52:

- 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)
- Standard Design Approval (SDA) Applications pursuant to 10 CFR 52.137(a)(19)

ACRONYMS AND ABBREVIATIONS

Acronym / Abbreviation	**Definition**
AE	Architect/Engineer
ANS	American Nuclear Society
ASL	Acceptable Suppliers List
ASME	The American Society of Mechanical Engineers
ATWS	Anticipated Transient Without Scram
CFR	Code of Federal Regulations
COL	Combined Operating License
CP	Construction Permit
ESP	Early Site Permit
FSAR	Final Safety Analysis Report
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
ITAAC	Inspection, Tests, Analysis, Acceptance Criteria
LWA	Limited Work Authorization
M&TE	Measuring and Test Equipment
MRA	Mutual Recognition Agreement
NEI	Nuclear Energy Institute
NIRMA	Nuclear Information and Records Management Association
NQAP	Nuclear Quality Assurance Plan
NRC	Nuclear Regulatory Commission
NSSS	Nuclear Steam Supply System
NUPIC	Nuclear Procurement Issues Corporation
OL	Operating License
QA	Quality Assurance
QAP	Quality Assurance Program
QAPD	Quality Assurance Program Description
QC	Quality Control
RG	Regulatory Guide
RIS	Regulatory Issues Summary
SBO	Station Blackout
SDA	Standard Design Approval
SMR	Small Modular Reactor
SSC	Structures, Systems, and Components
TVA	Tennessee Valley Authority

TABLE OF CONTENTS

POLICY STATEMENT

Tennessee Valley Authority (TVA) New Nuclear shall design, procure, deliver, construct, and operate the nuclear plant(s) in a manner that will ensure the health and safety of the public and workers. These activities shall be performed in compliance with the requirements of the Code of Federal Regulations (CFR) and applicable laws and regulations of the state and local governments.

The TVA New Nuclear Quality Assurance Program (QAP) is the Quality Assurance Program Description (QAPD) provided in this document and the associated implementing documents. Together they provide for control of TVA New Nuclear activities that affect the quality of safety-related nuclear plant structures, systems, and components (SSCs) and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service. The QAPD may also 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 QAPD is the top-level policy document that establishes the manner in which quality is to be achieved and presents the TVA New Nuclear overall philosophy regarding achievement and assurance of quality. Implementing documents assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAP. Senior management establishes overall expectations for effective implementation of the quality assurance program and is responsible for obtaining the desired end result. Compliance with the QAPD and implementing documents is mandatory for personnel directly or indirectly associated with implementation of the TVA New Nuclear QAP.

Robert M. Deacy
Senior Vice President, New Nuclear Projects

Date

PART I. INTRODUCTION

SECTION 1. GENERAL

The QAPD is the top-level policy document that establishes the quality assurance policy and assigns major functional responsibilities for all quality-related activities conducted by or for TVA New Nuclear. The QAPD describes the methods and establishes quality assurance (QA) and administrative control requirements that meet 10 CFR 50, Appendix B and 10 CFR 52. The QAPD is based on the requirements and guidance of ASME NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, with specific reference to selected Part III and Part IV sections, as identified in this document.

The QAP is defined by the NRC-approved regulatory document that describes the QA elements (i.e., the QAPD), along with the associated implementing documents. Procedures and instructions that control quality-related activities will be developed prior to commencement of those activities. Policies establish high-level responsibilities and authority for carrying out important administrative functions which are outside the scope of the QAPD. Procedures establish practices for certain activities which are common to all TVA New Nuclear organizations performing those activities so that the activity is controlled and carried out in a manner that meets QAPD requirements. Procedures specific to a site, organization, or group establish detailed implementation requirements and methods, and may be used to implement policies or be unique to particular functions or work activities.

1.1. Scope/Applicability

The QAPD applies to design phase, construction phase and operations phase activities, including those in support of Standard Design Approval (SDA), Design Certification (DC), Early Site Permit (ESP), Limited Work Authorization (LWA), Construction Permit (CP), construction/pre-operation, Operating License (OL), Combined Operating License (COL), and operation activities affecting the quality and performance of safety-related structures, systems, and components, including, but not limited to:

- Designing
- Siting
- Procuring
- Fabricating
- Cleaning
- Handling
- Shipping
- Receiving
- Storing
- Constructing
- Erecting
- Installing
- Inspecting
- Testing
- Startup
- Pre-operational activities (including ITAAC)
- Operating
- Maintaining
- Repairing
- Modifying
- Refueling
- Training
- Decommissioning

Safety-related SSCs, under the control of the QAPD, are identified by design documents. The technical aspects of these items are considered when determining program applicability, including, as appropriate, the item's design safety function. The QAPD may be applied to certain activities where regulations other than 10 CFR 50 and 10 CFR 52 establish QA requirements for activities within their scope.

The policy of TVA New Nuclear is to assure a high degree of availability and reliability of the nuclear plant while ensuring the health and safety of its workers and the public. To this end, selected elements of the QAPD are also applied to certain equipment and activities that are not safety-related, but support safe, economic, and reliable plant operations, or where other NRC guidance establishes quality assurance requirements. Implementing documents establish program element applicability.

The definitions provided in ASME NQA-1–2015, Part I, Section 400, apply to select terms as used in this document.

PART II. QUALITY ASSURANCE PROGRAM DESCRIPTION (QAPD) DETAILS

SECTION 1 ORGANIZATION

This section describes the TVA New Nuclear organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of the QAPD. Management gives careful consideration to the timing, extent, and effects of organizational structure changes.

The TVA New Nuclear organization is divided into two parts: New Nuclear Program and New Nuclear Projects. The New Nuclear Program addresses global infrastructure and programmatic matters with siting, licensing, and planning for multiple new nuclear projects across multiple sites. The New Nuclear Projects organization supports the engineering, procurement, construction, startup, and operational development activities of specific projects at designated sites.

The management position responsible for Quality Assurance is responsible to size the New Nuclear Project Quality Assurance staff commensurate with the duties and responsibilities assigned.

The responsibility for quality related activities during design, construction, and operations phases are shown below:

Design Phase	Construction Phase	Operations Phase
• Engineering • Fabrication • Supply Chain • Site Characterization • Document Control and Other Support Services • QA/QC	• Construction • Engineering • Fabrication • Supply Chain • Construction Testing • Document Control and Other Support Services • QA/QC	• Operations • Maintenance • Engineering • Supply Chain • Startup/Preop Testing • Document Control and Other Support Services • QA/QC

Design, engineering, environmental, and construction services may be provided to the TVA New Nuclear organization by contractors in accordance with their QAPDs compliant with 10 CFR 50, Appendix B, or shall be required to meet the requirements of the TVA New Nuclear QAPD or TVA Fleet QAPD.

The following sections describe the reporting relationships, functional responsibilities, and authorities for organizations implementing and supporting the QAP. The TVA New Nuclear Organization is shown in Figure II.1–1.

1.1. President/Chief Executive Officer

The President/Chief Executive Officer (CEO) is responsible for all aspects of design, construction, and operation of TVA's nuclear plants, including new nuclear projects developed under TVA New Nuclear. The President/CEO is also responsible for all technical and administrative support activities provided by TVA and contractors. The President/CEO directs the Chief Nuclear Officer and the Chief Operating Officer in the fulfillment of their responsibilities. The President/CEO reports to the TVA Board of Directors with respect to all matters.

1.2. Executive Vice President/Chief Nuclear Officer

The Chief Nuclear Officer (CNO) is responsible for the safe, reliable, and efficient operation of the TVA Nuclear Plants. The CNO also has the overall responsibility for the establishment, implementation, and administration of TVA's Fleet NQAP and the evaluation of its effectiveness. This responsibility is implemented through the General Manager, Quality Assurance. The CNO also supports the New Nuclear Program activities through the Senior Vice President, Engineering and Operations Support.

1.2.1. Senior Vice President, Engineering and Operations Support

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

1.2.1.1. Vice President, New Nuclear Program

Vice President, New Nuclear Program reports to the Senior Vice President, Nuclear Engineering and Operations Support. This position is responsible for nuclear site development, fabrication, supply chain, site characterization, document control and advanced design engineering. The Vice President, New Nuclear Program is also responsible for developing strategies for workforce development, training, and transition planning for the New Nuclear Program. The Vice President, New Nuclear Program is responsible for technical, administrative, and corporate support services provided by New Nuclear Program and contractors. The Vice President, New Nuclear Program is also responsible for establishing and managing the NSSS contract for the development of new nuclear generation.

The Vice President, New Nuclear Program is responsible for licensing activities related to the New Nuclear Program and New Nuclear Project Sites. These include, Early Site Permits (ESPs), Limited Work Authorizations (LWA), Construction Permits (CPs), Operating Licenses (OLs), Combined Operating Licenses (COLs), Design Certifications (DCs) and Standard Design Approval Applications (SDAs). Roles and responsibilities for these activities are contained in New Nuclear Program procedures and guidelines.

The Vice President, New Nuclear Program interfaces with the Vice President, Site Projects for project-related advanced nuclear technology development, Licensing, Supply Chain, and Safety during the design phase and for corporate support during construction and operations in fulfillment of their responsibilities.

1.2.2. General Manager, Quality Assurance

The General Manager, Quality Assurance is the management position responsible for the nuclear operating fleet, vendors, and the TVA New Nuclear Program. The General Manager, QA has an independent reporting relationship to the CNO on quality issues. The General Manager, QA, administers quality assurance responsibilities through the management positions responsible for Corporate QA, Site QA, and QA Services.

The General Manager, Quality Assurance is responsible for planning and performing activities to verify the development and effective implementation of the Fleet QAPD. Effective implementation includes but is not limited to developing and maintaining the TVA Fleet QAPD, evaluating compliance to QAP requirements, assuring compliance with regulatory requirements and procedures through audits and technical reviews; monitoring organizational processes to ensure conformance to commitments and licensing document requirements; and ensuring that vendors providing quality services, parts, and materials to site projects are meeting the requirements of 10 CFR 50, Appendix B through NUPIC, joint utility, or TVA vendor audits.

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. QA may make recommendations to management regarding improving the quality of work processes. If QA disagrees with any actions taken by the organization and is unable to obtain resolution, QA shall inform quality assurance management and bring the matter to the attention of the Chief Nuclear Officer (CNO), who will determine the final disposition.

1.3. Executive Vice President/Chief Operating Officer

The Chief Operating Officer (COO) is responsible for TVA's transmission and power supply, power operations, resource management and operations services, and generation projects and fleet services. The Chief Operating Officer supports TVA Nuclear through the Senior Vice President, Resource Management and Operations Support. Organizations that report through the Senior Vice President, Resource Management and Operations Support include Supply Chain, Nuclear Materials, Central Labs and Services, and Inspection Services. The COO also supports the New Nuclear Projects activities through the Senior Vice President, New Nuclear Projects.

The COO will interface with the CNO regarding QA decisions affecting the New Nuclear Program. The COO does not have the authority to disposition quality assurance issues affecting the New Nuclear Program organization.

1.3.1 Senior Vice President, Resource Management and Operations Support

The Senior Vice President, Resource Management and Operations Support reports to the Chief Operating Officer. The management position responsible for procurement reports through the Vice President, Supply Chain to the Senior Vice President, Resource Management and Operations Support and is responsible for ensuring that the QA requirements established by this program description are either included or referenced (as appropriate) in related Procurement sponsored program areas.

1.3.2 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. The Senior Vice President, New Nuclear Projects is also responsible for all technical and administrative support activities provided by the Site Project and its contractors.

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. During the transition of a New Nuclear project from design/construction phase to operational phase as defined by programs and procedures, 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 until it is deemed that they are no longer necessary.

During all phases, QA management has access to the Senior Vice President, New Nuclear Projects as the executive with overall responsibilities for QA. General Manager, New Nuclear Projects Quality Assurance shall have the freedom and authority to raise issues, that cannot be resolved at lower levels, to the Chief Operating Officer for final decision.

1.3.2.1 General Manager, New Nuclear Projects Quality Assurance

The General Manager, New Nuclear Projects Quality Assurance (QA) is the management position responsible for the quality aspects of New Nuclear Projects. The General Manager, New Nuclear Projects QA reports to the Senior Vice President, New Nuclear Projects with direct access to Chief Operating Officer on quality issues. The General Manager, New Nuclear Projects QA administers quality assurance responsibilities through the management positions responsible for New Nuclear Project Site QA.

The General Manager, New Nuclear Projects QA is responsible for assigning an individual to direct and manage the onsite New Nuclear Project QA. This individual has appropriate organizational position, responsibility, and authority to exercise proper control over the QAP at the project site. This individual is free from non-QA duties and can thus give full attention to ensuring that the QAP at the project site is effectively implemented. The General Manager, New Nuclear Projects QA is also responsible through the management position at the new nuclear project site for quality control and quality assurance activities during the design, construction, and operations phases of the project.

The General Manager, New Nuclear Projects QA is responsible for planning and performing activities to verify the development and effective implementation of the New Nuclear QAPD. Effective implementation includes but is not limited to developing and maintaining the New Nuclear QAPD, evaluating compliance to QAP requirements, assuring compliance with regulatory requirements and procedures through audits and technical reviews, monitoring organizational processes to ensure conformance to commitments and licensing document requirements, and ensuring that vendors providing quality services, parts, and materials to site projects are meeting the requirements of 10 CFR 50, Appendix B through NUPIC, joint utility, or TVA vendor audits.

The QA function has sufficient independence from other TVA New Nuclear priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas regarding TVA New Nuclear activities as appropriate. QA may make recommendations to management regarding improving the quality of work processes. If QA disagrees with any actions taken by the New Nuclear Projects organization and is unable to obtain resolution, QA shall inform quality assurance management and bring the matter to the attention of the Chief Operating Officer (COO), who will determine the final disposition.

1.3.2.2 Vice President, Site Project

The Vice President, Site Project reports to the Senior Vice President, New Nuclear Projects and is responsible for the Design Phase, Construction Phase and Operations Phase of a Project. This position is also responsible for the oversight of design changes and configuration management. The following provides the detailed oversight and execution responsibilities for Vice President, Site Project for each phase of the Site Project.

1.3.2.2.1 Design Phase Management Team

The Design Phase Management Team reports to the Vice President, Site Project and is responsible for Engineering, Fabrication, Supply Chain, Document Control, and support services.

The Design Phase Management Team is staffed and has the appropriate authority required to perform quality-related design activities. Interfaces between design phase management and corporate support is defined in implementing procedures.

1.3.2.2.2 Construction Phase Management Team

The Construction Phase Management Team reports to the Vice President, Site Project and is responsible for construction activities, including construction, engineering fabrication, supply chain, construction testing, document control and other support services.

The Construction Phase Management Team is staffed and has the appropriate authority required to perform quality-related construction activities. Interfaces between site/construction phase management and corporate support is defined in implementing procedures.

1.3.2.2.3 Operations Phase Management Team

The Operations Phase Management Team reports to the Vice President, Site Project and is responsible for plant operation activities, including operations, maintenance, engineering, supply chain, startup/preoperational testing, document control and other support services.

The Operations Phase Management Team is staffed and has the appropriate authority required to perform quality-related operations activities. It is anticipated that even after fuel load, construction activities will be ongoing. Those positions required to support these activities will retain their applicable construction/pre-operation responsibilities until it is deemed that they are no longer necessary. As the construction of systems (or portions thereof) is completed, control and authority (including oversight, configuration, and operations) are transferred from Construction Phase Management to the cognizant departments in the operational phase. During

the transition to an operating facility, responsibilities will be clearly defined in instructions and procedures to ensure appropriate authority is maintained for each SSC.

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.

1.4. Nuclear Steam Supply System (NSSS) Supplier

The Vice President, New Nuclear Program is responsible for establishing and managing oversight and execution activities of the Nuclear Steam Supply System (NSSS) Supplier. A NSSS Supplier provides engineering services for plant design and licensing of specific plant types for TVA New Nuclear. These engineering services for new nuclear generation include site-specific engineering and design necessary to support development of ESP, CP, OL and COL applications and preconstruction and construction activities.

1.5. Architect/Engineering (A/E) Suppliers

The Vice President, New Nuclear Program is responsible for establishing and managing oversight and execution activities of the Architect/Engineering (A/E) Suppliers. A/E Suppliers provide engineering services for the development of the ESP, CP, OL, and COL applications. These engineering services include site-specific licensing, engineering, and design activities, including planning and support for preconstruction and construction of new nuclear generation facilities.

1.6. Authority to Stop Work

Quality Assurance and Quality Control personnel have the authority, and the responsibility, 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 suppliers that furnish safety-related materials and services to TVA New Nuclear.

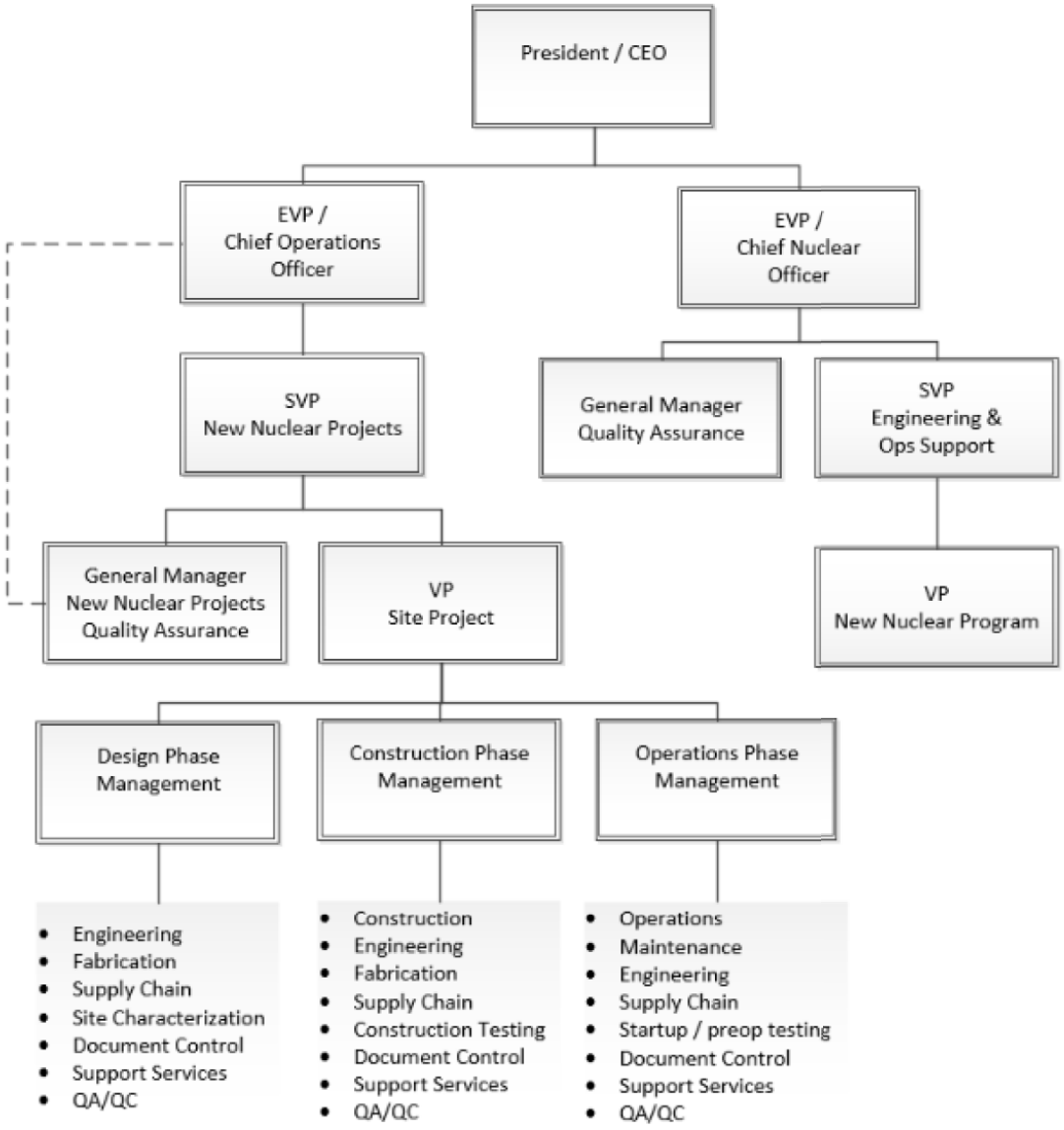
1.7. QA Organizational Independence

Independence shall be maintained between the organization(s) performing the checking (quality assurance and control) functions and the organizations performing the functions. This provision is not applicable to design review/verification.

1.8. NQA-1 Commitment

In establishing its organizational structure, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 1.

FIGURE II.1-1 TVA NEW NUCLEAR ORGANIZATION



QA function has direct access to levels of Management necessary to assure effective execution of the QA program irrespective of organizational structure.

SECTION 2 QUALITY ASSURANCE PROGRAM

TVA New Nuclear QA program ensures that activities affecting quality shall be accomplished under suitably controlled conditions, including (1) the use of appropriate equipment, (2) a suitable environment for accomplishing the activity, e.g., adequate cleanliness, and (3) compliance with necessary prerequisites for the given activity. 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 New Nuclear is committed to implementing the QAP in all aspects of work that are important to the safety of the nuclear plants as described and to the extent delineated in the QAPD. The QAP shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities important to safety are performed satisfactorily. Further, TVA New Nuclear ensures through the systematic process described herein that its suppliers of safety-related equipment or services meet the applicable requirements of 10 CFR 50, Appendix B. Senior management is regularly apprised of the adequacy of implementation of the QAP through the audit functions described in Part II, Section 18.

The objective of the QAP is to assure that the TVA New Nuclear generating plants are designed, constructed, and operated in accordance with governing regulations and license requirements. The program is based on the requirements of ASME NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," as endorsed by Regulatory Guide 1.28, Revision 5 and as described in this document. The QAP applies to those quality-related activities that involve the functions of safety-related structures, systems, and components (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. Examples of ESP, CP/OL, or COL program safety-related activities include, but are not limited to, site-specific engineering related to safety-related SSCs, site geotechnical investigations, site engineering analysis, seismic analysis, and meteorological analysis 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. Cost and scheduling challenges must be addressed; however, they do not prevent proper implementation of the QAP.

As described in Part III of the QAPD, specific program controls are applied to non-safety-related SSCs that are significant contributors to plant safety, for which 10 CFR 50, Appendix B, is not applicable. The specific program controls, consistent with applicable sections of the QAPD, are applied to those items in a select manner, targeted at those characteristics or critical attributes that qualifies the SSC as a significant contributor to plant safety. (This paragraph and Part III do not apply to ESP related activities.)

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 (ASL). Periodic audits and assessments of supplier QA programs are performed to assure compliance with the supplier's or principal contractor's QAPD and implementing procedures. In addition, routine interfaces with the supplier’s personnel provide added assurance that quality expectations are met.

For the ESP, CP/OL, and/or COL applications, the QAPD applies to those activities that can affect either directly or indirectly the safety-related site characteristics or analysis of those

characteristics. For DC and SDA applications, the QAPD applies to those activities that involve or affect safety-related functions. In addition, the QAPD applies to engineering activities that are used to characterize the site or analyze that characterization.

New nuclear plant construction will be the responsibility of TVA New Nuclear organization. Detailed engineering specifications and construction procedures will be developed to implement the QAPD prior to commencement of pre-construction and/or construction activities. Examples of Limited Work Authorization (LWA) activities that could impact safety-related SSCs include impacts of construction to existing facilities and, for construction of a new plant, the interface between nonsafety-related and safety-related SSCs and the placement of seismically designed backfill. (This requirement does not apply to ESP or operations related activities.)

In general, the program requirements specified herein are detailed in implementing procedures that are either TVA New Nuclear implementing procedures, or supplier implementing procedures governed by a supplier quality assurance program.

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 backwards by performing the activity early. Audit schedules are based on the month in which the audit starts.

2.1. Responsibilities

Personnel who work directly or indirectly for TVA New Nuclear are responsible for achieving acceptable quality in the work covered by the QAPD. This includes the activities delineated in Part I, Section 1.1. TVA New Nuclear personnel performing verification activities are responsible for verifying the achievement of acceptable quality. Activities governed by the QAPD are performed as directed by documented instructions, procedures, and drawings that are of a detail appropriate for the activity's complexity and effect on safety. Instructions, procedures, and drawings specify quantitative or qualitative acceptance criteria as applicable or appropriate for the activity, and verification is against these criteria. Provisions are established to designate or identify the proper documents to be used in an activity, and to ascertain that such documents are being used. QA is responsible to verify that processes and procedures comply with QAPD and other applicable requirements, that such processes or procedures are implemented, and that management appropriately ensures compliance.

2.2. Delegation of Work

TVA New Nuclear retains and exercises the responsibility for the scope and implementation of an effective QAP. Positions identified in Part II, Section 1, may delegate all or part of the activities of planning, establishing, and implementing the program for which they are responsible to others, but retain the responsibility for the program's effectiveness. Decisions affecting safety are made at the appropriate level based upon their nature and effect, with technical advice or review as appropriate.

2.3. Site Specific Safety-Related Design Basis Activities

Site-specific safety-related design basis activities are defined as those activities, including

sampling, testing, data collection, and supporting engineering calculations and reports, that will be used to determine the bounding physical parameters of the site. Appropriate quality assurance measures are applied. (This paragraph does not apply to operations activities.)

2.4. Periodic Review of the QA Program

Management of those organizations implementing the QAP, or portions thereof, shall 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.

However, the period for assessing the QAP during the operational phase may be extended to once every two years. (This requirement does not apply to non-operations activities.)

2.5. Issuance and Revision to QA Program

Administrative control of the QAPD will be in accordance with 10 CFR 50.55(f) and 10 CFR 50.54(a). Changes to the QAPD are evaluated by TVA New Nuclear QA to ensure that such changes do not degrade safety for previously approved quality assurance controls specified in the QAPD. New revisions to the document will be reviewed, at a minimum, by the General Manager, New Nuclear Quality Assurance and approved by the Senior Vice President, New Nuclear Projects.

Regulations require that the Final Safety Analysis Report (FSAR) include, among other things, the managerial and administrative controls to be used to assure safe operation, including a discussion of how the applicable requirements of 10 CFR 50, Appendix B will be satisfied. In order to comply with this requirement, the FSAR references the QAPD and, as a result, the requirements of 10 CFR 50.54(a) are satisfied by and apply to the QAPD.

2.6. Personnel Training and Qualifications

Personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. To this end, 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. The indoctrination, training, and qualification programs are commensurate with scope, complexity, and importance of the activities; and include or address the following, as appropriate:

- Education, experience, and proficiency of the personnel receiving training
- General criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements
- On-the-job training if direct hands-on applications or experience is needed to achieve and maintain proficiency.

Plant and support staff minimum qualification requirements are as delineated in the unit Technical Specifications. Other qualification requirements may be established but will not

reduce those required by Technical Specifications. (This paragraph does not apply to non-operations activities.)

Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in the applicable TVA New Nuclear procedures. Indoctrination includes the administrative and technical objectives, requirements of the applicable codes and standards, and the QAPD elements 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 that implement a systematic approach to training (This does not apply to non-operations activities.) Records of personnel training and qualification are maintained.

The minimum qualification of the New Nuclear QA Manager is that the manager holds an engineering or related science degree and a minimum of four years of related experience including two years of nuclear power plant experience, one year of supervisory or management experience, and one year of the experience is in performing quality verification activities. Special requirements shall include management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications for the individuals responsible for supervising QA or QC personnel is that each has a high school diploma or equivalent and has a minimum of one year of experience performing quality verification activities. Individuals who do not possess these formal education and experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications of individuals that are part of the QA organization responsible for planning, implementing, and maintaining the programs for the QAPD are that each has a high school diploma or equivalent and has a minimum of one year of related experience. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

2.7. NQA-1 Commitment / Exceptions

In establishing qualification and training programs, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 2 and the applicable regulatory position stated in Regulatory Guide 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 three (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.

SECTION 3 DESIGN CONTROL

TVA New Nuclear organization shall 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 shall support the facility design, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved. TVA New Nuclear has established and implements a process to control the design, design changes, and temporary modifications (e.g., temporary bypass lines, electrical jumpers, and lifted wires, and temporary setpoints) of items that are subject to the provisions of the QAPD. Applicable design inputs shall be identified and documented, and their selection reviewed and approved. The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a controlled manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. The design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within TVA New Nuclear and with suppliers. 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. 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. Design change processes and the division of responsibilities for design-related activities are detailed in TVA New Nuclear and supplier procedures. Changes to design inputs, final designs, and field changes, and temporary and permanent modifications ~~to operating facilities~~ are justified and subject to design control measures commensurate with those applied to the original design. The design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution, and revision of design inputs and outputs. Design changes and disposition of nonconforming items as "use as is" or "repair" arereviewed and approved by the New Nuclear, engineering or by other organizations so authorized by TVA New Nuclear.

Procedural control is established for design documents; this control differentiates between documents that receive formal design verification by interdisciplinary or multi-organizational teams and those which can be reviewed by a single individual (a signature and date is acceptable documentation for personnel certification). Design documents subject to procedural control include, but are not limited to, specifications, calculations, computer programs, system descriptions, Safety Analysis Report when used as a design document, and drawings including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams structural systems for major facilities, site arrangements, and equipment locations. Specialized reviews should be used when uniqueness or special design considerations warrant.

Design documents are reviewed by individuals knowledgeable in QA to ensure the documents contain the necessary QA requirements. (This paragraph does not apply to ESP activities),

3.1. Design Verification

TVA New Nuclear design processes provide for design verification to ensure that items, computer programs, and activities subject to the provisions of the QAPD are suitable for their intended application, consistent with their effect on safety. Design changes are subjected to

these controls, which include verification measures commensurate with those applied to original plant design.

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 verifier shall not have taken part in the selection of design inputs, the selection of design considerations, or the selection of a singular design approach, as applicable. This verification may be performed by the originator's supervisor provided the supervisor did not specify a singular design approach, rule out certain design considerations, and did not establish the design inputs used in the design, or if the supervisor is the only individual in the organization competent to perform the verification. If the verification is performed by the originator's supervisor, the justification of the need is documented and approved in advance by management.

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 designs. This includes design inputs, design outputs, and design changes. Design verification procedures are established and implemented to assure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria are identified, and the verification is satisfactorily accomplished and documented. Verification methods may include, but are not limited to, design reviews, alternative calculations, and qualification testing. 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.

TVA New Nuclear normally completes design verification activities before the design outputs are used by other organizations for design work, and before they are used to support other activities such as procurement, or construction. When such timing cannot be achieved, the design verification is completed 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.

3.2. Design Records

TVA New Nuclear maintains records sufficient to provide evidence that the design was properly accomplished. These records include the final design output and any revisions thereto, as well as record of the important design steps (e.g., calculations, analyses, and computer programs) and the sources of input that support the final output. Plant design drawings reflect the properly reviewed and approved configuration of the plant.

3.3. Computer Application and Digital Equipment Software

The QAPD governs the development, procurement, testing, maintenance, control, and use of computer applications and digital equipment software when used in safety-related applications and designated nonsafety-related applications. Computer program acceptability is pre-verified, or the results verified with the design analysis for each application. Pre-verified computer programs are controlled using a software configuration management process. TVA New Nuclear and suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. The procedures require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification. Each application software

and revision thereto are documented and approved by authorized personnel. The QAPD is also applicable to the administrative functions associated with the maintenance and security of computer hardware where such functions are considered essential in order to comply with other QAPD requirements such as QA records.

3.4. Setpoint Control

Instrument and equipment setpoints that could affect nuclear safety shall be controlled in accordance with written instructions. As a minimum, these written instructions shall:

- Identify responsibilities and processes for reviewing, approving, and revising setpoints and setpoint changes supplied by a supplier, Design Certification holder, or the plant's technical staff.
- Ensure that setpoints and setpoint changes are consistent with design and accident analysis requirements and assumptions.
- Provide for documentation of setpoints, including those determined operationally.
- Provide for access to necessary setpoint information for personnel who write or revise plant procedures, operate, or maintain plant equipment, develop, or revise design documents, or develop or revise accident analyses.

This subsection does not apply to ESP activities.

3.5. NQA-1 Commitment

In establishing its program for design control and verification, TVA New Nuclear commits to compliance with NQA-1-2015 Part I Requirement 3, NQA-1-2015 Part II, Subpart 2.7 Quality Assurance Requirements for Computer Software for nuclear facilities applications, NQA-1-2015, Part II, Subpart 2.14 Quality Assurance Requirements for Commercial Grade Items and Services, and Part II, Subpart 2.20 Quality Assurance Requirements for Subsurface Investigations for Nuclear Facilities (Subpart 2.20 does not apply to Operations activities).

SECTION 4 PROCUREMENT DOCUMENT CONTROL

TVA New Nuclear has established the necessary measures and governing procedures to assure that purchased items, computer programs, and services are subject to appropriate quality and technical requirements. Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents. These controls include provisions such that:

- Where original technical or quality assurance requirements cannot be determined, an engineering evaluation is conducted and documented by qualified staff to establish appropriate requirements and controls to assure that interfaces, interchangeability, safety, fit, and function, as applicable, are not adversely affected or contrary to applicable regulatory requirements.
- Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR 21) are invoked for procurement of items and services. 10 CFR 21 requirements for posting, evaluating, and reporting will be followed and imposed on suppliers when applicable. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of procurements (or the supplier may work under TVA New Nuclear approved QA program).

Reviews of procurement documents shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

4.1. NQA-1 COMMITMENT / EXCEPTIONS

In establishing controls for procurement, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 4, with the following clarifications and exceptions:

- With regard to service performed by a supplier, TVA New Nuclear procurement documents may allow the supplier to work under the QAP, including implementing procedures, in lieu of the supplier having its own QAP.
- Section 300 and 400 of 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 New Nuclear may satisfy this requirement through the review of the procurement specification when the specification contains the technical and quality assurance requirements of the procurement contract.

- Section 202, “Technical Requirements,” and 203, “Quality Assurance Program Requirements,” of Requirement 4, require that the technical and quality requirements be specified in the procurement documents. As a clarification, procurement documents for Commercial Grade Items that will be procured by TVA New Nuclear for use as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated in accordance with the QAPD, Part II, Section 7, “Control of Purchased Material, Equipment, and Services.”

SECTION 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

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 of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement the QAP as described in the QAPD. Such documents are prepared and controlled according to Part II, Section 6. In addition, means are provided to disseminate to the staff instructions of both general and continuing applicability, as well as those of short-term applicability. Provisions are included for reviewing, updating, and canceling such procedures.

5.1. Procedure Adherence

The TVA New Nuclear policy is that procedures are followed, and the requirements for use of procedures have been established in administrative procedures. Where procedures cannot be followed as written, provisions are established for making changes in accordance with Part II, Section 6. Requirements are established to identify the manner in which procedures are to be implemented, including identification of those tasks that require: (1) the written procedure to be present and followed step-by-step while the task is being performed, (2) the user to have committed the procedure steps to memory, (3) verification of completion of significant steps, by initials or signatures or use of check-off lists. Procedures that are required to be present and referred to directly are those developed for extensive or complex jobs where reliance on memory cannot be trusted, tasks that are infrequently performed, and tasks where steps must be performed in a specified sequence.

In cases of emergency, personnel are authorized to depart from approved procedures when necessary to prevent injury to personnel or damage to the plant. Such departures are recorded describing the prevailing conditions and reasons for the action taken.

5.2. Procedure Content

The established measures address the applicable content of procedures as described in the Introduction to Part II of NQA-1-2015. In addition, procedures governing tests, inspections, operational activities, and maintenance will include as applicable, initial conditions and prerequisites for the performance of the activity.

5.3. NQA-1 Commitment

In establishing procedural controls, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 5.

SECTION 6 DOCUMENT CONTROL

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 how activities affecting quality, including organizational interfaces, to ensure that correct documents are employed. The following controls, including electronic systems used to make documents available, are applied to documents and changes thereto:

- Identification of controlled documents
- Specified distribution of controlled documents for use at the appropriate location
- A method to identify the correct document (including revision) to be used and control of superseded documents
- Identification of individuals responsible for controlled document preparation, review, approval, and distribution
- Review of controlled documents for adequacy, completeness, and approval prior to distribution
- A method to ensure the correct documents are being used
- A method to provide feedback from users to improve procedures and work instructions
- Coordinating and controlling interface documents and procedures

The types of documents to be controlled include:

- Drawings such as design, fabrication, construction, installation, and as-built drawings
- Engineering calculations
- Design specifications
- Purchase orders and related documents
- Vendor-supplied documents
- Audit, surveillance, and quality verification/inspection procedures
- Inspection and test reports
- Instructions and procedures for activities covered by the QAPD including design, construction, installation, operating (including normal and emergency operations), maintenance, calibration, and routine testing
- Technical specifications
- Nonconformance reports and corrective action reports

During the operational phase, where temporary procedures are used, they shall include a designation of the period of time during which it is acceptable to use them.

6.1. Review and Approval of Documents

Documents are reviewed for adequacy by qualified persons other than the preparer. During the ESP or construction phase, procedures for design, construction, and installation are also reviewed by the organization responsible for quality verification to ensure quality assurance measures have been appropriately applied. (This requirement does not apply to operations activities.) The documented review signifies concurrence.

During the operational phase, documents affecting the configuration or operation of the station as described in the SAR are screened to identify those that require review by an Independent Review Group prior to implementation as described in Part V, Section 2.2.

To ensure effective and accurate procedures during the operational phase, applicable procedures are reviewed, and updated as necessary, based on the following conditions:

- Following any modification to a system
- Following an unusual incident, such as an accident, significant operator error, or equipment malfunction
- When procedure discrepancies are found
- Prior to use if not used in the previous two years
- Results of QA audits conducted in accordance with Part II, Section 18.1 (This section does not apply to non-operations activities.)

Prior to issuance or use, documents including revisions thereto, are approved by the designated authority. A listing of all controlled documents identifying the current approved revision, or date, is maintained so personnel can readily determine the appropriate document for use.

6.2. Changes to Documents

Changes to documents, other than those defined in implementing procedures as minor changes, are reviewed, and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization has access to pertinent background data or information upon which to base their approval.

Where temporary procedure changes are necessary during the operational phase, changes that clearly do not change the intent of the approved procedure may be implemented provided they are approved by two members of the staff knowledgeable in the areas affected by the procedures. (This requirement does not apply to non-operations activities.) Minor changes to documents, such as inconsequential editorial corrections, do not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a classification shall be clearly delineated in implementing procedures.

6.3. NQA-1 Commitment

In establishing provisions for document control, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 6.

SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

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.

7.1. Acceptance of Item or Service

TVA New Nuclear establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through contractors, 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. Verifications occur at the appropriate phases of the procurement process, including, as necessary, verification of activities of suppliers below the first tier.

Measures to assure the quality of purchased items and services include the following, as applicable:

- Items are inspected, identified, and stored to protect against damage, deterioration, or misuse.
- Prospective safety-related items and service suppliers are evaluated to assure only qualified suppliers are used. Qualified suppliers are audited on a triennial basis. In addition, if a subsequent contract or a contract modification significantly changes the scope, methods, or controls performed by a supplier, an audit of the changes is performed, thus starting a new triennial period.
- TVA New Nuclear may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet TVA New Nuclear requirements. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. Industry programs, such as those applied by ASME, Nuclear Procurement Issues Corporation (NUPIC) during construction or operation phases, or other established utility groups, are used as input or the basis for supplier qualification whenever appropriate. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.
- Provisions are made for accepting purchased items and services, such as source verification, receipt inspection, pre- and post-installation tests, certificates of conformance, and document reviews (including Certified Material Test Report/Certificate). Acceptance actions/documents should be established by the Purchaser with appropriate input from the Supplier and be completed to ensure that

procurement, inspection, and test requirements, as applicable, have been satisfied before relying on the item to perform its intended safety function.

- Controls are imposed for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt, and acceptance of commercial-grade services or items to assure they will perform satisfactorily in service in safety-related applications.
- If there is insufficient evidence of implementation of a QA program, the initial evaluation is of the existence of a QA program addressing the scope of services to be provided. The initial audit is performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.

7.2. NQA-1 Commitment / Exceptions

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 Regulatory Guide 1.28, Revision 5 with the following clarifications and exceptions:

- TVA New Nuclear considers that other 10 CFR Parts 50 and 52 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, 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.
- 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), a commercial grade survey need not be performed provided each of the following conditions are met:

  - A documented review of the laboratory’s accreditation is performed and includes a verification of the following:

    1. The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC-17025: 2017, "General Requirements for the Competence of Testing and Calibration Laboratories."
    2. For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
    3. For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.
    4. The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected accrediting body within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.

- The purchase order documents require that:

  1. The laboratory must provide the service in accordance with their accredited ISO/IEC-17025:2017 program and scope of accreditation.
  2. Reporting as-found calibration data in the certificate of calibration when calibrated items are found to be out-of-tolerance (for calibration services only).
  3. Identifying in the certificate of calibration, the equipment/standards used to perform the calibration (for calibration services only).
  4. The testing or calibration service supplier shall not subcontract the service to any other supplier.
  5. Notifying the customer of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
  6. Performance of the services listed on the order is contingent on the laboratory's accreditation having been achieved through an on-site accreditation assessment by the accrediting body within the past 48 months.
  7. Additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

- It is validated, at receipt inspection, that the laboratory's documentation certifies that:

  1. The contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2017 program, and has been performed within their scope of accreditation, and
  2. The purchase order's requirements are met.

The ILAC accreditation process cannot be used for commercial grade dedication of Nondestructive Examination (NDE) services in lieu of performing a Commercial Grade Survey.

- For Section 200, during periods of exigent conditions, TVA New Nuclear may conduct remote audits/surveys 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.

- For Section 501, 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 NQA-1 requirement for documents to be available at the site. Following completion of the construction period, sufficient as-built documentation will be turned over to TVA New Nuclear to support operations. The TVA New Nuclear records management system will provide for timely retrieval of necessary records.
- 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 following clarification:

  - For commercial grade items, quality verification requirements are established and described in TVA New Nuclear documents to provide the necessary assurance an item will perform satisfactorily in service. The TVA New Nuclear documents address determining the critical characteristics that ensure an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.
  - TVA New Nuclear will assume 10 CFR 21 reporting responsibility for all items that TVA New Nuclear dedicates as safety-related.

SECTION 8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

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 to affect the function or quality of the item.

8.1. NQA-1 Commitment

In establishing provisions for identification and control of items, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 8.

SECTION 9 CONTROL OF SPECIAL PROCESSES

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 qualification requirements. Personnel are qualified and special processes are performed in accordance with applicable codes, standards, specifications, criteria, or other specially established requirements. Records are maintained as appropriate for the currently qualified personnel, processes, and equipment for each special process. Special processes are those where the results are highly dependent on the control of the process or the skill of the operator, or both, and for which the specified quality cannot be fully and readily determined by inspection or test of the final product.

9.1. NQA-1 Commitment

In establishing measures for the control of special processes, TVA New Nuclear commits to NQA-1-2015 Requirement 9.

SECTION 10 INSPECTION

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 properly qualified persons independent of those who performed or directly supervised the work. Inspection results are documented.

10.1. Inspection Program

The inspection program establishes inspections (including surveillance of processes), as necessary to verify quality: (1) at the 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, and (4) upon receipt of items for a facility, as well as (5) during maintenance, modification, in-service, and operating activities.

The inspection program establishes requirements for planning inspections, such as the group or discipline responsible for performing the inspection, where inspection hold points are to be applied, determining applicable acceptance criteria, the frequency of inspection to be applied, and identification of special tools needed to perform the inspection. Inspection planning is performed by personnel qualified in the discipline related to the inspection and includes qualified inspectors or engineers. Inspection plans are based on, as a minimum, the importance of the item to the safety of the facility, the complexity of the item, technical requirements to be met, and design specifications. Where significant changes in inspection activities for the facilities are to occur, management responsible for the inspection programs evaluate the resource and planning requirements to ensure effective implementation of the inspection program.

Inspection program documents establish requirements for performing the planned inspections, and documenting required inspection information such as rejection, acceptance, and re-inspection results, and the person(s) performing the inspection.

Inspection records identify item inspected, date of inspection, the inspector’s identity, type of observation, inspection results and acceptability, and reference to information on action taken in connection with nonconformances. Inspection results are documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings.

10.2. Inspector Qualification

TVA New Nuclear has established qualification programs for personnel performing quality inspections. The qualification program requirements are described in Part II, Section 2. These qualification programs are applied to individuals performing quality inspections regardless of the functional group where they are assigned.

10.3. NQA-1 Commitment

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.

SECTION 11 TEST CONTROL

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 as a whole 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 Technical Specifications), to demonstrate that performance of plant systems is in accordance with design. Programs also include provisions to establish and adjust test schedules, and to maintain status for periodic or recurring tests. Tests are performed according to applicable procedures that include, consistent with the effect on safety: (1) instructions and prerequisites to perform the tests, (2) use of proper test equipment, (3) acceptance criteria, and (4) mandatory verification points as necessary to confirm satisfactory test completion. Test results are documented and evaluated by the organization performing the test and reviewed by a responsible authority to assure that the test requirements have been satisfied. If acceptance criteria are not met, re-testing is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure. 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 deviations noted, and the person evaluating test results.

The initial start-up test program is planned and scheduled to permit safe fuel loading and start-up; to increase power in safe increments; and to perform major testing at specified power levels. If tests require the variation of operating parameters outside of their normal range, the limits within which such variation is permitted will be prescribed. The scope of the testing demonstrates, insofar as practicable, that the plant is capable of withstanding the design transients and accidents. For new facility construction, the suitability of facility operating procedures is checked to the maximum extent possible during the pre-operational and initial start-up test programs.

Except for computer program testing, which is addressed in Part II, Section 11.1, tests are performed, and results documented in accordance with applicable technical and regulatory requirements, including those described in the Technical Specifications and SAR. Test programs ensure appropriate retention of test data in accordance with the records requirements of the QAPD. Personnel that perform or evaluate tests are qualified in accordance with the requirements established in Part II, Section 2.

11.1. NQA-1 Commitment for Computer Program Testing

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. To this end TVA New Nuclear commits to compliance with the requirements of NQA-1-2015 Requirement 11 Section 400 and Part II, Subpart 2.7 to establish the appropriate provisions in addition to the commitment to NQA-1-2015, Requirement 3.

11.2. NQA-1 Commitment

In establishing provisions for testing, TVA New Nuclear commits to compliance with NQA-1-2015 Requirement 11

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

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 gages, tools, reference and transfer standards, and nondestructive examination equipment. The suppliers of commercial-grade calibration services are controlled as described in Part II, Subsection 7.2.

12.1. Installed Instrument and Control Devices

For the operational phase of the facilities, TVA New Nuclear shall establish and implement procedures for the calibration and adjustment of instrument and control devices installed in the facility. The calibration and adjustment of these devices is accomplished through the facility maintenance programs to ensure the facility is operated within design and technical requirements. 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 no nationally recognized standards exist, the bases for calibration are documented. M&TE found out of calibration is tagged or segregated and not used until it is recalibrated. When M&TE is found out of calibration, an evaluation is made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested using the suspect M&TE. Any measuring or test equipment consistently found out of calibration is repaired or replaced. A calibration is performed when the accuracy of the equipment is suspect. Appropriate documentation will be maintained for these devices to indicate the control status, when the next calibration is due, and identify any limitations on use of the device. This paragraph does not apply to ESP activities.

12.2. NQA-1 Commitment

In establishing provisions for control of measuring and test equipment, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 12.

SECTION 13 HANDLING, STORAGE, AND SHIPPING

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 (such as containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels, and temperature levels) are provided when required to maintain acceptable quality.

Special or additional handling, storage, shipping, cleaning, and preservation requirements are identified and implemented as specified in procurement documents and applicable procedures. Where special requirements are specified, the items and containers (where used) are suitably marked.

Special handling tools and equipment are used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment are inspected and tested in accordance with procedures at specified time intervals or prior to use.

Operators of special handling and lifting equipment are experienced or trained in the use the equipment. During the operational phase, TVA New Nuclear establishes and implements controls over hoisting, rigging, and transport activities to the extent necessary to protect the integrity of the items involved, as well as potentially affected nearby structures and components. Where required, TVA New Nuclear complies with applicable hoisting, rigging and transportation regulations and codes.

13.1. Housekeeping

Housekeeping practices are established to account for conditions or environments that could affect the quality of structures, systems, and components within the plant. This includes control of 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. Housekeeping practices help assure that only proper materials, equipment, processes, and procedures are used, and that the quality of items is not degraded. Necessary procedures or work instructions, such as for electrical bus and control center cleaning, cleaning of control consoles, and radioactive decontamination are developed and used.

13.2. NQA-1 Commitment / Exceptions

In establishing provisions for handling, storage, and shipping, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 13. TVA New Nuclear also commits, during the construction and operational phase of the plant, 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:

NQA-1-2015, Part II, Subpart 2.1

Subpart 2.1, Section 301 and 302 establish criteria for classifying items into cleanness classes and requirements for each class. Instead of using the cleanness level system of Subpart 2.1, TVA New Nuclear may establish cleanness requirements on a case-by-case basis, consistent with the other provisions of Subpart 2.1. TVA New Nuclear establishes appropriate cleanliness controls for work on safety-related equipment to minimize introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities, including documented verification of absence of foreign material prior to system closure.

NQA-1-2015, Part II, Subpart 2.2

1. Subpart 2.2, Section 201 establishes criteria for classifying items into protection levels. Instead of classifying items into protection levels during the operational phase, TVA New Nuclear may establish controls for the 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. Prior to installation or use, the items are inspected and serviced as necessary to assure that no damage or deterioration exists which could affect their function.
2. Subpart 2.2, Section 606, "Storage Records:" This section requires written records be prepared containing information on personnel access. As an alternative to this requirement, TVA New Nuclear documents establish controls for storage areas that describe those authorized to access areas and the requirements for recording access of personnel. However, these records of access are not considered quality records and will be retained in accordance with the administrative controls of the applicable plant.

NQA-1-2015, Part II, Subpart 2.3

Subpart 2.3, Section 202 requires the establishment of five zone designations for housekeeping cleanliness controls. Instead of the five-level zone designation, 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. Factors considered in developing the procedures and instructions include cleanliness control, personnel safety, fire prevention and protection, radiation control, and security. The procedures and instructions make use of standard janitorial and work practices to the extent possible.

SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

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 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. These measures also establish the necessary authorities and controls for the application and removal of status indicators or labels.

In addition, temporary design changes (temporary modifications), such as temporary bypass lines, electrical jumpers, and lifted wires, and temporary trip-point settings, are controlled by procedures that include requirements for appropriate installation and removal, independent/concurrent verifications, and status tracking.

Administrative procedures also describe the measures taken to control altering the sequence of required tests, inspections, and other operations. Review and approval for these actions is subject to the same control as taken during the original review and approval of tests, inspections, and other operations.

14.1. NQA-1 Commitment

In establishing measures for control of inspection, test and operating status, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 14.

SECTION 15 CONTROL OF NONCONFORMING ITEMS

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, “Corrective Action”. Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. Controls are provided to address conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release. Item disposition, such as use-as-is, reject, repair, or rework shall be identified and documented. Conditional release of nonconforming items for installation requires the approval of the designated management. Nonconformances are corrected or resolved prior to depending on the item to perform its intended safety function. Nonconformances are evaluated for impact on operability of quality structures, systems, and components to assure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements dispositioned repair or use-as-is are subject to design control measures commensurate with those applied to the original design and the technical justification for acceptability of a nonconforming item, dispositioned 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, analysis of quality trends, and reports provided to the designated management. Significant trends are reported to management in accordance with TVA New Nuclear procedures, regulatory requirements, and industry standards.

15.1. Interface with the Reporting Program

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

15.2. NQA-1 Commitment

In establishing for nonconforming materials, parts, or components, TVA New Nuclear commits to compliance with NQA-1-2015 Requirement 15.

SECTION 16 CORRECTIVE ACTION

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. TVA New Nuclear procedures require personnel to identify known conditions adverse to quality. When complex issues arise where it cannot be readily determined if a condition adverse to quality exists, TVA New Nuclear documents establish the requirements for documentation and timely evaluation of the issue. 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.

16.1. Interface with the Reporting Program

TVA New Nuclear has appropriate interfaces with the corrective action program to satisfy the reporting requirements of 10 CFR 52 and 10 CFR 21 during design certification and standard design approval, 10 CFR 52, 10 CFR 50.55, and 10 CFR 21 during ESP/CP/COL design and construction, and 10 CFR 21 during operations.

16.2. NQA-1 Commitment

In establishing provisions for corrective action, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 16.

SECTION 17 QUALITY ASSURANCE RECORDS

TVA New Nuclear has 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 record retention program. The TVA New Nuclear records program provides provisions for the administration, receipt, storage, preservation, safekeeping, retrieval, and disposition of all records. All records must be retrievable, maintained in a readable format, and safeguarded against equipment malfunction or human error. Document access controls, user privileges, and other appropriate security controls must be established (ANSI/ANS 3.2).

17.1. Record Retention

Sufficient records shall be maintained to furnish evidence of activities affecting quality. 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 shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall meet the requirements of NQA-1-2015, Section 11.

Records shall be identifiable and retrievable. The records and retention times are based on Regulatory Position C.3.a.(1) for Lifetime Records and C.3.a.(2) for Non-permanent Records of Regulatory Guide 1.28, Revision 5 for design, construction, and initial start-up, and Regulatory Guide 1.33, Revision 3 for operational phase. Retention times for permanent and nonpermanent operational phase records are based on construction records that are similar in nature. In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met.

17.2. Electronic Records

When using optical disks for electronic records storage and retrieval systems, TVA New Nuclear complies with the NRC guidance in Generic Letter 88-18, “Plant Record Storage on Optical Disks.” TVA New Nuclear will manage the storage of QA Records in electronic media consistent with the intent of RIS 2000-18 and associated NIRMA Guidelines TG11-2011, TG15-2011, TG16-2011 and TG21-2011.

17.3. NQA-1 Commitment

In establishing provisions for records, TVA New Nuclear commits to compliance with NQA-1-2015 Requirement 17 as endorsed by Regulatory Guide 1.28, Revision 5, including Regulatory Positions C.3.a.(1) and C.3.a.(2).

SECTION 18 AUDITS

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. The audit programs themselves are reviewed for effectiveness as part of the overall audit process.

18.1. Performance of Audits

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. Functional areas of an organization's QA program for auditing include, at a minimum, verification of compliance and effectiveness of implementation of internal rules, procedures (e.g., operating, design, procurement, maintenance, modification, refueling, surveillance, test, security, radiation control procedures, and the emergency plan), Technical Specifications, regulations and license conditions, programs for training, retraining, qualification and performance of the operating staff, corrective actions, and observation of performance of operating, refueling, maintenance, and modification activities, including associated record keeping.

Audits shall be scheduled on a formal preplanned audit schedule and in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. Additional audits may be performed as deemed necessary by management. The scope of the audit is determined by the quality status and safety importance of the activities being performed. These audits are conducted by trained personnel not having direct responsibilities in the area being audited and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified lead auditor and the cognizance of the General Manager, New Nuclear Quality Assurance responsible for the day-to-day programs as documented in Part II, Section 1.

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 overall QAPD.

The results of each audit are reported in writing to the responsible Senior Executive responsible for the Quality Assurance program, or designee, as appropriate. Additional internal distribution is made to other concerned management levels and to management of internal audited organizations or activities in accordance with approved procedures. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

Management responds to all audit findings and initiates corrective action where indicated. Where corrective action measures are indicated, documented follow-up of applicable areas through inspections, reviews, re-audits, or other appropriate means is conducted to verify implementation of assigned corrective action.

Audits of suppliers of safety-related components and/or services are conducted as described in Part II, Subsection 7.1.

18.2. Internal Audits

Internal audits of organization and facility activities, conducted prior to placing the facility in operation, should be 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, should be 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 evaluation should include a detailed performance analysis of the functional area based upon applicable internal and external source data and due consideration of the impact of any functional area changes in responsibility, resources, or management. However, the internal audit frequency interval should not exceed a maximum of four years. If an adverse trend is identified in the applicable functional area, the extension of the internal audit frequency interval should be rescinded, and an audit scheduled as soon as practicable.

During the operational phase, audits are performed at a frequency commensurate with the safety significance of the activities and in such a manner to assure audits of all applicable QA program elements are completed within a period of two years. These audits will include, as a minimum, activities in the following areas:

- The conformance of facility operation to provisions contained within the Technical Specifications and applicable license conditions including administrative controls.
- The performance, training, and qualifications of the facility staff.
- The performance of activities required by the QAPD to meet the criteria of 10 CFR 50, Appendix B, and 10 CFR 72 Subpart G.
- The Fire Protection Program and implementing procedures. A fire protection equipment and program implementation inspection and audit are conducted utilizing either a qualified off-site licensed fire protection engineer or an outside qualified fire protection consultant.
- Other activities and documents considered appropriate by the Senior Vice President, New Nuclear Projects.

Audits may also be used to meet the periodic review requirements of the code for the Security, Emergency Preparedness, and Radiological Protection programs within the provisions of the applicable code. This requirement does not apply to a non-operations activity.

Internal audits include verification of compliance and effectiveness of the administrative controls established for implementing the requirements of the QAPD; regulations and license provisions; provisions for training, retraining, qualification, and performance of personnel performing

activities covered by the QAPD; corrective actions taken following abnormal occurrences; and, observation of the performance of construction, fabrication, operating, refueling, maintenance, and modification activities including associated record keeping.

18.3. NQA-1 Commitment / Exceptions

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 Regulatory Guide 1.28, Revision 5 with the following clarifications and exceptions:

- Section 201, Internal Audits - TVA New Nuclear may apply an extension, not to exceed 25 percent of the audit interval as follows:

    1. Audits shall be performed at the intervals designated for each audit area. Schedules shall be based on the month in which the audit starts.

    2. No extensions are allowed for scheduled audits of Emergency Preparedness, Security, Cyber Security, or Access Authorization.

    3. When an audit interval extension greater than one month is used, the next audit for that particular audit area will be scheduled from the original anniversary month rather than from the month of the extended audit.

- Section 202, External Audits – 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 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 and TVA New Nuclear

    Continued use of TVA New Nuclear suppliers that have exceeded the maximum allowed audit or survey time due to extenuating circumstances is allowed if the following conditions are met:

    1. A documented evaluation must be performed to summarize why the audit or survey could not be performed prior to the end of the 90-day grace period and to provide the basis for maintaining the supplier as an approved supplier during the 25% (9-month) grace period. While implementing procedures must describe elements to be included in the documented evaluation, the following items should be considered as applicable:
        a. For 10 CFR 50, Appendix B suppliers, verification that the supplier’s quality assurance program is still committed to meeting the requirements of 10 CFR 50, Appendix B.

   b. For commercial suppliers who are approved based on commercial grade survey, verification the supplier has maintained adequate documented programmatic controls in place for the activities affecting the critical characteristics of the item/services being procured.
   c. Evaluation of any significant open issues with the NRC, 10 CFR Part 21 Notifications, and any open findings since the previous triennial audits describing impact on the items/services being procured from that supplier.
   d. Review of procurement history since last triennial audit/survey including receipt inspection results to identify any potential issues. The results of the performance history must be included in the evaluation.
   e. The degree of standardization of the items being procured. For instance, suppliers of catalog items which are used across multiple industry with widely accepted good performance histories would be considered good candidates for a 25% (9-month) grace period.
2. If concerns are identified based on the above evaluation, the following mitigating actions may be considered:
   a. Enhanced receiving inspections beyond visual inspections and quality checks.
   b. Identification of any additional requirements/restrictions to be placed on the supplier.
3. For audits/surveys performed during the 25% grace period, the audit/survey shall include a review of activities performed by the supplier since the 36-month audit/survey expiration date.
4. The allowance would only apply to existing suppliers on TVA New Nuclear Acceptable Supplier List.
5. The 25% grace period discussed above is applicable to domestic and international suppliers.
6. For audits/surveys performed during the 25% grace period, the audit/survey “clock” does not have to reset backwards to the original expiration date for which the audit/survey should have been performed. The end of the audit or survey would determine the date of the next triennial audit/survey.

PART III. NONSAFETY-RELATED STRUCTURES, SYSTEMS, AND COMPONENTS (SSC) QUALITY CONTROL

SECTION 1 NONSAFETY-RELATED WITH SPECIAL TREATMENT

Specific program controls are applied to nonsafety-related SSCs with special treatment, for which 10 CFR 50, Appendix B is not applicable, that are relied on to perform safety-significant functions. The specific program controls consistent with applicable sections of the QAPD are applied to those items in a selected manner, targeted at those characteristics or critical attributes with safety-significant functions.

The following clarify the applicability of the QA Program to the nonsafety-related SSCs with special treatment and related activities, including the identification of exceptions to the QA Program described in Part II, Sections 1 through 18 taken for nonsafety-related SSCs with special treatment.

1.1. Organization

The verification activities described in this part may be performed by the TVA New Nuclear line organization. The QA organization described in Part II is not required to perform these functions.

1.2. QA Program

TVA New Nuclear QA requirements for nonsafety-related SSCs are established in the QAPD and appropriate procedures. Suppliers of these SSCs or related services describe the quality controls applied in appropriate procedures. A new or separate QA program is not required.

1.3. Design Control

TVA New Nuclear has design control measures to ensure that the contractually established design requirements are included in the design. These measures ensure that applicable design inputs are included or correctly translated into the design documents, and deviations from those requirements are controlled. Design verification is provided through the normal supervisory review of the designer's work.

1.4. Procurement Document Control

Procurement documents for items and services obtained by or for TVA New Nuclear include or reference documents describing applicable design bases, design requirements, and other requirements necessary to ensure component performance. The procurement documents are controlled to address deviations from the specified requirements.

1.5. Instructions, Procedures, and Drawings

TVA New Nuclear provides documents such as, but not limited to, written instructions, plant procedures, drawings, vendor technical manuals, and special instructions in work orders, to direct the performance of activities affecting quality. The method of instruction employed

provides an appropriate degree of guidance to the personnel performing the activity to achieve acceptable functional performance of the SSC.

1.6. Document Control

TVA New Nuclear controls the issuance and change of documents that specify quality requirements or prescribe activities affecting quality to ensure that correct documents are used. These controls include review and approval of documents, identification of the appropriate revision for use, and measures to preclude the use of superseded or obsolete documents.

1.7. Control of Purchased Items and Services

TVA New Nuclear employs measures, such as inspection of items or documents upon receipt or acceptance testing, to ensure that all purchased items and services conform to appropriate procurement documents.

1.8. Identification and Control of Purchased Items

TVA New Nuclear employs measures where necessary, to identify purchased items and preserve their functional performance capability. Storage controls take into account appropriate environmental, maintenance, or shelf-life restrictions for the items.

1.9. Control of Special Processes

TVA New Nuclear employs process and procedure controls for special processes, including welding, heat treating, and nondestructive testing. These controls are based on applicable codes, standards, specifications, criteria, or other special requirements for the special process.

1.10. Inspection

TVA New Nuclear uses documented instructions to ensure necessary inspections are performed to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. These inspections may be performed by knowledgeable personnel in the line organization. Knowledgeable personnel are from the same discipline and have experience related to the work being inspected.

1.11. Test Control

TVA New Nuclear employs measures to identify required testing that demonstrates that equipment conforms to design requirements. These tests are performed in accordance with test instructions or procedures. The test results are recorded, and authorized individuals evaluate the results to ensure that test requirements are met.

1.12. Control of Measuring and Test Equipment

TVA New Nuclear employs measures to control M&TE use, and calibration and adjustment at specific intervals or prior to use.

1.13. Handling, Storage, and Shipping

TVA New Nuclear employs measures to control the handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration. These measures include appropriate marking or labels, and identification of any special storage or handling requirements.

1.14. Inspection, Test, and Operating Status

TVA New Nuclear employs measures to identify items that have satisfactorily passed required tests and inspections and to indicate the status of inspection, test, and operability as appropriate.

1.15. Control of Nonconforming Items

TVA New Nuclear employs measures to identify and control items that do not conform to specified requirements to prevent their inadvertent installation or use.

1.16. Corrective Action

TVA New Nuclear employs measures to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected.

1.17. Records

TVA New Nuclear employs measures to ensure records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, inspection, and test activities have been met.

1.18. Audits

TVA New Nuclear employs measures for line management to periodically review and document the adequacy of the process, including taking any necessary corrective action. Audits independent of line management are not required. Line management is responsible for determining whether reviews conducted by line management or audits conducted by any organization independent of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities. Where the measures of this part (Part III) are implemented by the same programs, processes, or procedures as the comparable activities of Part II, the audits performed under the provisions of Part II may be used to satisfy the review requirements of this Section (Part III, Section 1.18).

SECTION 2. NONSAFETY-RELATED STRUCTURES, SYSTEMS, AND COMPONENTS CREDITED FOR REGULATORY EVENTS

The following criteria apply to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), the station blackout (SBO) (10 CFR 50.63) SSCs that are not safety-related:

- TVA New Nuclear implements quality requirements for the fire protection system in accordance with Regulatory Guide 1.189, Fire Protection for Nuclear Power Plants, Revision 4.

- TVA New Nuclear implements the quality requirements for nonsafety-related, safety significant ATWS equipment in accordance with Part III, Section 1, based on an assessment of the reactor technology's requirement for such equipment.
- TVA New Nuclear implements quality requirements for nonsafety-related, safety significant SBO equipment in accordance with Part III, Section 1, based on an assessment of the reactor technology's requirement for such equipment.

PART IV. REGULATORY COMMITMENTS

NRC Regulatory Guides and Quality Assurance Standards

This section identifies the NRC Regulatory Guides (RG) and the other quality assurance standards which have been selected to supplement and support the QAPD. TVA New Nuclear identifies the extent of conformance with these RG and quality assurance standards as described below or within applicable license application documents submitted in accordance with 10 CFR 50 (e.g., LWA, CP, OL) and 10 CFR 52 (e.g., ESP, DC, COL, SDA), as applicable. Commitment to a particular RG or standard does not constitute a commitment to other RGs or standards that may be referenced therein.

Regulatory Guides

Regulatory Guide 1.8, Revision 4, June 2019, Qualification and Training of Personnel for Nuclear Power Plants

Regulatory Guide 1.8, Rev. 4, provides guidance that is acceptable to the NRC staff regarding qualifications and training for nuclear power plant personnel. TVA New Nuclear identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications (e.g., safety analysis reports).

Regulatory Guide 1.26, Revision 6, December 2021, Quality Group Classifications and Standards for Water, Steam, And Radioactive-Waste-Containing Components of Nuclear Power Plants

Regulatory Guide 1.26, Rev. 6, defines classification systems and components. TVA New Nuclear identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications (e.g., safety analysis reports).

Regulatory Guide 1.28, Revision 5, October 2017, Quality Assurance Program Criteria (Design and Construction)

Regulatory Guide 1.28, Rev. 5,describes a method acceptable to the NRC staff for complying with the provisions of 10 CFR 50 Appendix B with regard to establishing and implementing the requisite quality assurance program for the design and construction of nuclear power plants. TVA New Nuclear identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications (e.g., safety analysis reports).

Regulatory Guide 1.29, Revision 6, July 2021 - Seismic Design Classification

Regulatory Guide 1.29, Rev. 6, defines light water reactor systems required to withstand a safe shutdown earthquake (SSE). TVA New Nuclear identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications (e.g., safety analysis reports).

Regulatory Guide 1.33, Revision 3, June 2013, Quality Assurance Program Requirements (Operations)

Regulatory Guide 1.33, Rev. 3, describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to overall quality assurance program requirements for the operation phase of nuclear power plants. Revision 3 of the Regulatory Guide endorses ANSI/ANS 3.2 – 2012, Managerial, Administrative, and Quality Assurance Controls for the Operational Phase of Nuclear Power Plants. TVA New Nuclear will conform with Regulatory Guide 1.33, Rev. 3 and comply with the Staff Regulatory Guidance for meeting the conditions described on the use of ANSI/ANS 3.2 – 2012.

Regulatory Guide 1.54, Revision 3, April 2017**,** Service Level I, II, III, and In-Scope License Renewal Protective Coatings Applied to Nuclear Power Plants

Regulatory Guide 1.54 provides guidance for the application of protective coatings within nuclear power plants to protect surfaces from corrosion, contamination from radionuclides and for wear protection. TVA New Nuclear identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications (e.g., safety analysis reports).

Regulatory Guide 1.164, Dedication of Commercial-Grade Items for Use in Nuclear Power Plant, Revision 0, June 2017

Regulatory Guide 1.164, Rev. 0, provides guidance for dedication of commercial-grade items and services used in nuclear power plants. This RG endorses, in part, the Electric Power Research Institute (EPRI) 3002002982, Revision 1 to EPRI NP-5652 and TR-102260, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications”, with respect to acceptance of commercial-grade dedication of items and services to be used as basic components for nuclear power plants. TVA New Nuclear identifies conformance and exceptions/clarifications for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications.

Regulatory Guide 1.189, Fire Protection for Nuclear Power Plants, Revision 4.

Regulatory Guide 1.189, Rev. 4, provides an approach that is acceptable to meet the regulatory requirements of Title 10 of the Code of Federal Regulations (10 CFR) section 50.48(a). The standards of record related to the design and installation of fire protection systems and features required to satisfy NRC requirements in all new reactor designs are those NFPA codes and standards in effect 180 days before the submittal of the application under 10 CFR Part 50 or 10 CFR Part 52. TVA New Nuclear identifies conformance with and exceptions/clarifications for the applicable regulatory position guidance in this regulatory guide in applicable license applications based on an assessment of the reactor technology’s requirements.

Regulatory Guide 1.231, Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants, Revision 0, January 2017

Regulatory Guide 1.231, Rev.0, provides guidance for the use of Revision 1 of EPRI Technical Report 1025243, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications”, with respect to acceptance of commercial-grade design and analysis computer programs associated with basic components for nuclear power plants. TVA New Nuclear identifies conformance and conditions for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications.

Regulatory Guide 1.234, Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21, Revision 0, April 2018.

Regulatory Guide 1.234, Rev 0 provides guidance on an acceptable method of evaluating and reporting defects under 10 CFR Part 21. This guidance will aid in minimizing compliance challenges to licensees and vendors that have been identified through inspection activities. This new guide endorses Nuclear Energy Institute (NEI) 14-09, “Guidelines for Implementations of 10 CFR Part 21 Reporting of Defects and Noncompliance,” Revision 1. TVA New Nuclear identifies conformance and clarifications for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications.

Standards

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

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.

Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs)

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

PART V. ADDITIONAL QUALITY ASSURANCE AND ADMINISTRATIVE CONTROLS FOR THE PLANT OPERATIONAL PHASE

TVA New Nuclear includes the requirements of Part V that follow when establishing the necessary measures and governing procedures for the operational phase of the plant. Implementation of the additional controls in this section shall apply 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 construction permit holders.

SECTION 1. DEFINITIONS

TVA New Nuclear uses the definitions of terms as provided in Section 400 of the Introduction of NQA-1-2015 in interpreting the requirements of NQA-1 and the other standards to which the QAPD commits. In addition, definitions are provided for the following terms not covered in NQA-1:

administrative controls: rules, orders, instructions, procedures, policies, practices, and designations of authority and responsibility

experiments: performance of plant operations carried out under controlled conditions in order to establish characteristics or values not previously known

independent review: review completed by personnel not having direct responsibility for the work function under review regardless of whether they operate as a part of an organizational unit or as individual staff members (see review)

nuclear power plant: any plant using a nuclear reactor to produce electric power, process steam, or provide space heating

on-site operating organization: on-site personnel concerned with the operation, maintenance, and certain technical services

operating activities: work functions associated with normal operation and maintenance of the plant, and technical services routinely assigned to the on-site operating organization

operational phase: that period of time during which the principal activity is associated with normal operation of the plant. This phase of plant life is considered to begin formally with commencement of initial fuel loading, and ends with plant decommissioning

review: a deliberately critical examination, including observation of plant operation, evaluation of assessment results, procedures, certain contemplated actions, and after-the-fact investigations of abnormal conditions

supervision: direction of personnel activities or monitoring of plant functions by an individual responsible and accountable for the activities they direct or monitor

surveillance testing: periodic testing to verify that safety related structures, systems, and components continue to function or are in a state of readiness to perform their functions

system: an integral part of nuclear power plant comprising components which may be operated or used as a separate entity to perform a specific function

SECTION 2. REVIEW OF ACTIVITIES AFFECTING SAFE PLANT OPERATION

2.1. Onsite Operating Organization Review

The TVA New Nuclear onsite organization employs reviews, both periodic and as situations demand, to evaluate plant operations and plan future activities. The important elements of the reviews are documented and subjects of potential concern for the independent review described below are brought to the attention of Operations Phase Management. 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 in keeping abreast of general plant conditions and to verify that day-to-day operations are conducted safely in accordance with the established administrative controls. The manager responsible for Operations Phase Management ensures the timely referral of the applicable matters discussed in the reviews to appropriate management and independent reviewers.

2.2. Independent Review

Activities occurring during the operational phase shall be independently reviewed on a periodic basis. The independent review program shall be functional prior to initial core loading. The independent review function performs the following:

- Reviews proposed changes to the facility as described in the safety analysis report (SAR). The Independent Review Committee (IRC) also verifies that changes do not adversely affect safety and if a technical specification change or NRC review is required.
- Reviews proposed tests and experiments not described in the SAR prior to implementation. Verifies the determination of whether changes to proposed tests and experiments not described in the SAR require a technical specification change or license amendment.
- Reviews proposed technical specification changes and license amendments relating to nuclear safety prior to NRC submittal and implementation, except in those cases where the change is identical to a previously approved change.
- Reviews violations, deviations, and events that are required to be reported to the NRC. This review includes the results of investigations and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.
- Reviews any matter related to nuclear safety that is requested by the Vice President, Site Project or Operations Phase Management or any Independent Review Committee member.
- Reviews corrective actions for significant conditions adverse to quality.
- Reviews internal audit reports.

- Reviews the adequacy of the internal audit program every 24 months.

Independent Review Committee

A formally established group functions as an Independent Review Committee (IRC). In discharging its review responsibilities, the IRC keeps safety considerations paramount when opposed to cost or schedule considerations. The IRC performs its functions in the following manner:

- An Independent Review Committee is assigned independent review responsibilities and reports to the Vice President, Site Project.
- The Independent Review Committee shall be composed of no less than 5 persons; no more than a minority of members are from the on-site operating organization.
  - For example, at least 3 of the 5 members must be from off-site if there are 5 members on the committee. A minimum of the chairman or alternative chairman and 2 members must be present for all meetings.
- During the period of initial operation, meetings are conducted no less frequently than once per calendar quarter. Afterwards meetings are conduced no less than twice a year.
- Results of the meeting are documented and recorded.
- Consultants and contractors are used for the review of complex problems beyond the expertise of the off-site/on site independent review committee.
- Persons on the Independent Review Committee are qualified as follows:

  Supervisor or Chairman of the Independent Review Committee

  - Education: Baccalaureate in engineering or related science
  - Minimum experience: Six (6) years combined managerial and technical support

  Independent Review Committee members

  - Education: Baccalaureate in engineering or related science for those personnel required to review problems in nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, non-destructive testing, instrumentation and control, radiological safety, mechanical engineering, or electrical engineering.
  - High school diploma for those independent review personnel required to review problems in administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment.
  - Minimum experience: Five (5) years' experience in their own area of responsibility (nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, non-destructive testing, instrumentation and control, radiological safety, mechanical engineering, and electrical engineering, administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment).

SECTION 3. OPERATIONAL PHASE PROCEDURES

The following is a description of the various types of procedures used by TVA New Nuclear to govern the design, operation, and maintenance of its nuclear generating plants. TVA New Nuclear follows the guidance of Regulatory Guide 1.33 in identifying the types of activities that should have procedures or instructions to control the activity. Each procedure shall be sufficiently detailed for a qualified individual to perform the required function without direct supervision but need not provide a complete description of the system or plant process.

3.1. Format and Content

Procedure format and content may vary from one location to the other; however, procedures include the following elements as appropriate to the purpose or task to be described.

Title/Status

Each procedure is given a title descriptive of the work or subject it addresses and includes a revision number and/or date and an approval status.

Purpose/Statement of Applicability/Scope

The purpose for which the procedure is intended is clearly stated (if not clear from the title). The systems, structures, components, processes, or conditions to which the procedure applies are also clearly described.

References

Applicable references, including reference to appropriate Technical Specifications, are required. References are included within the body of the procedure when the sequence of steps requires other tasks to be performed (according to the reference) prior to or concurrent with a particular step.

Prerequisites/Initial Conditions

Prerequisites/initial conditions identify independent actions or procedures that must be accomplished and plant conditions which must exist prior to performing the procedure; including prerequisites applicable to only a specific portion of a procedure.

Precautions

Precautions alert the user to those important measures to be used to protect equipment and personnel, including the public, or to avoid an abnormal or emergency situation during performance of the procedure. Cautionary notes applicable to specific steps are included in the main body of the procedure and are identified as such.

Limitations and actions

Limitations on the parameters being controlled and appropriate corrective measures to return the parameter to the normal control band are specified.

Main body

The main body of the procedure contains the step-by-step instructions in the degree of detail necessary for performing the required function or task.

Acceptance criteria

The acceptance criteria provide the quantitative or qualitative criteria against which the success or failure (as of a test-type activity) of the step or action would be judged.

Checklists

Complex procedures utilize checklists which may be included as part of the procedure or appended to it.

3.2. Procedure Types

Procedure types may vary from one location to the other based on scope of activities; however, procedures are developed in each of the following categories.

Administrative Control Procedures

These include administrative procedures, directives, policies, standards, and similar documents that control the programmatic aspects of facility activities. These administrative documents ensure that the requirements of regulatory and license commitments are implemented. Several levels of administrative controls are applied ranging from those affecting the entire Company to those prepared at the implementing group level. These documents establish responsibilities, interfaces, and standard methods (rules of practice) for implementing programs. In addition to the administrative controls described throughout this QAPD, instructions governing the following activities are provided:

Operating Orders/Procedures

Instructions of general and continuing applicability to the conduct of business to the plant staff are provided. Examples include, but are not limited to, job turnover and relief, designation of confines of control room, definition of duties of operators and others, transmittal of operating data to management, filing of charts, limitations on access to certain areas and equipment, shipping and receiving instructions. Provisions are made for periodic review and updating of these documents, where appropriate.

Special Orders

Management instructions, which have short-term applicability and require dissemination, are issued to encompass special operations, housekeeping, data taking, publications and their distribution, plotting process parameters, personnel actions, or other similar matters. Provisions are made for periodic review, updating, and cancellation of these documents, where appropriate.

Plant Security and Visitor Control

Procedures or instructions developed to supplement features and physical barriers designed to control access to the plant and, as appropriate, to vital areas within the plant. Information concerning specific design features and administrative provisions of the plant security program is confidential and thus accorded limited distribution. The security and visitor control procedures consider, for example, physical provisions, such as: fences and lighting; lock controls for doors, gates and compartments containing sensitive equipment; and provisions for traffic and access control. Administrative provisions, such as: visitor sign-in and sign-out procedures; escorts and badges for visitors; emphasis on inspection, observation and challenging of strangers by operating crews; and a program of pre-employment screening for potential employees are also considered.

Temporary Procedures

Temporary procedures may be used to direct operations during testing, refueling, maintenance, and modifications to provide guidance in unusual situations not within the scope of the normal procedures. These procedures ensure orderly and uniform operations for short periods when the plant, a system, or a component of a system is performing in a manner not covered by existing detailed procedures or has been modified or extended in such a manner that portions of existing procedures do not apply. Temporary Procedures include designation of the period of time during which they may be used and are subject to the procedure review process as applicable.

Engineering Procedures

These documents provide instructions for the preparation of engineering documents, engineering analysis, and implementation of engineering programs. This includes activities such as designs; calculations; fabrication, equipment, construction, and installation specifications; drawings; analysis and topical reports; and testing plans or procedures. They include appropriate references to industry codes and standards, design inputs, and technical requirements.

Configuration Management Procedures

These documents provide instructions for the responsibility and authority for functions that affect the configuration of the facility including activities such as operations, design, maintenance, construction, licensing, and procurement. TVA New Nuclear shall

establish and document a time or event when configuration management shall be established for the facility.

Installation Procedures

These documents provide instructions for the installation of components generally related to new construction and certain modification activities. They include appropriate reference to industry standards, installation specifications, design drawings, and supplier and technical manuals for the performance of activities. These documents include provisions, such as hold or witness points, for conducting and recording results of required inspections or tests. These documents may include applicable inspection and test instructions subject to the requirements for test and inspection procedures below.

System Procedures

These documents contain instructions for energizing, filling, venting, draining, starting up, shutting down, changing modes of operation, and other instructions appropriate for operations of systems related to the safety of the plant. Actions to correct off-normal conditions are invoked following an operator observation or an annunciator alarm indicating a condition which, if not corrected, could degenerate into a condition requiring action under an emergency procedure. Separate procedures may be developed for correcting off-normal conditions for those events where system complexity may lead to operator uncertainty. Appropriate procedures will also be developed for the fire protection program.

Start-up Procedures

These documents contain instructions for starting the reactor from cold or hot conditions and establishing power operation. This includes documented determination that prerequisites have been met, including confirmation that necessary instruments are operable and properly set; valves are properly aligned, necessary system procedures, tests and calibrations have been completed; and required approvals have been obtained.

Shutdown Procedures

These documents contain guidance for operations during controlled shutdown and following reactor trips, including instructions for establishing or maintaining hot shutdown/standby or cold shutdown conditions, as applicable. The major steps involved in shutting down the plant are specified, including instructions for such actions as monitoring and controlling reactivity, load reduction and cooldown rates, sequence for activating or deactivating equipment, requirements for prompt analysis for causes of reactor trips or abnormal conditions requiring unplanned controlled shutdowns, and provisions for decay heat removal.

Power Operation and Load Changing Procedures

These documents contain instructions for steady-state power operation and load changing. These types of documents include, as examples, provisions for use of control rods, chemical shim, coolant flow control, or any other system available for short-term or long-term control of reactivity, making deliberate load changes, responding to unanticipated load changes, and adjusting operating parameters.

Process Monitoring Procedures

These documents contain instructions for monitoring performance of plant systems to assure that core thermal margins and coolant quality are maintained in acceptable status at all times, that integrity of fission product barriers is maintained, and that engineered safety features and emergency equipment are in a state of readiness to keep the plant in a safe condition if needed. Maximum and minimum limits for process parameters are appropriately identified. Operating procedures address the appropriate nature and frequency of this monitoring.

Fuel Handling Procedures

These documents contain instructions for core alterations, accountability of fuel and partial or complete refueling operations that include, for example, continuous monitoring of neutron flux throughout core loading, periodic data recording, audible annunciation of abnormal flux increases, and evaluation of core neutron multiplication to verify safety of loading increments. Procedures are also provided for receipt and inspection of new fuel, and for fuel movements in the spent fuel storage areas. Fuel handling procedures include prerequisites to verify the status of systems required for fuel handling and movement; inspection of replacement fuel and control rods; designation of proper tools, proper conditions for spent fuel movement, proper conditions for fuel cask loading and movement; and status of interlocks, reactor trip circuits and mode switches. These procedures provide requirements for refueling, including proper sequencing, orientation and seating of fuel and components, rules for minimum operable instrumentation, actions for response to fuel damage, verification of shutdown margin, communications between the control room and fuel handling station, independent verification of fuel and component locations, criteria for stopping fuel movements, and documentation of final fuel and component serial numbers (or other unique identifiers) and locations.

Maintenance Procedures

These documents contain instructions in sufficient detail to permit maintenance work to be performed correctly and safely, and include provisions, such as hold or witness points, for conducting and recording results of required inspections or tests. These documents may include applicable inspection or test instructions subject to the requirements for test and inspection procedures below. Appropriate referencing to other procedures, standards, specifications, or supplier manuals is provided. When not provided through other documents, instructions for equipment removal and return to service, and applicable radiation protection measures (such as protective clothing and

radiation monitoring) will be included. Additional maintenance procedure requirements are addressed in NQA-1-2015, Subpart 2.18, Section 202, Procedures.

Radiation Control Procedures

These documents contain instructions for implementation of the radiation control program requirements necessary to meet regulatory commitments, including acquisition of data and use of equipment to perform necessary radiation surveys, measurements and evaluations for the assessment and control of radiation hazards. These procedures provide requirements for monitoring both external and internal exposures of employees, utilizing accepted techniques; routine radiation surveys of work areas; effluent and environmental monitoring in the vicinity of the plant; radiation monitoring of maintenance and special work activities, and for maintaining records demonstrating the adequacy of measures taken to control radiation exposures to employees and others.

Calibration and Test Procedures

These documents contain instructions for periodic calibration and testing of instrumentation and control systems, and for periodic calibration of measuring and test equipment used in activities affecting the quality of these systems. These documents provide for meeting surveillance requirements and for assuring measurement accuracy adequate to keep safety-related parameters within operational and safety limits.

Chemical and Radiochemical Control Procedures

These documents contain instructions for chemical and radiochemical control activities and include: the nature and frequency of sampling and analyses; instructions for maintaining coolant quality within prescribed limits; and limitations on concentrations of agents that could cause corrosive attack, foul heat transfer surfaces, or become sources of radiation hazards due to activation. These documents also provide for the control, treatment and management of radioactive wastes, and control of radioactive calibration sources.

Emergency Operating Procedures

These documents contain instructions for response to potential emergencies so that a trained operator will know in advance the expected course of events that will identify an emergency and the immediate actions that are taken in response. Format and content of emergency procedures are based on NUREG and Owner’s Group(s) guidance that identify potential emergency conditions and require such procedures to include, as appropriate, a title, symptoms to aid in identification of the nature of the emergency, automatic actions to be expected from protective systems, immediate operator actions for operation of controls or confirmation of automatic actions, and subsequent operator actions to return the reactor to a normal condition or provide for a safe extended shutdown period under abnormal or emergency conditions.

Emergency Plan Implementing Procedures

These documents contain instructions for activating the Emergency Response Organization and facilities, protective action levels, organizing emergency response actions, establishing necessary communications with local, state, and federal agencies, and for periodically testing the procedures, communications, and alarm systems to assure they function properly. Format and content of such procedures are such that requirements of each facility's NRC approved Emergency Plan are met.

Test and Inspection Procedures

These documents provide the necessary measures to assure quality is achieved and maintained for the nuclear facilities. The instructions for tests and inspections may be included within other procedures, such as installation and maintenance procedures, but will contain the objectives, acceptance criteria, prerequisites for performing the test or inspection, limiting conditions, and appropriate instructions for performing the test or inspection, as applicable. These procedures also specify any special equipment or calibrations required to conduct the test or inspection and provide for appropriate documentation and evaluation by responsible authority to assure test or inspection requirements have been satisfied. Where necessary, hold or witness points are identified within the procedures and require appropriate approval for the work to continue beyond the designated point. These procedures provide for recording the date, identification of those performing the test or inspection, as-found condition, corrective actions performed (if any), and as-left condition, as appropriate for the subject test or inspection.

SECTION 4. CONTROL OF SYSTEMS AND EQUIPMENT IN THE OPERATIONAL PHASE

Permission to release systems and equipment for maintenance or modification is controlled by designated operating personnel and documented measures, such as installation of tags or locks and releasing stored energy, are used to ensure personnel and equipment safety. When entry into a closed system is required, TVA New Nuclear has established control measures to prevent entry of extraneous material and to assure that foreign material is removed before the system is reclosed.

Administrative procedures require the designated operating personnel to verify that the system or equipment can be released and determine the length of time it may be out of service. In making this determination, attention is given to the potentially degraded degree of protection where one subsystem of a redundant safety system is not available for service. Conditions to be considered in preparing equipment for maintenance include, for example: shutdown margin; establishment of a path for decay heat removal; temperature and pressure of the system; valves between work and hazardous material; venting, draining, and flushing; entry into closed vessels; hazardous atmospheres; handling hazardous materials; and electrical hazards.

When systems or equipment are ready to be returned to service, designated operating personnel control placing the items in service and document its functional acceptability. Attention is given to restoration of normal conditions, such as removal of jumpers or signals

used in maintenance or testing, or actions such as returning valves, breakers or switches to proper start-up or operating positions from "test" or "manual" positions. Where necessary, the equipment placed into service receives additional surveillance during the run-in period.

Independent verifications, where appropriate, are used to ensure that the necessary measures have been implemented correctly. The minimum requirements and standards for using independent verification are established in company documents.

SECTION 5. PLANT MAINTENANCE

TVA New Nuclear establishes controls for the maintenance or modification of items and equipment subject to this QAPD to ensure quality at least equivalent to that specified in original design bases and requirements, such that safety-related structures, systems, and components are maintained in a manner that assures their ability to perform their intended safety function(s). Maintenance activities (both corrective and preventive) are scheduled and planned so as not to unnecessarily compromise the safety of the plant.

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 shall be interpreted to mean the applicable standards and requirements established within the QAPD.
- Section 203 requires cleanliness during maintenance to be in accordance with Subpart 2.1. The commitment to Subpart 2.1 is described in the QAPD, Part II, Section 13.2.

Enclosure 3

NNP-TR-001-NP, Revision 1, Quality Assurance Program Description for TVA New Nuclear

NNP-TR-001-NP
Revision 1
Document Date: February 2023

Quality Assurance Program Description for TVA New Nuclear

Topical Report

Non-Proprietary

REVISION LOG

Revision	Date	Description of Revision
0	August 2022	Initial Issuance
1	February 2023	Updated to address final RAIs (eRAI-386). Changed title to New Nuclear versus New Nuclear Program QAP to further eliminate confusion. Also, changed references, where applicable, from New Nuclear Programs and New Nuclear Projects to New Nuclear.

EXECUTIVE SUMMARY

This topical report provides a description of the TVA New Nuclear Quality Assurance Program (QAP) for the site-selection, design, construction, and operation of nuclear plant(s) at multiple sites and projects. The QAP has been prepared in accordance with the requirements of Title 10, Part 50 of the Code of Federal Regulations (10 CFR 50), "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" and ASME NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications" as endorsed by Regulatory Guide (RG) 1.28, Revision 5, "Quality Assurance Program Criteria (Design and Construction)." This topical report considered the guidance in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 17.5, and is based on the Nuclear Energy Institute (NEI) 11-04A, "Nuclear Generation Quality Assurance Program Description" template. Departures from the NEI 11-04A template were necessary in some instances to conform to the Nuclear Regulatory Commission endorsement of NQA-1-2015 in RG 1.28, Revision 5.

The early site permit (ESP) for the Clinch River Small Modular Reactor (SMR) Project was produced under the TVA Nuclear Quality Assurance Plan (NQAP), TVA-NQA-PLN89-A, Revision 39, and is excluded from compliance with this QAP. ESPs for future SMR projects will comply with this QAP. Consistent with common licensing practice, text is written in the present tense, active voice, including discussions of activities and processes associated with a phased implementation of design, construction, and operation.

The topical report is divided into five parts:

- Introduction and Scope
- Quality Assurance Program Description (QAPD) Details
- Non-safety-Related Structures, Systems, and Components (SSC) Quality Control
- Regulatory Commitments, and
- Additional QA and Administrative Controls for the Plant Operational Phase

TVA New Nuclear requests NRC review and approval of this topical report to be used to satisfy quality assurance requirements for use by nuclear power plant applications submitted in accordance with 10 CFR 50 and 10 CFR 52:

- 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)
- Standard Design Approval (SDA) Applications pursuant to 10 CFR 52.137(a)(19)

ACRONYMS AND ABBREVIATIONS

Acronym / Abbreviation	**Definition**
AE	Architect/Engineer
ANS	American Nuclear Society
ASL	Acceptable Suppliers List
ASME	The American Society of Mechanical Engineers
ATWS	Anticipated Transient Without Scram
CFR	Code of Federal Regulations
COL	Combined Operating License
CP	Construction Permit
ESP	Early Site Permit
FSAR	Final Safety Analysis Report
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
ITAAC	Inspection, Tests, Analysis, Acceptance Criteria
LWA	Limited Work Authorization
M&TE	Measuring and Test Equipment
MRA	Mutual Recognition Agreement
NEI	Nuclear Energy Institute
NIRMA	Nuclear Information and Records Management Association
NQAP	Nuclear Quality Assurance Plan
NRC	Nuclear Regulatory Commission
NSSS	Nuclear Steam Supply System
NUPIC	Nuclear Procurement Issues Corporation
OL	Operating License
QA	Quality Assurance
QAP	Quality Assurance Program
QAPD	Quality Assurance Program Description
QC	Quality Control
RG	Regulatory Guide
RIS	Regulatory Issues Summary
SBO	Station Blackout
SDA	Standard Design Approval
SMR	Small Modular Reactor
SSC	Structures, Systems, and Components
TVA	Tennessee Valley Authority

TABLE OF CONTENTS

POLICY STATEMENT

Tennessee Valley Authority (TVA) New Nuclear shall design, procure, deliver, construct, and operate the nuclear plant(s) in a manner that will ensure the health and safety of the public and workers. These activities shall be performed in compliance with the requirements of the Code of Federal Regulations (CFR) and applicable laws and regulations of the state and local governments.

The TVA New Nuclear Quality Assurance Program (QAP) is the Quality Assurance Program Description (QAPD) provided in this document and the associated implementing documents. Together they provide for control of TVA New Nuclear activities that affect the quality of safety-related nuclear plant structures, systems, and components (SSCs) and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service. The QAPD may also 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 QAPD is the top-level policy document that establishes the manner in which quality is to be achieved and presents the TVA New Nuclear overall philosophy regarding achievement and assurance of quality. Implementing documents assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAP. Senior management establishes overall expectations for effective implementation of the quality assurance program and is responsible for obtaining the desired end result. Compliance with the QAPD and implementing documents is mandatory for personnel directly or indirectly associated with implementation of the TVA New Nuclear QAP.

Robert M. Deacy
Senior Vice President, New Nuclear Projects

2/14/2023
Date

PART I. INTRODUCTION

SECTION 1. GENERAL

The QAPD is the top-level policy document that establishes the quality assurance policy and assigns major functional responsibilities for all quality-related activities conducted by or for TVA New Nuclear. The QAPD describes the methods and establishes quality assurance (QA) and administrative control requirements that meet 10 CFR 50, Appendix B and 10 CFR 52. The QAPD is based on the requirements and guidance of ASME NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, with specific reference to selected Part III and Part IV sections, as identified in this document.

The QAP is defined by the NRC-approved regulatory document that describes the QA elements (i.e., the QAPD), along with the associated implementing documents. Procedures and instructions that control quality-related activities will be developed prior to commencement of those activities. Policies establish high-level responsibilities and authority for carrying out important administrative functions which are outside the scope of the QAPD. Procedures establish practices for certain activities which are common to all TVA New Nuclear organizations performing those activities so that the activity is controlled and carried out in a manner that meets QAPD requirements. Procedures specific to a site, organization, or group establish detailed implementation requirements and methods, and may be used to implement policies or be unique to particular functions or work activities.

1.1. Scope/Applicability

The QAPD applies to design phase, construction phase and operations phase activities, including those in support of Standard Design Approval (SDA), Design Certification (DC), Early Site Permit (ESP), Limited Work Authorization (LWA), Construction Permit (CP), construction/pre-operation, Operating License (OL), Combined Operating License (COL), and operation activities affecting the quality and performance of safety-related structures, systems, and components, including, but not limited to:

- Designing
- Siting
- Procuring
- Fabricating
- Cleaning
- Handling
- Shipping
- Receiving
- Storing
- Constructing
- Erecting
- Installing
- Inspecting
- Testing
- Startup
- Pre-operational activities (including ITAAC)
- Operating
- Maintaining
- Repairing
- Modifying
- Refueling
- Training
- Decommissioning

Safety-related SSCs, under the control of the QAPD, are identified by design documents. The technical aspects of these items are considered when determining program applicability, including, as appropriate, the item's design safety function. The QAPD may be applied to certain activities where regulations other than 10 CFR 50 and 10 CFR 52 establish QA requirements for activities within their scope.

The policy of TVA New Nuclear is to assure a high degree of availability and reliability of the nuclear plant while ensuring the health and safety of its workers and the public. To this end, selected elements of the QAPD are also applied to certain equipment and activities that are not safety-related, but support safe, economic, and reliable plant operations, or where other NRC guidance establishes quality assurance requirements. Implementing documents establish program element applicability.

The definitions provided in ASME NQA-1–2015, Part I, Section 400, apply to select terms as used in this document.

PART II. QUALITY ASSURANCE PROGRAM DESCRIPTION (QAPD) DETAILS

SECTION 1 ORGANIZATION

This section describes the TVA New Nuclear organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of the QAPD. Management gives careful consideration to the timing, extent, and effects of organizational structure changes.

The TVA New Nuclear organization is divided into two parts: New Nuclear Program and New Nuclear Projects. The New Nuclear Program addresses global infrastructure and programmatic matters with siting, licensing, and planning for multiple new nuclear projects across multiple sites. The New Nuclear Projects organization supports the engineering, procurement, construction, startup, and operational development activities of specific projects at designated sites.

The management position responsible for Quality Assurance is responsible to size the New Nuclear Project Quality Assurance staff commensurate with the duties and responsibilities assigned.

The responsibility for quality related activities during design, construction, and operations phases are shown below:

Design Phase	Construction Phase	Operations Phase
• Engineering • Fabrication • Supply Chain • Site Characterization • Document Control and Other Support Services • QA/QC	• Construction • Engineering • Fabrication • Supply Chain • Construction Testing • Document Control and Other Support Services • QA/QC	• Operations • Maintenance • Engineering • Supply Chain • Startup/Preop Testing • Document Control and Other Support Services • QA/QC

Design, engineering, environmental, and construction services may be provided to the TVA New Nuclear organization by contractors in accordance with their QAPDs compliant with 10 CFR 50, Appendix B, or shall be required to meet the requirements of the TVA New Nuclear QAPD or TVA Fleet QAPD.

The following sections describe the reporting relationships, functional responsibilities, and authorities for organizations implementing and supporting the QAP. The TVA New Nuclear Organization is shown in Figure II.1–1.

1.1. President/Chief Executive Officer

The President/Chief Executive Officer (CEO) is responsible for all aspects of design, construction, and operation of TVA's nuclear plants, including new nuclear projects developed under TVA New Nuclear. The President/CEO is also responsible for all technical and administrative support activities provided by TVA and contractors. The President/CEO directs the Chief Nuclear Officer and the Chief Operating Officer in the fulfillment of their responsibilities. The President/CEO reports to the TVA Board of Directors with respect to all matters.

1.2. Executive Vice President/Chief Nuclear Officer

The Chief Nuclear Officer (CNO) is responsible for the safe, reliable, and efficient operation of the TVA Nuclear Plants. The CNO also has the overall responsibility for the establishment, implementation, and administration of TVA's Fleet NQAP and the evaluation of its effectiveness. This responsibility is implemented through the General Manager, Quality Assurance. The CNO also supports the New Nuclear Program activities through the Senior Vice President, Engineering and Operations Support.

1.2.1. Senior Vice President, Engineering and Operations Support

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

1.2.1.1. Vice President, New Nuclear Program

Vice President, New Nuclear Program reports to the Senior Vice President, Nuclear Engineering and Operations Support. This position is responsible for nuclear site development, fabrication, supply chain, site characterization, document control and advanced design engineering. The Vice President, New Nuclear Program is also responsible for developing strategies for workforce development, training, and transition planning for the New Nuclear Program. The Vice President, New Nuclear Program is responsible for technical, administrative, and corporate support services provided by New Nuclear Program and contractors. The Vice President, New Nuclear Program is also responsible for establishing and managing the NSSS contract for the development of new nuclear generation.

The Vice President, New Nuclear Program is responsible for licensing activities related to the New Nuclear Program and New Nuclear Project Sites. These include, Early Site Permits (ESPs), Limited Work Authorizations (LWA), Construction Permits (CPs), Operating Licenses (OLs), Combined Operating Licenses (COLs), Design Certifications (DCs) and Standard Design Approval Applications (SDAs). Roles and responsibilities for these activities are contained in New Nuclear Program procedures and guidelines.

The Vice President, New Nuclear Program interfaces with the Vice President, Site Projects for project-related advanced nuclear technology development, Licensing, Supply Chain, and Safety during the design phase and for corporate support during construction and operations in fulfillment of their responsibilities.

1.2.2. General Manager, Quality Assurance

The General Manager, Quality Assurance is the management position responsible for the nuclear operating fleet, vendors, and the TVA New Nuclear Program. The General Manager, QA has an independent reporting relationship to the CNO on quality issues. The General Manager, QA, administers quality assurance responsibilities through the management positions responsible for Corporate QA, Site QA, and QA Services.

The General Manager, Quality Assurance is responsible for planning and performing activities to verify the development and effective implementation of the Fleet QAPD. Effective implementation includes but is not limited to developing and maintaining the TVA Fleet QAPD, evaluating compliance to QAP requirements, assuring compliance with regulatory requirements and procedures through audits and technical reviews; monitoring organizational processes to ensure conformance to commitments and licensing document requirements; and ensuring that vendors providing quality services, parts, and materials to site projects are meeting the requirements of 10 CFR 50, Appendix B through NUPIC, joint utility, or TVA vendor audits.

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. QA may make recommendations to management regarding improving the quality of work processes. If QA disagrees with any actions taken by the organization and is unable to obtain resolution, QA shall inform quality assurance management and bring the matter to the attention of the Chief Nuclear Officer (CNO), who will determine the final disposition.

1.3. Executive Vice President/Chief Operating Officer

The Chief Operating Officer (COO) is responsible for TVA's transmission and power supply, power operations, resource management and operations services, and generation projects and fleet services. The Chief Operating Officer supports TVA Nuclear through the Senior Vice President, Resource Management and Operations Support. Organizations that report through the Senior Vice President, Resource Management and Operations Support include Supply Chain, Nuclear Materials, Central Labs and Services, and Inspection Services. The COO also supports the New Nuclear Projects activities through the Senior Vice President, New Nuclear Projects.

The COO will interface with the CNO regarding QA decisions affecting the New Nuclear Program. The COO does not have the authority to disposition quality assurance issues affecting the New Nuclear Program organization.

1.3.1 Senior Vice President, Resource Management and Operations Support

The Senior Vice President, Resource Management and Operations Support reports to the Chief Operating Officer. The management position responsible for procurement reports through the Vice President, Supply Chain to the Senior Vice President, Resource Management and Operations Support and is responsible for ensuring that the QA requirements established by this program description are either included or referenced (as appropriate) in related Procurement sponsored program areas.

1.3.2 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. The Senior Vice President, New Nuclear Projects is also responsible for all technical and administrative support activities provided by the Site Project and its contractors.

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. During the transition of a New Nuclear project from design/construction phase to operational phase as defined by programs and procedures, 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 until it is deemed that they are no longer necessary.

During all phases, QA management has access to the Senior Vice President, New Nuclear Projects as the executive with overall responsibilities for QA. General Manager, New Nuclear Projects Quality Assurance shall have the freedom and authority to raise issues, that cannot be resolved at lower levels, to the Chief Operating Officer for final decision.

1.3.2.1 General Manager, New Nuclear Projects Quality Assurance

The General Manager, New Nuclear Projects Quality Assurance (QA) is the management position responsible for the quality aspects of New Nuclear Projects. The General Manager, New Nuclear Projects QA reports to the Senior Vice President, New Nuclear Projects with direct access to Chief Operating Officer on quality issues. The General Manager, New Nuclear Projects QA administers quality assurance responsibilities through the management positions responsible for New Nuclear Project Site QA.

The General Manager, New Nuclear Projects QA is responsible for assigning an individual to direct and manage the onsite New Nuclear Project QA. This individual has appropriate organizational position, responsibility, and authority to exercise proper control over the QAP at the project site. This individual is free from non-QA duties and can thus give full attention to ensuring that the QAP at the project site is effectively implemented. The General Manager, New Nuclear Projects QA is also responsible through the management position at the new nuclear project site for quality control and quality assurance activities during the design, construction, and operations phases of the project.

The General Manager, New Nuclear Projects QA is responsible for planning and performing activities to verify the development and effective implementation of the New Nuclear QAPD. Effective implementation includes but is not limited to developing and maintaining the New Nuclear QAPD, evaluating compliance to QAP requirements, assuring compliance with regulatory requirements and procedures through audits and technical reviews, monitoring organizational processes to ensure conformance to commitments and licensing document requirements, and ensuring that vendors providing quality services, parts, and materials to site projects are meeting the requirements of 10 CFR 50, Appendix B through NUPIC, joint utility, or TVA vendor audits.

The QA function has sufficient independence from other TVA New Nuclear priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas regarding TVA New Nuclear activities as appropriate. QA may make recommendations to management regarding improving the quality of work processes. If QA disagrees with any actions taken by the New Nuclear Projects organization and is unable to obtain resolution, QA shall inform quality assurance management and bring the matter to the attention of the Chief Operating Officer (COO), who will determine the final disposition.

1.3.2.2 Vice President, Site Project

The Vice President, Site Project reports to the Senior Vice President, New Nuclear Projects and is responsible for the Design Phase, Construction Phase and Operations Phase of a Project. This position is also responsible for the oversight of design changes and configuration management. The following provides the detailed oversight and execution responsibilities for Vice President, Site Project for each phase of the Site Project.

1.3.2.2.1 Design Phase Management Team

The Design Phase Management Team reports to the Vice President, Site Project and is responsible for Engineering, Fabrication, Supply Chain, Document Control, and support services.

The Design Phase Management Team is staffed and has the appropriate authority required to perform quality-related design activities. Interfaces between design phase management and corporate support is defined in implementing procedures.

1.3.2.2.2 Construction Phase Management Team

The Construction Phase Management Team reports to the Vice President, Site Project and is responsible for construction activities, including construction, engineering fabrication, supply chain, construction testing, document control and other support services.

The Construction Phase Management Team is staffed and has the appropriate authority required to perform quality-related construction activities. Interfaces between site/construction phase management and corporate support is defined in implementing procedures.

1.3.2.2.3 Operations Phase Management Team

The Operations Phase Management Team reports to the Vice President, Site Project and is responsible for plant operation activities, including operations, maintenance, engineering, supply chain, startup/preoperational testing, document control and other support services.

The Operations Phase Management Team is staffed and has the appropriate authority required to perform quality-related operations activities. It is anticipated that even after fuel load, construction activities will be ongoing. Those positions required to support these activities will retain their applicable construction/pre-operation responsibilities until it is deemed that they are no longer necessary. As the construction of systems (or portions thereof) is completed, control and authority (including oversight, configuration, and operations) are transferred from Construction Phase Management to the cognizant departments in the operational phase. During

the transition to an operating facility, responsibilities will be clearly defined in instructions and procedures to ensure appropriate authority is maintained for each SSC.

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.

1.4. Nuclear Steam Supply System (NSSS) Supplier

The Vice President, New Nuclear Program is responsible for establishing and managing oversight and execution activities of the Nuclear Steam Supply System (NSSS) Supplier. A NSSS Supplier provides engineering services for plant design and licensing of specific plant types for TVA New Nuclear. These engineering services for new nuclear generation include site-specific engineering and design necessary to support development of ESP, CP, OL and COL applications and preconstruction and construction activities.

1.5. Architect/Engineering (A/E) Suppliers

The Vice President, New Nuclear Program is responsible for establishing and managing oversight and execution activities of the Architect/Engineering (A/E) Suppliers. A/E Suppliers provide engineering services for the development of the ESP, CP, OL, and COL applications. These engineering services include site-specific licensing, engineering, and design activities, including planning and support for preconstruction and construction of new nuclear generation facilities.

1.6. Authority to Stop Work

Quality Assurance and Quality Control personnel have the authority, and the responsibility, 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 suppliers that furnish safety-related materials and services to TVA New Nuclear.

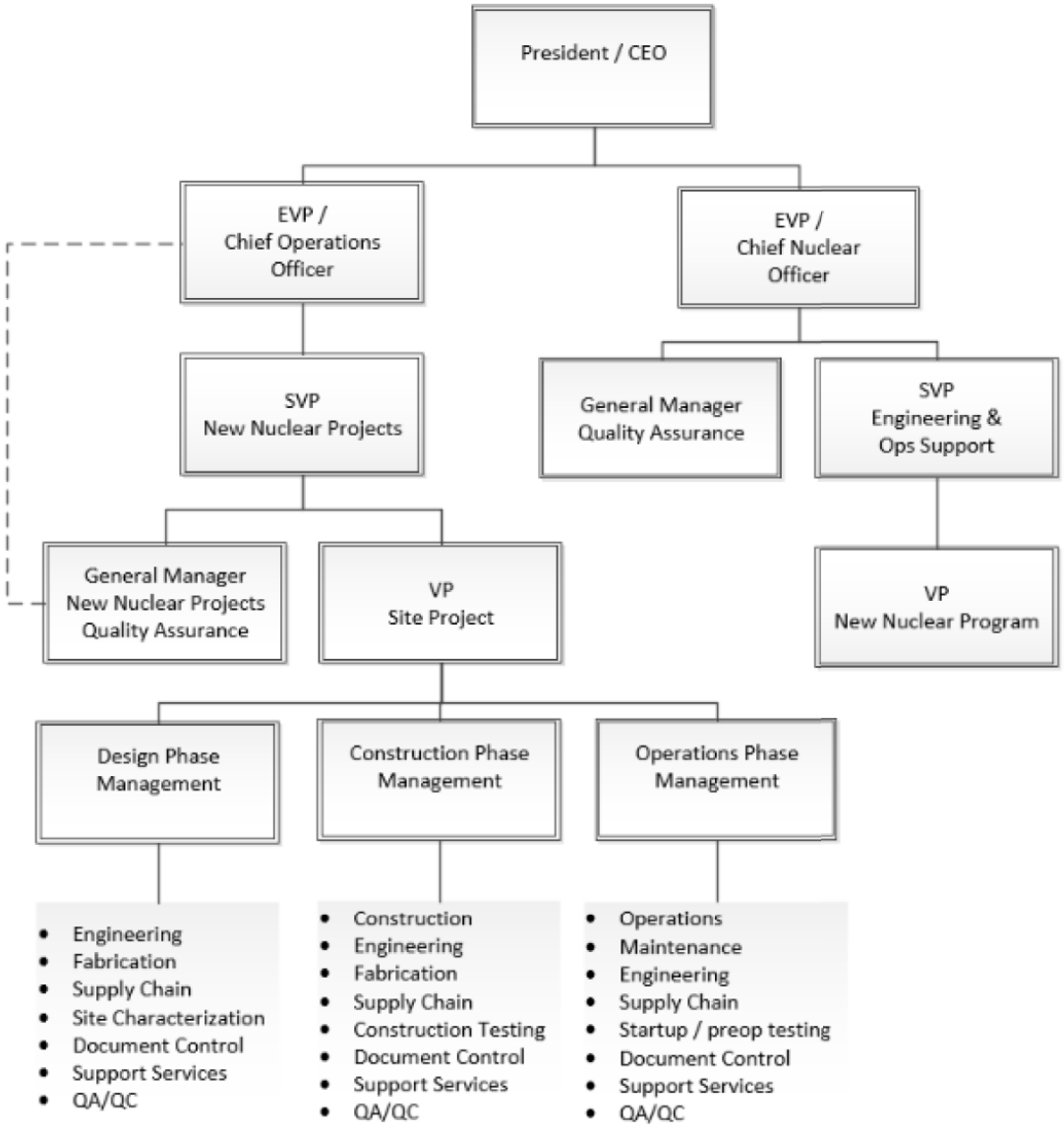
1.7. QA Organizational Independence

Independence shall be maintained between the organization(s) performing the checking (quality assurance and control) functions and the organizations performing the functions. This provision is not applicable to design review/verification.

1.8. NQA-1 Commitment

In establishing its organizational structure, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 1.

FIGURE II.1-1 TVA NEW NUCLEAR ORGANIZATION



QA function has direct access to levels of Management necessary to assure effective execution of the QA program irrespective of organizational structure.

SECTION 2 QUALITY ASSURANCE PROGRAM

TVA New Nuclear QA program ensures that activities affecting quality shall be accomplished under suitably controlled conditions, including (1) the use of appropriate equipment, (2) a suitable environment for accomplishing the activity, e.g., adequate cleanliness, and (3) compliance with necessary prerequisites for the given activity. 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 New Nuclear is committed to implementing the QAP in all aspects of work that are important to the safety of the nuclear plants as described and to the extent delineated in the QAPD. The QAP shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities important to safety are performed satisfactorily. Further, TVA New Nuclear ensures through the systematic process described herein that its suppliers of safety-related equipment or services meet the applicable requirements of 10 CFR 50, Appendix B. Senior management is regularly apprised of the adequacy of implementation of the QAP through the audit functions described in Part II, Section 18.

The objective of the QAP is to assure that the TVA New Nuclear generating plants are designed, constructed, and operated in accordance with governing regulations and license requirements. The program is based on the requirements of ASME NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," as endorsed by Regulatory Guide 1.28, Revision 5 and as described in this document. The QAP applies to those quality-related activities that involve the functions of safety-related structures, systems, and components (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. Examples of ESP, CP/OL, or COL program safety-related activities include, but are not limited to, site-specific engineering related to safety-related SSCs, site geotechnical investigations, site engineering analysis, seismic analysis, and meteorological analysis 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. Cost and scheduling challenges must be addressed; however, they do not prevent proper implementation of the QAP.

As described in Part III of the QAPD, specific program controls are applied to non-safety-related SSCs that are significant contributors to plant safety, for which 10 CFR 50, Appendix B, is not applicable. The specific program controls, consistent with applicable sections of the QAPD, are applied to those items in a select manner, targeted at those characteristics or critical attributes that qualifies the SSC as a significant contributor to plant safety. (This paragraph and Part III do not apply to ESP related activities.)

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 (ASL). Periodic audits and assessments of supplier QA programs are performed to assure compliance with the supplier's or principal contractor's QAPD and implementing procedures. In addition, routine interfaces with the supplier’s personnel provide added assurance that quality expectations are met.

For the ESP, CP/OL, and/or COL applications, the QAPD applies to those activities that can affect either directly or indirectly the safety-related site characteristics or analysis of those

characteristics. For DC and SDA applications, the QAPD applies to those activities that involve or affect safety-related functions. In addition, the QAPD applies to engineering activities that are used to characterize the site or analyze that characterization.

New nuclear plant construction will be the responsibility of TVA New Nuclear organization. Detailed engineering specifications and construction procedures will be developed to implement the QAPD prior to commencement of pre-construction and/or construction activities. Examples of Limited Work Authorization (LWA) activities that could impact safety-related SSCs include impacts of construction to existing facilities and, for construction of a new plant, the interface between nonsafety-related and safety-related SSCs and the placement of seismically designed backfill. (This requirement does not apply to ESP or operations related activities.)

In general, the program requirements specified herein are detailed in implementing procedures that are either TVA New Nuclear implementing procedures, or supplier implementing procedures governed by a supplier quality assurance program.

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 backwards by performing the activity early. Audit schedules are based on the month in which the audit starts.

2.1. Responsibilities

Personnel who work directly or indirectly for TVA New Nuclear are responsible for achieving acceptable quality in the work covered by the QAPD. This includes the activities delineated in Part I, Section 1.1. TVA New Nuclear personnel performing verification activities are responsible for verifying the achievement of acceptable quality. Activities governed by the QAPD are performed as directed by documented instructions, procedures, and drawings that are of a detail appropriate for the activity's complexity and effect on safety. Instructions, procedures, and drawings specify quantitative or qualitative acceptance criteria as applicable or appropriate for the activity, and verification is against these criteria. Provisions are established to designate or identify the proper documents to be used in an activity, and to ascertain that such documents are being used. QA is responsible to verify that processes and procedures comply with QAPD and other applicable requirements, that such processes or procedures are implemented, and that management appropriately ensures compliance.

2.2. Delegation of Work

TVA New Nuclear retains and exercises the responsibility for the scope and implementation of an effective QAP. Positions identified in Part II, Section 1, may delegate all or part of the activities of planning, establishing, and implementing the program for which they are responsible to others, but retain the responsibility for the program's effectiveness. Decisions affecting safety are made at the appropriate level based upon their nature and effect, with technical advice or review as appropriate.

2.3. Site Specific Safety-Related Design Basis Activities

Site-specific safety-related design basis activities are defined as those activities, including

sampling, testing, data collection, and supporting engineering calculations and reports, that will be used to determine the bounding physical parameters of the site. Appropriate quality assurance measures are applied. (This paragraph does not apply to operations activities.)

2.4. Periodic Review of the QA Program

Management of those organizations implementing the QAP, or portions thereof, shall 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.

However, the period for assessing the QAP during the operational phase may be extended to once every two years. (This requirement does not apply to non-operations activities.)

2.5. Issuance and Revision to QA Program

Administrative control of the QAPD will be in accordance with 10 CFR 50.55(f) and 10 CFR 50.54(a). Changes to the QAPD are evaluated by TVA New Nuclear QA to ensure that such changes do not degrade safety for previously approved quality assurance controls specified in the QAPD. New revisions to the document will be reviewed, at a minimum, by the General Manager, New Nuclear Quality Assurance and approved by the Senior Vice President, New Nuclear Projects.

Regulations require that the Final Safety Analysis Report (FSAR) include, among other things, the managerial and administrative controls to be used to assure safe operation, including a discussion of how the applicable requirements of 10 CFR 50, Appendix B will be satisfied. In order to comply with this requirement, the FSAR references the QAPD and, as a result, the requirements of 10 CFR 50.54(a) are satisfied by and apply to the QAPD.

2.6. Personnel Training and Qualifications

Personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. To this end, 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. The indoctrination, training, and qualification programs are commensurate with scope, complexity, and importance of the activities; and include or address the following, as appropriate:

- Education, experience, and proficiency of the personnel receiving training
- General criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements
- On-the-job training if direct hands-on applications or experience is needed to achieve and maintain proficiency.

Plant and support staff minimum qualification requirements are as delineated in the unit Technical Specifications. Other qualification requirements may be established but will not

reduce those required by Technical Specifications. (This paragraph does not apply to non-operations activities.)

Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in the applicable TVA New Nuclear procedures. Indoctrination includes the administrative and technical objectives, requirements of the applicable codes and standards, and the QAPD elements 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 that implement a systematic approach to training (This does not apply to non-operations activities.) Records of personnel training and qualification are maintained.

The minimum qualification of the New Nuclear QA Manager is that the manager holds an engineering or related science degree and a minimum of four years of related experience including two years of nuclear power plant experience, one year of supervisory or management experience, and one year of the experience is in performing quality verification activities. Special requirements shall include management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications for the individuals responsible for supervising QA or QC personnel is that each has a high school diploma or equivalent and has a minimum of one year of experience performing quality verification activities. Individuals who do not possess these formal education and experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications of individuals that are part of the QA organization responsible for planning, implementing, and maintaining the programs for the QAPD are that each has a high school diploma or equivalent and has a minimum of one year of related experience. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

2.7. NQA-1 Commitment / Exceptions

In establishing qualification and training programs, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 2 and the applicable regulatory position stated in Regulatory Guide 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 three (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.

SECTION 3 DESIGN CONTROL

TVA New Nuclear organization shall 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 shall support the facility design, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved. TVA New Nuclear has established and implements a process to control the design, design changes, and temporary modifications (e.g., temporary bypass lines, electrical jumpers, and lifted wires, and temporary setpoints) of items that are subject to the provisions of the QAPD. Applicable design inputs shall be identified and documented, and their selection reviewed and approved. The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a controlled manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. The design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within TVA New Nuclear and with suppliers. 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. 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. Design change processes and the division of responsibilities for design-related activities are detailed in TVA New Nuclear and supplier procedures. 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. The design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution, and revision of design inputs and outputs. Design changes and disposition of nonconforming items as "use as is" or "repair" are reviewed and approved by the New Nuclear, engineering or by other organizations so authorized by TVA New Nuclear.

Procedural control is established for design documents; this control differentiates between documents that receive formal design verification by interdisciplinary or multi-organizational teams and those which can be reviewed by a single individual (a signature and date is acceptable documentation for personnel certification). Design documents subject to procedural control include, but are not limited to, specifications, calculations, computer programs, system descriptions, Safety Analysis Report when used as a design document, and drawings including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams structural systems for major facilities, site arrangements, and equipment locations. Specialized reviews should be used when uniqueness or special design considerations warrant.

Design documents are reviewed by individuals knowledgeable in QA to ensure the documents contain the necessary QA requirements. (This paragraph does not apply to ESP activities),

3.1. Design Verification

TVA New Nuclear design processes provide for design verification to ensure that items, computer programs, and activities subject to the provisions of the QAPD are suitable for their intended application, consistent with their effect on safety. Design changes are subjected to

these controls, which include verification measures commensurate with those applied to original plant design.

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 verifier shall not have taken part in the selection of design inputs, the selection of design considerations, or the selection of a singular design approach, as applicable. This verification may be performed by the originator's supervisor provided the supervisor did not specify a singular design approach, rule out certain design considerations, and did not establish the design inputs used in the design, or if the supervisor is the only individual in the organization competent to perform the verification. If the verification is performed by the originator's supervisor, the justification of the need is documented and approved in advance by management.

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 designs. This includes design inputs, design outputs, and design changes. Design verification procedures are established and implemented to assure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria are identified, and the verification is satisfactorily accomplished and documented. Verification methods may include, but are not limited to, design reviews, alternative calculations, and qualification testing. 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.

TVA New Nuclear normally completes design verification activities before the design outputs are used by other organizations for design work, and before they are used to support other activities such as procurement, or construction. When such timing cannot be achieved, the design verification is completed 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.

3.2. Design Records

TVA New Nuclear maintains records sufficient to provide evidence that the design was properly accomplished. These records include the final design output and any revisions thereto, as well as record of the important design steps (e.g., calculations, analyses, and computer programs) and the sources of input that support the final output. Plant design drawings reflect the properly reviewed and approved configuration of the plant.

3.3. Computer Application and Digital Equipment Software

The QAPD governs the development, procurement, testing, maintenance, control, and use of computer applications and digital equipment software when used in safety-related applications and designated nonsafety-related applications. Computer program acceptability is pre-verified, or the results verified with the design analysis for each application. Pre-verified computer programs are controlled using a software configuration management process. TVA New Nuclear and suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. The procedures require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification. Each application software

and revision thereto are documented and approved by authorized personnel. The QAPD is also applicable to the administrative functions associated with the maintenance and security of computer hardware where such functions are considered essential in order to comply with other QAPD requirements such as QA records.

3.4. Setpoint Control

Instrument and equipment setpoints that could affect nuclear safety shall be controlled in accordance with written instructions. As a minimum, these written instructions shall:

- Identify responsibilities and processes for reviewing, approving, and revising setpoints and setpoint changes supplied by a supplier, Design Certification holder, or the plant's technical staff.
- Ensure that setpoints and setpoint changes are consistent with design and accident analysis requirements and assumptions.
- Provide for documentation of setpoints, including those determined operationally.
- Provide for access to necessary setpoint information for personnel who write or revise plant procedures, operate, or maintain plant equipment, develop, or revise design documents, or develop or revise accident analyses.

This subsection does not apply to ESP activities.

3.5. NQA-1 Commitment

In establishing its program for design control and verification, TVA New Nuclear commits to compliance with NQA-1-2015 Part I Requirement 3, NQA-1-2015 Part II, Subpart 2.7 Quality Assurance Requirements for Computer Software for nuclear facilities applications, NQA-1-2015, Part II, Subpart 2.14 Quality Assurance Requirements for Commercial Grade Items and Services, and Part II, Subpart 2.20 Quality Assurance Requirements for Subsurface Investigations for Nuclear Facilities (Subpart 2.20 does not apply to Operations activities).

SECTION 4 PROCUREMENT DOCUMENT CONTROL

TVA New Nuclear has established the necessary measures and governing procedures to assure that purchased items, computer programs, and services are subject to appropriate quality and technical requirements. Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents. These controls include provisions such that:

- Where original technical or quality assurance requirements cannot be determined, an engineering evaluation is conducted and documented by qualified staff to establish appropriate requirements and controls to assure that interfaces, interchangeability, safety, fit, and function, as applicable, are not adversely affected or contrary to applicable regulatory requirements.
- Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR 21) are invoked for procurement of items and services. 10 CFR 21 requirements for posting, evaluating, and reporting will be followed and imposed on suppliers when applicable. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of procurements (or the supplier may work under TVA New Nuclear approved QA program).

Reviews of procurement documents shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

4.1. NQA-1 COMMITMENT / EXCEPTIONS

In establishing controls for procurement, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 4, with the following clarifications and exceptions:

- With regard to service performed by a supplier, TVA New Nuclear procurement documents may allow the supplier to work under the QAP, including implementing procedures, in lieu of the supplier having its own QAP.
- Section 300 and 400 of 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 New Nuclear may satisfy this requirement through the review of the procurement specification when the specification contains the technical and quality assurance requirements of the procurement contract.

- Section 202, “Technical Requirements,” and 203, “Quality Assurance Program Requirements,” of Requirement 4, require that the technical and quality requirements be specified in the procurement documents. As a clarification, procurement documents for Commercial Grade Items that will be procured by TVA New Nuclear for use as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated in accordance with the QAPD, Part II, Section 7, “Control of Purchased Material, Equipment, and Services.”

SECTION 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

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 of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement the QAP as described in the QAPD. Such documents are prepared and controlled according to Part II, Section 6. In addition, means are provided to disseminate to the staff instructions of both general and continuing applicability, as well as those of short-term applicability. Provisions are included for reviewing, updating, and canceling such procedures.

5.1. Procedure Adherence

The TVA New Nuclear policy is that procedures are followed, and the requirements for use of procedures have been established in administrative procedures. Where procedures cannot be followed as written, provisions are established for making changes in accordance with Part II, Section 6. Requirements are established to identify the manner in which procedures are to be implemented, including identification of those tasks that require: (1) the written procedure to be present and followed step-by-step while the task is being performed, (2) the user to have committed the procedure steps to memory, (3) verification of completion of significant steps, by initials or signatures or use of check-off lists. Procedures that are required to be present and referred to directly are those developed for extensive or complex jobs where reliance on memory cannot be trusted, tasks that are infrequently performed, and tasks where steps must be performed in a specified sequence.

In cases of emergency, personnel are authorized to depart from approved procedures when necessary to prevent injury to personnel or damage to the plant. Such departures are recorded describing the prevailing conditions and reasons for the action taken.

5.2. Procedure Content

The established measures address the applicable content of procedures as described in the Introduction to Part II of NQA-1-2015. In addition, procedures governing tests, inspections, operational activities, and maintenance will include as applicable, initial conditions and prerequisites for the performance of the activity.

5.3. NQA-1 Commitment

In establishing procedural controls, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 5.

SECTION 6 DOCUMENT CONTROL

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 how activities affecting quality, including organizational interfaces, to ensure that correct documents are employed. The following controls, including electronic systems used to make documents available, are applied to documents and changes thereto:

- Identification of controlled documents
- Specified distribution of controlled documents for use at the appropriate location
- A method to identify the correct document (including revision) to be used and control of superseded documents
- Identification of individuals responsible for controlled document preparation, review, approval, and distribution
- Review of controlled documents for adequacy, completeness, and approval prior to distribution
- A method to ensure the correct documents are being used
- A method to provide feedback from users to improve procedures and work instructions
- Coordinating and controlling interface documents and procedures

The types of documents to be controlled include:

- Drawings such as design, fabrication, construction, installation, and as-built drawings
- Engineering calculations
- Design specifications
- Purchase orders and related documents
- Vendor-supplied documents
- Audit, surveillance, and quality verification/inspection procedures
- Inspection and test reports
- Instructions and procedures for activities covered by the QAPD including design, construction, installation, operating (including normal and emergency operations), maintenance, calibration, and routine testing
- Technical specifications
- Nonconformance reports and corrective action reports

During the operational phase, where temporary procedures are used, they shall include a designation of the period of time during which it is acceptable to use them.

6.1. Review and Approval of Documents

Documents are reviewed for adequacy by qualified persons other than the preparer. During the ESP or construction phase, procedures for design, construction, and installation are also reviewed by the organization responsible for quality verification to ensure quality assurance measures have been appropriately applied. (This requirement does not apply to operations activities.) The documented review signifies concurrence.

During the operational phase, documents affecting the configuration or operation of the station as described in the SAR are screened to identify those that require review by an Independent Review Group prior to implementation as described in Part V, Section 2.2.

To ensure effective and accurate procedures during the operational phase, applicable procedures are reviewed, and updated as necessary, based on the following conditions:

- Following any modification to a system
- Following an unusual incident, such as an accident, significant operator error, or equipment malfunction
- When procedure discrepancies are found
- Prior to use if not used in the previous two years
- Results of QA audits conducted in accordance with Part II, Section 18.1 (This section does not apply to non-operations activities.)

Prior to issuance or use, documents including revisions thereto, are approved by the designated authority. A listing of all controlled documents identifying the current approved revision, or date, is maintained so personnel can readily determine the appropriate document for use.

6.2. Changes to Documents

Changes to documents, other than those defined in implementing procedures as minor changes, are reviewed, and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization has access to pertinent background data or information upon which to base their approval.

Where temporary procedure changes are necessary during the operational phase, changes that clearly do not change the intent of the approved procedure may be implemented provided they are approved by two members of the staff knowledgeable in the areas affected by the procedures. (This requirement does not apply to non-operations activities.) Minor changes to documents, such as inconsequential editorial corrections, do not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a classification shall be clearly delineated in implementing procedures.

6.3. NQA-1 Commitment

In establishing provisions for document control, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 6.

SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

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.

7.1. Acceptance of Item or Service

TVA New Nuclear establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through contractors, 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. Verifications occur at the appropriate phases of the procurement process, including, as necessary, verification of activities of suppliers below the first tier.

Measures to assure the quality of purchased items and services include the following, as applicable:

- Items are inspected, identified, and stored to protect against damage, deterioration, or misuse.
- Prospective safety-related items and service suppliers are evaluated to assure only qualified suppliers are used. Qualified suppliers are audited on a triennial basis. In addition, if a subsequent contract or a contract modification significantly changes the scope, methods, or controls performed by a supplier, an audit of the changes is performed, thus starting a new triennial period.
- TVA New Nuclear may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet TVA New Nuclear requirements. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. Industry programs, such as those applied by ASME, Nuclear Procurement Issues Corporation (NUPIC) during construction or operation phases, or other established utility groups, are used as input or the basis for supplier qualification whenever appropriate. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.
- Provisions are made for accepting purchased items and services, such as source verification, receipt inspection, pre- and post-installation tests, certificates of conformance, and document reviews (including Certified Material Test Report/Certificate). Acceptance actions/documents should be established by the Purchaser with appropriate input from the Supplier and be completed to ensure that

procurement, inspection, and test requirements, as applicable, have been satisfied before relying on the item to perform its intended safety function.

- Controls are imposed for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt, and acceptance of commercial-grade services or items to assure they will perform satisfactorily in service in safety-related applications.
- If there is insufficient evidence of implementation of a QA program, the initial evaluation is of the existence of a QA program addressing the scope of services to be provided. The initial audit is performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.

7.2. NQA-1 Commitment / Exceptions

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 Regulatory Guide 1.28, Revision 5 with the following clarifications and exceptions:

- TVA New Nuclear considers that other 10 CFR Parts 50 and 52 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, 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.
- 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), a commercial grade survey need not be performed provided each of the following conditions are met:

  - A documented review of the laboratory’s accreditation is performed and includes a verification of the following:

    1. The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC-17025: 2017, "General Requirements for the Competence of Testing and Calibration Laboratories."
    2. For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
    3. For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.
    4. The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected accrediting body within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.

- The purchase order documents require that:

  1. The laboratory must provide the service in accordance with their accredited ISO/IEC-17025:2017 program and scope of accreditation.
  2. Reporting as-found calibration data in the certificate of calibration when calibrated items are found to be out-of-tolerance (for calibration services only).
  3. Identifying in the certificate of calibration, the equipment/standards used to perform the calibration (for calibration services only).
  4. The testing or calibration service supplier shall not subcontract the service to any other supplier.
  5. Notifying the customer of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
  6. Performance of the services listed on the order is contingent on the laboratory's accreditation having been achieved through an on-site accreditation assessment by the accrediting body within the past 48 months.
  7. Additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

- It is validated, at receipt inspection, that the laboratory's documentation certifies that:

  1. The contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2017 program, and has been performed within their scope of accreditation, and
  2. The purchase order's requirements are met.

The ILAC accreditation process cannot be used for commercial grade dedication of Nondestructive Examination (NDE) services in lieu of performing a Commercial Grade Survey.

- For Section 200, during periods of exigent conditions, TVA New Nuclear may conduct remote audits/surveys 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.

- For Section 501, 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 NQA-1 requirement for documents to be available at the site. Following completion of the construction period, sufficient as-built documentation will be turned over to TVA New Nuclear to support operations. The TVA New Nuclear records management system will provide for timely retrieval of necessary records.
- 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 following clarification:

  - For commercial grade items, quality verification requirements are established and described in TVA New Nuclear documents to provide the necessary assurance an item will perform satisfactorily in service. The TVA New Nuclear documents address determining the critical characteristics that ensure an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.
  - TVA New Nuclear will assume 10 CFR 21 reporting responsibility for all items that TVA New Nuclear dedicates as safety-related.

SECTION 8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

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 to affect the function or quality of the item.

8.1. NQA-1 Commitment

In establishing provisions for identification and control of items, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 8.

SECTION 9 CONTROL OF SPECIAL PROCESSES

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 qualification requirements. Personnel are qualified and special processes are performed in accordance with applicable codes, standards, specifications, criteria, or other specially established requirements. Records are maintained as appropriate for the currently qualified personnel, processes, and equipment for each special process. Special processes are those where the results are highly dependent on the control of the process or the skill of the operator, or both, and for which the specified quality cannot be fully and readily determined by inspection or test of the final product.

9.1. NQA-1 Commitment

In establishing measures for the control of special processes, TVA New Nuclear commits to NQA-1-2015 Requirement 9.

SECTION 10 INSPECTION

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 properly qualified persons independent of those who performed or directly supervised the work. Inspection results are documented.

10.1. Inspection Program

The inspection program establishes inspections (including surveillance of processes), as necessary to verify quality: (1) at the 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, and (4) upon receipt of items for a facility, as well as (5) during maintenance, modification, in-service, and operating activities.

The inspection program establishes requirements for planning inspections, such as the group or discipline responsible for performing the inspection, where inspection hold points are to be applied, determining applicable acceptance criteria, the frequency of inspection to be applied, and identification of special tools needed to perform the inspection. Inspection planning is performed by personnel qualified in the discipline related to the inspection and includes qualified inspectors or engineers. Inspection plans are based on, as a minimum, the importance of the item to the safety of the facility, the complexity of the item, technical requirements to be met, and design specifications. Where significant changes in inspection activities for the facilities are to occur, management responsible for the inspection programs evaluate the resource and planning requirements to ensure effective implementation of the inspection program.

Inspection program documents establish requirements for performing the planned inspections, and documenting required inspection information such as rejection, acceptance, and re-inspection results, and the person(s) performing the inspection.

Inspection records identify item inspected, date of inspection, the inspector’s identity, type of observation, inspection results and acceptability, and reference to information on action taken in connection with nonconformances. Inspection results are documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings.

10.2. Inspector Qualification

TVA New Nuclear has established qualification programs for personnel performing quality inspections. The qualification program requirements are described in Part II, Section 2. These qualification programs are applied to individuals performing quality inspections regardless of the functional group where they are assigned.

10.3. NQA-1 Commitment

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.

SECTION 11 TEST CONTROL

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 as a whole 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 Technical Specifications), to demonstrate that performance of plant systems is in accordance with design. Programs also include provisions to establish and adjust test schedules, and to maintain status for periodic or recurring tests. Tests are performed according to applicable procedures that include, consistent with the effect on safety: (1) instructions and prerequisites to perform the tests, (2) use of proper test equipment, (3) acceptance criteria, and (4) mandatory verification points as necessary to confirm satisfactory test completion. Test results are documented and evaluated by the organization performing the test and reviewed by a responsible authority to assure that the test requirements have been satisfied. If acceptance criteria are not met, re-testing is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure. 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 deviations noted, and the person evaluating test results.

The initial start-up test program is planned and scheduled to permit safe fuel loading and start-up; to increase power in safe increments; and to perform major testing at specified power levels. If tests require the variation of operating parameters outside of their normal range, the limits within which such variation is permitted will be prescribed. The scope of the testing demonstrates, insofar as practicable, that the plant is capable of withstanding the design transients and accidents. For new facility construction, the suitability of facility operating procedures is checked to the maximum extent possible during the pre-operational and initial start-up test programs.

Except for computer program testing, which is addressed in Part II, Section 11.1, tests are performed, and results documented in accordance with applicable technical and regulatory requirements, including those described in the Technical Specifications and SAR. Test programs ensure appropriate retention of test data in accordance with the records requirements of the QAPD. Personnel that perform or evaluate tests are qualified in accordance with the requirements established in Part II, Section 2.

11.1. NQA-1 Commitment for Computer Program Testing

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. To this end TVA New Nuclear commits to compliance with the requirements of NQA-1-2015 Requirement 11 Section 400 and Part II, Subpart 2.7 to establish the appropriate provisions in addition to the commitment to NQA-1-2015, Requirement 3.

11.2. NQA-1 Commitment

In establishing provisions for testing, TVA New Nuclear commits to compliance with NQA-1-2015 Requirement 11

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

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 gages, tools, reference and transfer standards, and nondestructive examination equipment. The suppliers of commercial-grade calibration services are controlled as described in Part II, Subsection 7.2.

12.1. Installed Instrument and Control Devices

For the operational phase of the facilities, TVA New Nuclear shall establish and implement procedures for the calibration and adjustment of instrument and control devices installed in the facility. The calibration and adjustment of these devices is accomplished through the facility maintenance programs to ensure the facility is operated within design and technical requirements. 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 no nationally recognized standards exist, the bases for calibration are documented. M&TE found out of calibration is tagged or segregated and not used until it is recalibrated. When M&TE is found out of calibration, an evaluation is made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested using the suspect M&TE. Any measuring or test equipment consistently found out of calibration is repaired or replaced. A calibration is performed when the accuracy of the equipment is suspect. Appropriate documentation will be maintained for these devices to indicate the control status, when the next calibration is due, and identify any limitations on use of the device. This paragraph does not apply to ESP activities.

12.2. NQA-1 Commitment

In establishing provisions for control of measuring and test equipment, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 12.

SECTION 13 HANDLING, STORAGE, AND SHIPPING

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 (such as containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels, and temperature levels) are provided when required to maintain acceptable quality.

Special or additional handling, storage, shipping, cleaning, and preservation requirements are identified and implemented as specified in procurement documents and applicable procedures. Where special requirements are specified, the items and containers (where used) are suitably marked.

Special handling tools and equipment are used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment are inspected and tested in accordance with procedures at specified time intervals or prior to use.

Operators of special handling and lifting equipment are experienced or trained in the use the equipment. During the operational phase, TVA New Nuclear establishes and implements controls over hoisting, rigging, and transport activities to the extent necessary to protect the integrity of the items involved, as well as potentially affected nearby structures and components. Where required, TVA New Nuclear complies with applicable hoisting, rigging and transportation regulations and codes.

13.1. Housekeeping

Housekeeping practices are established to account for conditions or environments that could affect the quality of structures, systems, and components within the plant. This includes control of 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. Housekeeping practices help assure that only proper materials, equipment, processes, and procedures are used, and that the quality of items is not degraded. Necessary procedures or work instructions, such as for electrical bus and control center cleaning, cleaning of control consoles, and radioactive decontamination are developed and used.

13.2. NQA-1 Commitment / Exceptions

In establishing provisions for handling, storage, and shipping, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 13. TVA New Nuclear also commits, during the construction and operational phase of the plant, 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:

NQA-1-2015, Part II, Subpart 2.1

Subpart 2.1, Section 301 and 302 establish criteria for classifying items into cleanness classes and requirements for each class. Instead of using the cleanness level system of Subpart 2.1, TVA New Nuclear may establish cleanness requirements on a case-by-case basis, consistent with the other provisions of Subpart 2.1. TVA New Nuclear establishes appropriate cleanliness controls for work on safety-related equipment to minimize introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities, including documented verification of absence of foreign material prior to system closure.

NQA-1-2015, Part II, Subpart 2.2

1. Subpart 2.2, Section 201 establishes criteria for classifying items into protection levels. Instead of classifying items into protection levels during the operational phase, TVA New Nuclear may establish controls for the 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. Prior to installation or use, the items are inspected and serviced as necessary to assure that no damage or deterioration exists which could affect their function.
2. Subpart 2.2, Section 606, "Storage Records:" This section requires written records be prepared containing information on personnel access. As an alternative to this requirement, TVA New Nuclear documents establish controls for storage areas that describe those authorized to access areas and the requirements for recording access of personnel. However, these records of access are not considered quality records and will be retained in accordance with the administrative controls of the applicable plant.

NQA-1-2015, Part II, Subpart 2.3

Subpart 2.3, Section 202 requires the establishment of five zone designations for housekeeping cleanliness controls. Instead of the five-level zone designation, 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. Factors considered in developing the procedures and instructions include cleanliness control, personnel safety, fire prevention and protection, radiation control, and security. The procedures and instructions make use of standard janitorial and work practices to the extent possible.

SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

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 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. These measures also establish the necessary authorities and controls for the application and removal of status indicators or labels.

In addition, temporary design changes (temporary modifications), such as temporary bypass lines, electrical jumpers, and lifted wires, and temporary trip-point settings, are controlled by procedures that include requirements for appropriate installation and removal, independent/concurrent verifications, and status tracking.

Administrative procedures also describe the measures taken to control altering the sequence of required tests, inspections, and other operations. Review and approval for these actions is subject to the same control as taken during the original review and approval of tests, inspections, and other operations.

14.1. NQA-1 Commitment

In establishing measures for control of inspection, test and operating status, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 14.

SECTION 15 CONTROL OF NONCONFORMING ITEMS

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, “Corrective Action”. Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. Controls are provided to address conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release. Item disposition, such as use-as-is, reject, repair, or rework shall be identified and documented. Conditional release of nonconforming items for installation requires the approval of the designated management. Nonconformances are corrected or resolved prior to depending on the item to perform its intended safety function. Nonconformances are evaluated for impact on operability of quality structures, systems, and components to assure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements dispositioned repair or use-as-is are subject to design control measures commensurate with those applied to the original design and the technical justification for acceptability of a nonconforming item, dispositioned 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, analysis of quality trends, and reports provided to the designated management. Significant trends are reported to management in accordance with TVA New Nuclear procedures, regulatory requirements, and industry standards.

15.1. Interface with the Reporting Program

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

15.2. NQA-1 Commitment

In establishing for nonconforming materials, parts, or components, TVA New Nuclear commits to compliance with NQA-1-2015 Requirement 15.

SECTION 16 CORRECTIVE ACTION

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. TVA New Nuclear procedures require personnel to identify known conditions adverse to quality. When complex issues arise where it cannot be readily determined if a condition adverse to quality exists, TVA New Nuclear documents establish the requirements for documentation and timely evaluation of the issue. 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.

16.1. Interface with the Reporting Program

TVA New Nuclear has appropriate interfaces with the corrective action program to satisfy the reporting requirements of 10 CFR 52 and 10 CFR 21 during design certification and standard design approval, 10 CFR 52, 10 CFR 50.55, and 10 CFR 21 during ESP/CP/COL design and construction, and 10 CFR 21 during operations.

16.2. NQA-1 Commitment

In establishing provisions for corrective action, TVA New Nuclear commits to compliance with NQA-1-2015, Requirement 16.

SECTION 17 QUALITY ASSURANCE RECORDS

TVA New Nuclear has 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 record retention program. The TVA New Nuclear records program provides provisions for the administration, receipt, storage, preservation, safekeeping, retrieval, and disposition of all records. All records must be retrievable, maintained in a readable format, and safeguarded against equipment malfunction or human error. Document access controls, user privileges, and other appropriate security controls must be established (ANSI/ANS 3.2).

17.1. Record Retention

Sufficient records shall be maintained to furnish evidence of activities affecting quality. 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 shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall meet the requirements of NQA-1-2015, Section 11.

Records shall be identifiable and retrievable. The records and retention times are based on Regulatory Position C.3.a.(1) for Lifetime Records and C.3.a.(2) for Non-permanent Records of Regulatory Guide 1.28, Revision 5 for design, construction, and initial start-up, and Regulatory Guide 1.33, Revision 3 for operational phase. Retention times for permanent and nonpermanent operational phase records are based on construction records that are similar in nature. In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met.

17.2. Electronic Records

When using optical disks for electronic records storage and retrieval systems, TVA New Nuclear complies with the NRC guidance in Generic Letter 88-18, “Plant Record Storage on Optical Disks.” TVA New Nuclear will manage the storage of QA Records in electronic media consistent with the intent of RIS 2000-18 and associated NIRMA Guidelines TG11-2011, TG15-2011, TG16-2011 and TG21-2011.

17.3. NQA-1 Commitment

In establishing provisions for records, TVA New Nuclear commits to compliance with NQA-1-2015 Requirement 17 as endorsed by Regulatory Guide 1.28, Revision 5, including Regulatory Positions C.3.a.(1) and C.3.a.(2).

SECTION 18 AUDITS

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. The audit programs themselves are reviewed for effectiveness as part of the overall audit process.

18.1. Performance of Audits

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. Functional areas of an organization's QA program for auditing include, at a minimum, verification of compliance and effectiveness of implementation of internal rules, procedures (e.g., operating, design, procurement, maintenance, modification, refueling, surveillance, test, security, radiation control procedures, and the emergency plan), Technical Specifications, regulations and license conditions, programs for training, retraining, qualification and performance of the operating staff, corrective actions, and observation of performance of operating, refueling, maintenance, and modification activities, including associated record keeping.

Audits shall be scheduled on a formal preplanned audit schedule and in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. Additional audits may be performed as deemed necessary by management. The scope of the audit is determined by the quality status and safety importance of the activities being performed. These audits are conducted by trained personnel not having direct responsibilities in the area being audited and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified lead auditor and the cognizance of the General Manager, New Nuclear Quality Assurance responsible for the day-to-day programs as documented in Part II, Section 1.

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 overall QAPD.

The results of each audit are reported in writing to the responsible Senior Executive responsible for the Quality Assurance program, or designee, as appropriate. Additional internal distribution is made to other concerned management levels and to management of internal audited organizations or activities in accordance with approved procedures. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

Management responds to all audit findings and initiates corrective action where indicated. Where corrective action measures are indicated, documented follow-up of applicable areas through inspections, reviews, re-audits, or other appropriate means is conducted to verify implementation of assigned corrective action.

Audits of suppliers of safety-related components and/or services are conducted as described in Part II, Subsection 7.1.

18.2. Internal Audits

Internal audits of organization and facility activities, conducted prior to placing the facility in operation, should be 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, should be 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 evaluation should include a detailed performance analysis of the functional area based upon applicable internal and external source data and due consideration of the impact of any functional area changes in responsibility, resources, or management. However, the internal audit frequency interval should not exceed a maximum of four years. If an adverse trend is identified in the applicable functional area, the extension of the internal audit frequency interval should be rescinded, and an audit scheduled as soon as practicable.

During the operational phase, audits are performed at a frequency commensurate with the safety significance of the activities and in such a manner to assure audits of all applicable QA program elements are completed within a period of two years. These audits will include, as a minimum, activities in the following areas:

- The conformance of facility operation to provisions contained within the Technical Specifications and applicable license conditions including administrative controls.
- The performance, training, and qualifications of the facility staff.
- The performance of activities required by the QAPD to meet the criteria of 10 CFR 50, Appendix B, and 10 CFR 72 Subpart G.
- The Fire Protection Program and implementing procedures. A fire protection equipment and program implementation inspection and audit are conducted utilizing either a qualified off-site licensed fire protection engineer or an outside qualified fire protection consultant.
- Other activities and documents considered appropriate by the Senior Vice President, New Nuclear Projects.

Audits may also be used to meet the periodic review requirements of the code for the Security, Emergency Preparedness, and Radiological Protection programs within the provisions of the applicable code. This requirement does not apply to a non-operations activity.

Internal audits include verification of compliance and effectiveness of the administrative controls established for implementing the requirements of the QAPD; regulations and license provisions; provisions for training, retraining, qualification, and performance of personnel performing

activities covered by the QAPD; corrective actions taken following abnormal occurrences; and, observation of the performance of construction, fabrication, operating, refueling, maintenance, and modification activities including associated record keeping.

18.3. NQA-1 Commitment / Exceptions

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 Regulatory Guide 1.28, Revision 5 with the following clarifications and exceptions:

- Section 201, Internal Audits - TVA New Nuclear may apply an extension, not to exceed 25 percent of the audit interval as follows:

    1. Audits shall be performed at the intervals designated for each audit area. Schedules shall be based on the month in which the audit starts.

    2. No extensions are allowed for scheduled audits of Emergency Preparedness, Security, Cyber Security, or Access Authorization.

    3. When an audit interval extension greater than one month is used, the next audit for that particular audit area will be scheduled from the original anniversary month rather than from the month of the extended audit.

- Section 202, External Audits – 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 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 and TVA New Nuclear

    Continued use of TVA New Nuclear suppliers that have exceeded the maximum allowed audit or survey time due to extenuating circumstances is allowed if the following conditions are met:

    1. A documented evaluation must be performed to summarize why the audit or survey could not be performed prior to the end of the 90-day grace period and to provide the basis for maintaining the supplier as an approved supplier during the 25% (9-month) grace period. While implementing procedures must describe elements to be included in the documented evaluation, the following items should be considered as applicable:
        a. For 10 CFR 50, Appendix B suppliers, verification that the supplier’s quality assurance program is still committed to meeting the requirements of 10 CFR 50, Appendix B.

   b. For commercial suppliers who are approved based on commercial grade survey, verification the supplier has maintained adequate documented programmatic controls in place for the activities affecting the critical characteristics of the item/services being procured.
   c. Evaluation of any significant open issues with the NRC, 10 CFR Part 21 Notifications, and any open findings since the previous triennial audits describing impact on the items/services being procured from that supplier.
   d. Review of procurement history since last triennial audit/survey including receipt inspection results to identify any potential issues. The results of the performance history must be included in the evaluation.
   e. The degree of standardization of the items being procured. For instance, suppliers of catalog items which are used across multiple industry with widely accepted good performance histories would be considered good candidates for a 25% (9-month) grace period.
2. If concerns are identified based on the above evaluation, the following mitigating actions may be considered:
   a. Enhanced receiving inspections beyond visual inspections and quality checks.
   b. Identification of any additional requirements/restrictions to be placed on the supplier.
3. For audits/surveys performed during the 25% grace period, the audit/survey shall include a review of activities performed by the supplier since the 36-month audit/survey expiration date.
4. The allowance would only apply to existing suppliers on TVA New Nuclear Acceptable Supplier List.
5. The 25% grace period discussed above is applicable to domestic and international suppliers.
6. For audits/surveys performed during the 25% grace period, the audit/survey “clock” does not have to reset backwards to the original expiration date for which the audit/survey should have been performed. The end of the audit or survey would determine the date of the next triennial audit/survey.

PART III. NONSAFETY-RELATED STRUCTURES, SYSTEMS, AND COMPONENTS (SSC) QUALITY CONTROL

SECTION 1 NONSAFETY-RELATED WITH SPECIAL TREATMENT

Specific program controls are applied to nonsafety-related SSCs with special treatment, for which 10 CFR 50, Appendix B is not applicable, that are relied on to perform safety-significant functions. The specific program controls consistent with applicable sections of the QAPD are applied to those items in a selected manner, targeted at those characteristics or critical attributes with safety-significant functions.

The following clarify the applicability of the QA Program to the nonsafety-related SSCs with special treatment and related activities, including the identification of exceptions to the QA Program described in Part II, Sections 1 through 18 taken for nonsafety-related SSCs with special treatment.

1.1. Organization

The verification activities described in this part may be performed by the TVA New Nuclear line organization. The QA organization described in Part II is not required to perform these functions.

1.2. QA Program

TVA New Nuclear QA requirements for nonsafety-related SSCs are established in the QAPD and appropriate procedures. Suppliers of these SSCs or related services describe the quality controls applied in appropriate procedures. A new or separate QA program is not required.

1.3. Design Control

TVA New Nuclear has design control measures to ensure that the contractually established design requirements are included in the design. These measures ensure that applicable design inputs are included or correctly translated into the design documents, and deviations from those requirements are controlled. Design verification is provided through the normal supervisory review of the designer's work.

1.4. Procurement Document Control

Procurement documents for items and services obtained by or for TVA New Nuclear include or reference documents describing applicable design bases, design requirements, and other requirements necessary to ensure component performance. The procurement documents are controlled to address deviations from the specified requirements.

1.5. Instructions, Procedures, and Drawings

TVA New Nuclear provides documents such as, but not limited to, written instructions, plant procedures, drawings, vendor technical manuals, and special instructions in work orders, to direct the performance of activities affecting quality. The method of instruction employed

provides an appropriate degree of guidance to the personnel performing the activity to achieve acceptable functional performance of the SSC.

1.6. Document Control

TVA New Nuclear controls the issuance and change of documents that specify quality requirements or prescribe activities affecting quality to ensure that correct documents are used. These controls include review and approval of documents, identification of the appropriate revision for use, and measures to preclude the use of superseded or obsolete documents.

1.7. Control of Purchased Items and Services

TVA New Nuclear employs measures, such as inspection of items or documents upon receipt or acceptance testing, to ensure that all purchased items and services conform to appropriate procurement documents.

1.8. Identification and Control of Purchased Items

TVA New Nuclear employs measures where necessary, to identify purchased items and preserve their functional performance capability. Storage controls take into account appropriate environmental, maintenance, or shelf-life restrictions for the items.

1.9. Control of Special Processes

TVA New Nuclear employs process and procedure controls for special processes, including welding, heat treating, and nondestructive testing. These controls are based on applicable codes, standards, specifications, criteria, or other special requirements for the special process.

1.10. Inspection

TVA New Nuclear uses documented instructions to ensure necessary inspections are performed to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. These inspections may be performed by knowledgeable personnel in the line organization. Knowledgeable personnel are from the same discipline and have experience related to the work being inspected.

1.11. Test Control

TVA New Nuclear employs measures to identify required testing that demonstrates that equipment conforms to design requirements. These tests are performed in accordance with test instructions or procedures. The test results are recorded, and authorized individuals evaluate the results to ensure that test requirements are met.

1.12. Control of Measuring and Test Equipment

TVA New Nuclear employs measures to control M&TE use, and calibration and adjustment at specific intervals or prior to use.

1.13. Handling, Storage, and Shipping

TVA New Nuclear employs measures to control the handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration. These measures include appropriate marking or labels, and identification of any special storage or handling requirements.

1.14. Inspection, Test, and Operating Status

TVA New Nuclear employs measures to identify items that have satisfactorily passed required tests and inspections and to indicate the status of inspection, test, and operability as appropriate.

1.15. Control of Nonconforming Items

TVA New Nuclear employs measures to identify and control items that do not conform to specified requirements to prevent their inadvertent installation or use.

1.16. Corrective Action

TVA New Nuclear employs measures to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected.

1.17. Records

TVA New Nuclear employs measures to ensure records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, inspection, and test activities have been met.

1.18. Audits

TVA New Nuclear employs measures for line management to periodically review and document the adequacy of the process, including taking any necessary corrective action. Audits independent of line management are not required. Line management is responsible for determining whether reviews conducted by line management or audits conducted by any organization independent of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities. Where the measures of this part (Part III) are implemented by the same programs, processes, or procedures as the comparable activities of Part II, the audits performed under the provisions of Part II may be used to satisfy the review requirements of this Section (Part III, Section 1.18).

SECTION 2. NONSAFETY-RELATED STRUCTURES, SYSTEMS, AND COMPONENTS CREDITED FOR REGULATORY EVENTS

The following criteria apply to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), the station blackout (SBO) (10 CFR 50.63) SSCs that are not safety-related:

- TVA New Nuclear implements quality requirements for the fire protection system in accordance with Regulatory Guide 1.189, Fire Protection for Nuclear Power Plants, Revision 4.
- TVA New Nuclear implements the quality requirements for nonsafety-related, safety significant ATWS equipment in accordance with Part III, Section 1, based on an assessment of the reactor technology's requirement for such equipment.
- TVA New Nuclear implements quality requirements for nonsafety-related, safety significant SBO equipment in accordance with Part III, Section 1, based on an assessment of the reactor technology's requirement for such equipment.

PART IV. REGULATORY COMMITMENTS

NRC Regulatory Guides and Quality Assurance Standards

This section identifies the NRC Regulatory Guides (RG) and the other quality assurance standards which have been selected to supplement and support the QAPD. TVA New Nuclear identifies the extent of conformance with these RG and quality assurance standards as described below or within applicable license application documents submitted in accordance with 10 CFR 50 (e.g., LWA, CP, OL) and 10 CFR 52 (e.g., ESP, DC, COL, SDA), as applicable. Commitment to a particular RG or standard does not constitute a commitment to other RGs or standards that may be referenced therein.

Regulatory Guides

Regulatory Guide 1.8, Revision 4, June 2019, Qualification and Training of Personnel for Nuclear Power Plants

Regulatory Guide 1.8, Rev. 4, provides guidance that is acceptable to the NRC staff regarding qualifications and training for nuclear power plant personnel. TVA New Nuclear identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications (e.g., safety analysis reports).

Regulatory Guide 1.26, Revision 6, December 2021, Quality Group Classifications and Standards for Water, Steam, And Radioactive-Waste-Containing Components of Nuclear Power Plants

Regulatory Guide 1.26, Rev. 6, defines classification systems and components. TVA New Nuclear identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications (e.g., safety analysis reports).

Regulatory Guide 1.28, Revision 5, October 2017, Quality Assurance Program Criteria (Design and Construction)

Regulatory Guide 1.28, Rev. 5,describes a method acceptable to the NRC staff for complying with the provisions of 10 CFR 50 Appendix B with regard to establishing and implementing the requisite quality assurance program for the design and construction of nuclear power plants. TVA New Nuclear identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications (e.g., safety analysis reports).

Regulatory Guide 1.29, Revision 6, July 2021 - Seismic Design Classification

Regulatory Guide 1.29, Rev. 6, defines light water reactor systems required to withstand a safe shutdown earthquake (SSE). TVA New Nuclear identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications (e.g., safety analysis reports).

Regulatory Guide 1.33, Revision 3, June 2013, Quality Assurance Program Requirements (Operations)

Regulatory Guide 1.33, Rev. 3, describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to overall quality assurance program requirements for the operation phase of nuclear power plants. Revision 3 of the Regulatory Guide endorses ANSI/ANS 3.2 – 2012, Managerial, Administrative, and Quality Assurance Controls for the Operational Phase of Nuclear Power Plants. TVA New Nuclear will conform with Regulatory Guide 1.33, Rev. 3 and comply with the Staff Regulatory Guidance for meeting the conditions described on the use of ANSI/ANS 3.2 – 2012.

Regulatory Guide 1.54, Revision 3, April 2017**,** Service Level I, II, III, and In-Scope License Renewal Protective Coatings Applied to Nuclear Power Plants

Regulatory Guide 1.54, Rev. 3, provides guidance for the application of protective coatings within nuclear power plants to protect surfaces from corrosion, contamination from radionuclides and for wear protection. TVA New Nuclear identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications (e.g., safety analysis reports).

Regulatory Guide 1.164, Dedication of Commercial-Grade Items for Use in Nuclear Power Plant, Revision 0, June 2017

Regulatory Guide 1.164, Rev. 0, provides guidance for dedication of commercial-grade items and services used in nuclear power plants. This RG endorses, in part, the Electric Power Research Institute (EPRI) 3002002982, Revision 1 to EPRI NP-5652 and TR-102260, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications”, with respect to acceptance of commercial-grade dedication of items and services to be used as basic components for nuclear power plants. TVA New Nuclear identifies conformance and exceptions/clarifications for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications.

Regulatory Guide 1.189, Fire Protection for Nuclear Power Plants, Revision 4.

Regulatory Guide 1.189, Rev. 4, provides an approach that is acceptable to meet the regulatory requirements of Title 10 of the Code of Federal Regulations (10 CFR) section 50.48(a). The standards of record related to the design and installation of fire protection systems and features required to satisfy NRC requirements in all new reactor designs are those NFPA codes and standards in effect 180 days before the submittal of the application under 10 CFR Part 50 or 10 CFR Part 52. TVA New Nuclear identifies conformance with and exceptions/clarifications for the applicable regulatory position guidance in this regulatory guide in applicable license applications based on an assessment of the reactor technology’s requirements.

Regulatory Guide 1.231, Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants, Revision 0, January 2017

Regulatory Guide 1.231, Rev.0, provides guidance for the use of Revision 1 of EPRI Technical Report 1025243, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications”, with respect to acceptance of commercial-grade design and analysis computer programs associated with basic components for nuclear power plants. TVA New Nuclear identifies conformance and conditions for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications.

Regulatory Guide 1.234, Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21, Revision 0, April 2018.

Regulatory Guide 1.234, Rev 0 provides guidance on an acceptable method of evaluating and reporting defects under 10 CFR Part 21. This guidance will aid in minimizing compliance challenges to licensees and vendors that have been identified through inspection activities. This new guide endorses Nuclear Energy Institute (NEI) 14-09, “Guidelines for Implementations of 10 CFR Part 21 Reporting of Defects and Noncompliance,” Revision 1. TVA New Nuclear identifies conformance and clarifications for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications.

Standards

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

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.

Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs)

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

PART V. ADDITIONAL QUALITY ASSURANCE AND ADMINISTRATIVE CONTROLS FOR THE PLANT OPERATIONAL PHASE

TVA New Nuclear includes the requirements of Part V that follow when establishing the necessary measures and governing procedures for the operational phase of the plant. Implementation of the additional controls in this section shall apply 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 construction permit holders.

SECTION 1. DEFINITIONS

TVA New Nuclear uses the definitions of terms as provided in Section 400 of the Introduction of NQA-1-2015 in interpreting the requirements of NQA-1 and the other standards to which the QAPD commits. In addition, definitions are provided for the following terms not covered in NQA-1:

administrative controls: rules, orders, instructions, procedures, policies, practices, and designations of authority and responsibility

experiments: performance of plant operations carried out under controlled conditions in order to establish characteristics or values not previously known

independent review: review completed by personnel not having direct responsibility for the work function under review regardless of whether they operate as a part of an organizational unit or as individual staff members (see review)

nuclear power plant: any plant using a nuclear reactor to produce electric power, process steam, or provide space heating

on-site operating organization: on-site personnel concerned with the operation, maintenance, and certain technical services

operating activities: work functions associated with normal operation and maintenance of the plant, and technical services routinely assigned to the on-site operating organization

operational phase: that period of time during which the principal activity is associated with normal operation of the plant. This phase of plant life is considered to begin formally with commencement of initial fuel loading, and ends with plant decommissioning

review: a deliberately critical examination, including observation of plant operation, evaluation of assessment results, procedures, certain contemplated actions, and after-the-fact investigations of abnormal conditions

supervision: direction of personnel activities or monitoring of plant functions by an individual responsible and accountable for the activities they direct or monitor

surveillance testing: periodic testing to verify that safety related structures, systems, and components continue to function or are in a state of readiness to perform their functions

system: an integral part of nuclear power plant comprising components which may be operated or used as a separate entity to perform a specific function

SECTION 2. REVIEW OF ACTIVITIES AFFECTING SAFE PLANT OPERATION

2.1. Onsite Operating Organization Review

The TVA New Nuclear onsite organization employs reviews, both periodic and as situations demand, to evaluate plant operations and plan future activities. The important elements of the reviews are documented and subjects of potential concern for the independent review described below are brought to the attention of Operations Phase Management. 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 in keeping abreast of general plant conditions and to verify that day-to-day operations are conducted safely in accordance with the established administrative controls. The manager responsible for Operations Phase Management ensures the timely referral of the applicable matters discussed in the reviews to appropriate management and independent reviewers.

2.2. Independent Review

Activities occurring during the operational phase shall be independently reviewed on a periodic basis. The independent review program shall be functional prior to initial core loading. The independent review function performs the following:

- Reviews proposed changes to the facility as described in the safety analysis report (SAR). The Independent Review Committee (IRC) also verifies that changes do not adversely affect safety and if a technical specification change or NRC review is required.
- Reviews proposed tests and experiments not described in the SAR prior to implementation. Verifies the determination of whether changes to proposed tests and experiments not described in the SAR require a technical specification change or license amendment.
- Reviews proposed technical specification changes and license amendments relating to nuclear safety prior to NRC submittal and implementation, except in those cases where the change is identical to a previously approved change.
- Reviews violations, deviations, and events that are required to be reported to the NRC. This review includes the results of investigations and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.
- Reviews any matter related to nuclear safety that is requested by the Vice President, Site Project or Operations Phase Management or any Independent Review Committee member.
- Reviews corrective actions for significant conditions adverse to quality.
- Reviews internal audit reports.

- Reviews the adequacy of the internal audit program every 24 months.

Independent Review Committee

A formally established group functions as an Independent Review Committee (IRC). In discharging its review responsibilities, the IRC keeps safety considerations paramount when opposed to cost or schedule considerations. The IRC performs its functions in the following manner:

- An Independent Review Committee is assigned independent review responsibilities and reports to the Vice President, Site Project.
- The Independent Review Committee shall be composed of no less than 5 persons; no more than a minority of members are from the on-site operating organization.
  - For example, at least 3 of the 5 members must be from off-site if there are 5 members on the committee. A minimum of the chairman or alternative chairman and 2 members must be present for all meetings.
- During the period of initial operation, meetings are conducted no less frequently than once per calendar quarter. Afterwards meetings are conduced no less than twice a year.
- Results of the meeting are documented and recorded.
- Consultants and contractors are used for the review of complex problems beyond the expertise of the off-site/on site independent review committee.
- Persons on the Independent Review Committee are qualified as follows:

  Supervisor or Chairman of the Independent Review Committee

  - Education: Baccalaureate in engineering or related science
  - Minimum experience: Six (6) years combined managerial and technical support

  Independent Review Committee members

  - Education: Baccalaureate in engineering or related science for those personnel required to review problems in nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, non-destructive testing, instrumentation and control, radiological safety, mechanical engineering, or electrical engineering.
  - High school diploma for those independent review personnel required to review problems in administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment.
  - Minimum experience: Five (5) years' experience in their own area of responsibility (nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, non-destructive testing, instrumentation and control, radiological safety, mechanical engineering, and electrical engineering, administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment).

SECTION 3. OPERATIONAL PHASE PROCEDURES

The following is a description of the various types of procedures used by TVA New Nuclear to govern the design, operation, and maintenance of its nuclear generating plants. TVA New Nuclear follows the guidance of Regulatory Guide 1.33 in identifying the types of activities that should have procedures or instructions to control the activity. Each procedure shall be sufficiently detailed for a qualified individual to perform the required function without direct supervision but need not provide a complete description of the system or plant process.

3.1. Format and Content

Procedure format and content may vary from one location to the other; however, procedures include the following elements as appropriate to the purpose or task to be described.

Title/Status

Each procedure is given a title descriptive of the work or subject it addresses and includes a revision number and/or date and an approval status.

Purpose/Statement of Applicability/Scope

The purpose for which the procedure is intended is clearly stated (if not clear from the title). The systems, structures, components, processes, or conditions to which the procedure applies are also clearly described.

References

Applicable references, including reference to appropriate Technical Specifications, are required. References are included within the body of the procedure when the sequence of steps requires other tasks to be performed (according to the reference) prior to or concurrent with a particular step.

Prerequisites/Initial Conditions

Prerequisites/initial conditions identify independent actions or procedures that must be accomplished and plant conditions which must exist prior to performing the procedure; including prerequisites applicable to only a specific portion of a procedure.

Precautions

Precautions alert the user to those important measures to be used to protect equipment and personnel, including the public, or to avoid an abnormal or emergency situation during performance of the procedure. Cautionary notes applicable to specific steps are included in the main body of the procedure and are identified as such.

Limitations and actions

Limitations on the parameters being controlled and appropriate corrective measures to return the parameter to the normal control band are specified.

Main body

The main body of the procedure contains the step-by-step instructions in the degree of detail necessary for performing the required function or task.

Acceptance criteria

The acceptance criteria provide the quantitative or qualitative criteria against which the success or failure (as of a test-type activity) of the step or action would be judged.

Checklists

Complex procedures utilize checklists which may be included as part of the procedure or appended to it.

3.2. Procedure Types

Procedure types may vary from one location to the other based on scope of activities; however, procedures are developed in each of the following categories.

Administrative Control Procedures

These include administrative procedures, directives, policies, standards, and similar documents that control the programmatic aspects of facility activities. These administrative documents ensure that the requirements of regulatory and license commitments are implemented. Several levels of administrative controls are applied ranging from those affecting the entire Company to those prepared at the implementing group level. These documents establish responsibilities, interfaces, and standard methods (rules of practice) for implementing programs. In addition to the administrative controls described throughout this QAPD, instructions governing the following activities are provided:

Operating Orders/Procedures

Instructions of general and continuing applicability to the conduct of business to the plant staff are provided. Examples include, but are not limited to, job turnover and relief, designation of confines of control room, definition of duties of operators and others, transmittal of operating data to management, filing of charts, limitations on access to certain areas and equipment, shipping and receiving instructions. Provisions are made for periodic review and updating of these documents, where appropriate.

Special Orders

Management instructions, which have short-term applicability and require dissemination, are issued to encompass special operations, housekeeping, data taking, publications and their distribution, plotting process parameters, personnel actions, or other similar matters. Provisions are made for periodic review, updating, and cancellation of these documents, where appropriate.

Plant Security and Visitor Control

Procedures or instructions developed to supplement features and physical barriers designed to control access to the plant and, as appropriate, to vital areas within the plant. Information concerning specific design features and administrative provisions of the plant security program is confidential and thus accorded limited distribution. The security and visitor control procedures consider, for example, physical provisions, such as: fences and lighting; lock controls for doors, gates and compartments containing sensitive equipment; and provisions for traffic and access control. Administrative provisions, such as: visitor sign-in and sign-out procedures; escorts and badges for visitors; emphasis on inspection, observation and challenging of strangers by operating crews; and a program of pre-employment screening for potential employees are also considered.

Temporary Procedures

Temporary procedures may be used to direct operations during testing, refueling, maintenance, and modifications to provide guidance in unusual situations not within the scope of the normal procedures. These procedures ensure orderly and uniform operations for short periods when the plant, a system, or a component of a system is performing in a manner not covered by existing detailed procedures or has been modified or extended in such a manner that portions of existing procedures do not apply. Temporary Procedures include designation of the period of time during which they may be used and are subject to the procedure review process as applicable.

Engineering Procedures

These documents provide instructions for the preparation of engineering documents, engineering analysis, and implementation of engineering programs. This includes activities such as designs; calculations; fabrication, equipment, construction, and installation specifications; drawings; analysis and topical reports; and testing plans or procedures. They include appropriate references to industry codes and standards, design inputs, and technical requirements.

Configuration Management Procedures

These documents provide instructions for the responsibility and authority for functions that affect the configuration of the facility including activities such as operations, design, maintenance, construction, licensing, and procurement. TVA New Nuclear shall

establish and document a time or event when configuration management shall be established for the facility.

Installation Procedures

These documents provide instructions for the installation of components generally related to new construction and certain modification activities. They include appropriate reference to industry standards, installation specifications, design drawings, and supplier and technical manuals for the performance of activities. These documents include provisions, such as hold or witness points, for conducting and recording results of required inspections or tests. These documents may include applicable inspection and test instructions subject to the requirements for test and inspection procedures below.

System Procedures

These documents contain instructions for energizing, filling, venting, draining, starting up, shutting down, changing modes of operation, and other instructions appropriate for operations of systems related to the safety of the plant. Actions to correct off-normal conditions are invoked following an operator observation or an annunciator alarm indicating a condition which, if not corrected, could degenerate into a condition requiring action under an emergency procedure. Separate procedures may be developed for correcting off-normal conditions for those events where system complexity may lead to operator uncertainty. Appropriate procedures will also be developed for the fire protection program.

Start-up Procedures

These documents contain instructions for starting the reactor from cold or hot conditions and establishing power operation. This includes documented determination that prerequisites have been met, including confirmation that necessary instruments are operable and properly set; valves are properly aligned, necessary system procedures, tests and calibrations have been completed; and required approvals have been obtained.

Shutdown Procedures

These documents contain guidance for operations during controlled shutdown and following reactor trips, including instructions for establishing or maintaining hot shutdown/standby or cold shutdown conditions, as applicable. The major steps involved in shutting down the plant are specified, including instructions for such actions as monitoring and controlling reactivity, load reduction and cooldown rates, sequence for activating or deactivating equipment, requirements for prompt analysis for causes of reactor trips or abnormal conditions requiring unplanned controlled shutdowns, and provisions for decay heat removal.

Power Operation and Load Changing Procedures

These documents contain instructions for steady-state power operation and load changing. These types of documents include, as examples, provisions for use of control rods, chemical shim, coolant flow control, or any other system available for short-term or long-term control of reactivity, making deliberate load changes, responding to unanticipated load changes, and adjusting operating parameters.

Process Monitoring Procedures

These documents contain instructions for monitoring performance of plant systems to assure that core thermal margins and coolant quality are maintained in acceptable status at all times, that integrity of fission product barriers is maintained, and that engineered safety features and emergency equipment are in a state of readiness to keep the plant in a safe condition if needed. Maximum and minimum limits for process parameters are appropriately identified. Operating procedures address the appropriate nature and frequency of this monitoring.

Fuel Handling Procedures

These documents contain instructions for core alterations, accountability of fuel and partial or complete refueling operations that include, for example, continuous monitoring of neutron flux throughout core loading, periodic data recording, audible annunciation of abnormal flux increases, and evaluation of core neutron multiplication to verify safety of loading increments. Procedures are also provided for receipt and inspection of new fuel, and for fuel movements in the spent fuel storage areas. Fuel handling procedures include prerequisites to verify the status of systems required for fuel handling and movement; inspection of replacement fuel and control rods; designation of proper tools, proper conditions for spent fuel movement, proper conditions for fuel cask loading and movement; and status of interlocks, reactor trip circuits and mode switches. These procedures provide requirements for refueling, including proper sequencing, orientation and seating of fuel and components, rules for minimum operable instrumentation, actions for response to fuel damage, verification of shutdown margin, communications between the control room and fuel handling station, independent verification of fuel and component locations, criteria for stopping fuel movements, and documentation of final fuel and component serial numbers (or other unique identifiers) and locations.

Maintenance Procedures

These documents contain instructions in sufficient detail to permit maintenance work to be performed correctly and safely, and include provisions, such as hold or witness points, for conducting and recording results of required inspections or tests. These documents may include applicable inspection or test instructions subject to the requirements for test and inspection procedures below. Appropriate referencing to other procedures, standards, specifications, or supplier manuals is provided. When not provided through other documents, instructions for equipment removal and return to service, and applicable radiation protection measures (such as protective clothing and

radiation monitoring) will be included. Additional maintenance procedure requirements are addressed in NQA-1-2015, Subpart 2.18, Section 202, Procedures.

Radiation Control Procedures

These documents contain instructions for implementation of the radiation control program requirements necessary to meet regulatory commitments, including acquisition of data and use of equipment to perform necessary radiation surveys, measurements and evaluations for the assessment and control of radiation hazards. These procedures provide requirements for monitoring both external and internal exposures of employees, utilizing accepted techniques; routine radiation surveys of work areas; effluent and environmental monitoring in the vicinity of the plant; radiation monitoring of maintenance and special work activities, and for maintaining records demonstrating the adequacy of measures taken to control radiation exposures to employees and others.

Calibration and Test Procedures

These documents contain instructions for periodic calibration and testing of instrumentation and control systems, and for periodic calibration of measuring and test equipment used in activities affecting the quality of these systems. These documents provide for meeting surveillance requirements and for assuring measurement accuracy adequate to keep safety-related parameters within operational and safety limits.

Chemical and Radiochemical Control Procedures

These documents contain instructions for chemical and radiochemical control activities and include: the nature and frequency of sampling and analyses; instructions for maintaining coolant quality within prescribed limits; and limitations on concentrations of agents that could cause corrosive attack, foul heat transfer surfaces, or become sources of radiation hazards due to activation. These documents also provide for the control, treatment and management of radioactive wastes, and control of radioactive calibration sources.

Emergency Operating Procedures

These documents contain instructions for response to potential emergencies so that a trained operator will know in advance the expected course of events that will identify an emergency and the immediate actions that are taken in response. Format and content of emergency procedures are based on NUREG and Owner’s Group(s) guidance that identify potential emergency conditions and require such procedures to include, as appropriate, a title, symptoms to aid in identification of the nature of the emergency, automatic actions to be expected from protective systems, immediate operator actions for operation of controls or confirmation of automatic actions, and subsequent operator actions to return the reactor to a normal condition or provide for a safe extended shutdown period under abnormal or emergency conditions.

Emergency Plan Implementing Procedures

These documents contain instructions for activating the Emergency Response Organization and facilities, protective action levels, organizing emergency response actions, establishing necessary communications with local, state, and federal agencies, and for periodically testing the procedures, communications, and alarm systems to assure they function properly. Format and content of such procedures are such that requirements of each facility's NRC approved Emergency Plan are met.

Test and Inspection Procedures

These documents provide the necessary measures to assure quality is achieved and maintained for the nuclear facilities. The instructions for tests and inspections may be included within other procedures, such as installation and maintenance procedures, but will contain the objectives, acceptance criteria, prerequisites for performing the test or inspection, limiting conditions, and appropriate instructions for performing the test or inspection, as applicable. These procedures also specify any special equipment or calibrations required to conduct the test or inspection and provide for appropriate documentation and evaluation by responsible authority to assure test or inspection requirements have been satisfied. Where necessary, hold or witness points are identified within the procedures and require appropriate approval for the work to continue beyond the designated point. These procedures provide for recording the date, identification of those performing the test or inspection, as-found condition, corrective actions performed (if any), and as-left condition, as appropriate for the subject test or inspection.

SECTION 4. CONTROL OF SYSTEMS AND EQUIPMENT IN THE OPERATIONAL PHASE

Permission to release systems and equipment for maintenance or modification is controlled by designated operating personnel and documented measures, such as installation of tags or locks and releasing stored energy, are used to ensure personnel and equipment safety. When entry into a closed system is required, TVA New Nuclear has established control measures to prevent entry of extraneous material and to assure that foreign material is removed before the system is reclosed.

Administrative procedures require the designated operating personnel to verify that the system or equipment can be released and determine the length of time it may be out of service. In making this determination, attention is given to the potentially degraded degree of protection where one subsystem of a redundant safety system is not available for service. Conditions to be considered in preparing equipment for maintenance include, for example: shutdown margin; establishment of a path for decay heat removal; temperature and pressure of the system; valves between work and hazardous material; venting, draining, and flushing; entry into closed vessels; hazardous atmospheres; handling hazardous materials; and electrical hazards.

When systems or equipment are ready to be returned to service, designated operating personnel control placing the items in service and document its functional acceptability. Attention is given to restoration of normal conditions, such as removal of jumpers or signals

used in maintenance or testing, or actions such as returning valves, breakers or switches to proper start-up or operating positions from "test" or "manual" positions. Where necessary, the equipment placed into service receives additional surveillance during the run-in period.

Independent verifications, where appropriate, are used to ensure that the necessary measures have been implemented correctly. The minimum requirements and standards for using independent verification are established in company documents.

SECTION 5. PLANT MAINTENANCE

TVA New Nuclear establishes controls for the maintenance or modification of items and equipment subject to this QAPD to ensure quality at least equivalent to that specified in original design bases and requirements, such that safety-related structures, systems, and components are maintained in a manner that assures their ability to perform their intended safety function(s). Maintenance activities (both corrective and preventive) are scheduled and planned so as not to unnecessarily compromise the safety of the plant.

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 shall be interpreted to mean the applicable standards and requirements established within the QAPD.
- Section 203 requires cleanliness during maintenance to be in accordance with Subpart 2.1. The commitment to Subpart 2.1 is described in the QAPD, Part II, Section 13.2.