

CHAPTER 17 TABLE OF CONTENTS

<u>Section</u>	<u>Title</u>	<u>Page</u>
CHAPTER 17	QUALITY ASSURANCE	17.5-1
17.5	Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants	17.5-1
17.5.1	Introduction	17.5-1
17.5.2	Summary	17.5-1
17.5.3	Regulatory Basis	17.5-1
17.5.4	Evaluation	17.5-2
17.5.4.1	Organization	17.5-2
17.5.4.2	Quality Assurance Program	17.5-2
17.5.4.3	Design Control and Verification	17.5-2
17.5.4.4	Procurement Document Control	17.5-3
17.5.4.5	Instructions, Procedures and Drawings	17.5-3
17.5.4.6	Document Control	17.5-3
17.5.4.7	Control of Purchased Material, Equipment, and Services	17.5-3
17.5.4.8	Identification and Control of Materials, Parts, and Components	17.5-3
17.5.4.9	Control of Special Processes	17.5-3
17.5.4.10	Inspection	17.5-4
17.5.4.11	Test Control	17.5-4
17.5.4.12	Control of Measuring and Test Equipment	17.5-4
17.5.4.13	Handling, Storage, and Shipping	17.5-4
17.5.4.14	Inspection, Test, and Operating Status	17.5-4
17.5.4.15	Nonconforming Materials, Parts, or Components	17.5-4
17.5.4.16	Corrective Action	17.5-4
17.5.4.17	Quality Assurance Records	17.5-5
17.5.4.18	Quality Assurance Audits	17.5-5
17.5.4.19	Nonsafety-Related SSC Quality Controls	17.5-5
17.5.4.20	Quality Assurance Program Commitments	17.5-5

CHAPTER 17 QUALITY ASSURANCE

17.5 QUALITY ASSURANCE PROGRAM DESCRIPTION – DESIGN CERTIFICATION, EARLY SITE PERMIT AND NEW LICENSE APPLICANTS

17.5.1 Introduction

The Quality Assurance Program implemented during the development of this Early Site Permit Application (ESPA) for safety-related activities is described in the TVA “Nuclear Quality Assurance Plan (Quality Assurance Program Description),” TVA-NQA-PLN89-A (NQAP). The NQAP and associated procedures provide for control of TVA activities that have the potential to affect the quality of safety-related structures, systems, and components (SSC) of the proposed small modular reactors. The NQAP is a separately controlled document and is included in Part 8 of the ESPA.

17.5.2 Summary

This section identifies the NQAP implemented during the development of the ESPA.

The NQAP is a top-level policy document that defines the quality policy and assigns major functional responsibilities. The NQAP applies to TVA personnel, organizations, or contractors performing activities within the scope of the NQAP that could affect the quality of safety-related structures, systems, and components at TVA's nuclear plants. It applies to design, construction, testing, operation, maintenance, repair, replacement, and modification of TVA nuclear facilities, including the site-related activities associated with the preparation of the ESPA. It is the same NRC-approved quality program that governs TVA's operating reactors and that was used in recent TVA-related licensing actions at the Watts Bar Nuclear Plant Unit 2.

The NQAP applies to site suitability quality assurance (QA) activities associated with the ESPA, including designing, procuring, handling, testing, siting, inspecting, storing, training, and shipping. The NQAP is based on the applicable portions of Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities,” Regulatory Guide 1.28, Revision 3, (ANSI N45.2-1971, “Quality Assurance Program Requirements for Nuclear Power Plants”), and Regulatory Guide 1.33, Revision 2, (ANSI 18.7-1976/ANS-3.2, “Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants”).

17.5.3 Regulatory Basis

10 CFR 50, “Domestic Licensing of Production and Utilization Facilities,” Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” establishes the NRC QA requirements for the design, fabrication, construction, and testing of the facility SSC. These requirements apply to all activities affecting the safety-related functions of those SSC. This includes, but is not limited to, designing, procuring, handling, testing, siting, inspecting, storing, training, and shipping. The technical information requirements for ESP applications are in 10 CFR 52.17, “Contents of Applications; Technical Information.” 10 CFR 52.17(a)(1)(xi) requires that ESP applications provide a description of the QA program applied to site-related activities for the future design, fabrication, construction, and testing of the SSC of a facility or facilities that may be constructed on the site.

17.5.4 Evaluation

10 CFR 52.17(a)(1)(xii) requires an evaluation of the site against applicable sections of the Standard Review Plan (SRP) revision in effect six months before the docket date of the application. SRP (NUREG-0800), Chapter 17, "Quality Assurance," Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," Revision 1, is based on 10 CFR Part 50, Appendix B, and reflects alignment with the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-2008 and the NQA-1a-2009 Addenda, "Quality Assurance Program Requirements for Nuclear Facility Applications," which the NRC staff found acceptable for meeting the requirement of Appendix B.

TVA's NQAP is based on 10 CFR 50, Appendix B, and reflects alignment with an earlier set of standards considered by the NRC to be acceptable methods for complying with the provisions of 10 CFR 50, Appendix B. The TVA NQAP is approved by the NRC to govern operations at multiple TVA operating nuclear plants, as well as to support license submittal for, and NRC issuance of, a new operating license at the Watts Bar Nuclear Plant Unit 2. Activities conducted by TVA under the NQAP are of a manner consistent with those associated with site-related activities performed in support of the Clinch River Nuclear (CRN) Site ESPA. Accordingly, TVA judges that the existing, NRC-approved NQAP is sufficient for use in support of the ESPA. To demonstrate this conclusion, the NQAP has been compared against specific provisions of SRP Section 17.5, with the results provided below.

17.5.4.1 Organization

The NQAP follows the guidance of SRP Section 17.5, Paragraph II.A for ESP applicant QA programs, and provides an organizational description that includes an organizational structure, functional responsibilities, levels of authority, and interfaces to establish, execute, and verify NQAP implementation. In addition, the NQAP allows management to size the QA organization according to the duties and responsibilities assigned.

17.5.4.2 Quality Assurance Program

The NQAP follows the guidance of SRP Section 17.5, Paragraph II.B, in describing all aspects of work that are important to safety. The NQAP comprises those planned and systematic actions necessary to provide confidence that SSC will perform their intended safety function, as described in the Site Safety Analysis Report. The NQAP provides measures to assess its adequacy and to ensure effective implementation in accordance with NRC Regulations for design and construction phase units. The NQAP also follows the guidance of SRP Section 17.5, Paragraphs II.S and II.T, in establishing and maintaining training programs for personnel who perform, verify, or maintain activities within the scope of the NQAP. The NQAP provides the minimum training requirements for managers responsible for its implementation.

17.5.4.3 Design Control and Verification

The NQAP follows the guidance of SRP Section 17.5, Paragraph II.C, for controlling the design of SSC that are subject to the provisions of the NQAP, including design changes. The NQAP design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces with TVA and its suppliers. These provisions ensure that the design inputs (e.g., design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (e.g., analyses, specifications, drawings, procedures, and instructions).

17.5.4.4 Procurement Document Control

The NQAP follows the guidance of SRP Section 17.5, Paragraph II.D for ensuring that procurement documents include or reference applicable regulatory, technical, and QA program requirements. These requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21, "Reporting of Defects and Noncompliance") are invoked for procurement of items and services.

17.5.4.5 Instructions, Procedures and Drawings

The NQAP follows the guidance of SRP Section 17.5, Paragraph II.E, to establish the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, and drawings.

17.5.4.6 Document Control

The NQAP follows the guidance of SRP Section 17.5, Paragraph II.F, to control the preparation, review, approval, issuance, and changes of documents that specify quality requirements or prescribe measures for controlling activities that affect quality, including organizational interfaces. The NQAP provides measures to ensure that the same organization that performed the original review and approval also reviews and approves changes, unless other organizations are specifically designated. A listing of all controlled documents that identify the current approved revision or date is maintained so personnel can readily determine the appropriate document for use.

17.5.4.7 Control of Purchased Material, Equipment, and Services

The NQAP follows the guidance of SRP Section 17.5, Paragraph II.G, to control the procurement of items and services to comply with requirements. The program provides measures for evaluating prospective suppliers and selecting only those that are qualified. In addition, the program provides guidelines for auditing and evaluating suppliers to ensure that qualified suppliers continue to provide acceptable products and services. The program provides for acceptance actions (e.g., source verification, receipt inspection, pre- and post-installation tests) and review of documentation (e.g., conformance certificates) to ensure that the procurement, inspection, and test requirements have been satisfied before relying on the item to perform its intended safety function. The program provides for the procurement of domestic calibration services from laboratories accredited by National Voluntary Laboratory Accreditation Program or American Association for Laboratory Accreditation in lieu of performing a commercial grade survey as part of the commercial grade dedication process, subject to the conditions identified in SRP 17.5, Paragraph II.G.12.

17.5.4.8 Identification and Control of Materials, Parts, and Components

The NQAP follows the guidance of SRP Section 17.5, Paragraph II.H, for establishing the necessary measures for the identification and control of items such as materials, including consumables and items with limited shelf life, parts, components, and partially fabricated subassemblies. The identification of items is maintained throughout fabrication, erection, installation, and use so that the item can be traced to its documentation.

17.5.4.9 Control of Special Processes

The NQAP addresses this element, but the guidance in SRP Section 17.5, Paragraph II.I states that it is not applicable to ESP applicants. Control of Special Processes will be addressed in the combined license application (COLA).

17.5.4.10 Inspection

The NQAP follows the guidance of SRP Section 17.5, Paragraph II.J, to ensure that items, services, and activities that affect safety meet requirements and conform to specifications, instructions, procedures, and design documents. The inspection program establishes requirements for planning inspections, determining applicable acceptance criteria, setting the frequency of inspection, and identifying special tools needed to perform the inspection. Inspectors are properly qualified personnel who are independent of those who performed or directly supervised the work.

17.5.4.11 Test Control

The NQAP follows the guidance of SRP Section 17.5, Paragraph II.K, to demonstrate that items subject to the provisions of the NQAP will perform satisfactorily in service, that the plant can be operated safely as designed, and that the operation of the plant as a whole is satisfactory.

17.5.4.12 Control of Measuring and Test Equipment

The NQAP follows the guidance of SRP Section 17.5, Paragraph II.L, for controlling the calibration, maintenance, and use of measuring and test equipment used in activities affecting the quality of safety-related SSC.

17.5.4.13 Handling, Storage, and Shipping

The NQAP follows the guidance of SRP Section 17.5, Paragraph II.M, for controlling the handling, storage, packaging, shipping, cleaning, and preserving items to prevent inadvertent damage or loss and to minimize deterioration.

17.5.4.14 Inspection, Test, and Operating Status

The NQAP addresses this element, but the guidance in SRP Section 17.5, Paragraph II.N states that it is not applicable to ESP applicants. Inspection, Test, and Operating Status will be addressed in the COLA.

17.5.4.15 Nonconforming Materials, Parts, or Components

The NQAP follows the guidance of SRP Section 17.5, Paragraph II.O, to control items, including services that do not conform to specified requirements to prevent inadvertent installation or use. Instances of nonconformance are evaluated for their impact on operability of quality SSC to ensure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Results of evaluations of conditions adverse to quality are analyzed to identify quality trends. The results are then documented and reported to upper management.

In addition, the NQAP provides for establishing the necessary measures to implement a reporting program to identify, evaluate, and report defects and non-compliances in accordance with the requirements of 10 CFR 50.55(e) and/or 10 CFR Part 21, as applicable.

17.5.4.16 Corrective Action

The NQAP follows the guidance of SRP Section 17.5, Paragraph II.P, to promptly identify, control, document, classify, and correct conditions adverse to quality. The NQAP requires personnel to identify conditions adverse to quality and find trends. Significant conditions adverse to quality are documented and reported to responsible management. In the case of contractor

activities that could affect quality-related SSC, TVA may delegate specific responsibility for the corrective action program, but maintains responsibility for the program's effectiveness.

In addition, the NQAP provides for establishing the necessary measures to implement a program to identify, evaluate, and report defects and non-compliances in accordance with the requirements of 10 CFR 50.55(e) and/or 10 CFR Part 21, as applicable.

17.5.4.17 Quality Assurance Records

The NQAP follows SRP Section 17.5, Paragraph II.Q to ensure that records of items and activities affecting quality are generated, identified, retained, maintained, and retrievable.

17.5.4.18 Quality Assurance Audits

The NQAP follows the guidance of SRP Section 17.5, Paragraph II.R to audit activities covered by the NQAP. The NQAP provides for TVA to conduct periodic internal and external audits. Internal audits determine the adequacy and effectiveness of the TVA QA Program. Internal audits are performed with a frequency commensurate with safety significance. At a minimum, an audit of all QA program elements and functional areas applicable to the ESP project are conducted on an annual basis. External audits are performed on frequency to not exceed 36 months. External audits determine the adequacy and effectiveness of a supplier's or contractor's QA program. Audit results are documented and reviewed. Management responds to all audit findings and initiates corrective action. In addition, where corrective actions are indicated, documented follow-up of identified findings through inspections, review, re-audits, or other means is conducted to verify corrective action.

17.5.4.19 Nonsafety-Related SSC Quality Controls

The NQAP establishes QA program controls for nonsafety-related SSC that are significant contributors to plant safety, but the guidance for establishing such controls in SRP Section 17.5, Paragraph II.U is not applicable to ESP applicants. Nonsafety-related SSC quality controls will be addressed in the COLA.

17.5.4.20 Quality Assurance Program Commitments

17.5.4.20.1 Regulatory Commitments

To supplement and support the TVA QA Program, the NQAP follows the guidance of SRP Section 17.5, Paragraph II.V, to establish QA program commitments to specific NRC Regulatory Guides (RG) and Generic Letters (GL) as described below.

- RG 1.26, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," March 2007. This regulatory guide does not apply to ESP applications using a plant parameter envelope.
- RG 1.29, "Seismic Design Classification for Nuclear Power Plants," March 2007 is not applicable for the ESP. Seismic design interfaces will be addressed in the COLA, when a reactor technology has been selected.
- RG 1.37, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants," Revision 1: This RG does not apply to ESP site activities enveloped by the CRN Site ESPA.

- GL 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," and GL 91-05, "Licensee Commercial Grade-Dedication Programs." TVA commits to implementing the actions and policies required by NRC GL 89-02 and GL 91-05. Nuclear Power Group Procurement Engineering procedures for commercial grade dedication and receipt inspection activities are consistent with the GLs.

17.5.4.20.2 Quality Standards

To supplement and support the TVA QA Program, the NQAP follows the guidance of SRP Section 17.5, Paragraph II.V, to establish QA program commitments to specific quality standards as described below.

- In lieu of Subpart 2.2, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants," ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition identified in SRP 17.5, TVA commits to ANSI N45.2.2 1972, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plant," as endorsed by RG 1.38, Revision 2, and the exceptions in NQAP Appendix B, "Regulatory Guide Conformance Status." However, this criteria is not applicable for the ESP.
- In lieu of Subpart 2.4, "Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities," ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition identified in SRP 17.5, TVA commits to ANSI N45.2.4 1972, "Installation, Inspection, and Testing Requirements for Instrumentation and Electric Equipment During the Construction of Nuclear Power Generating Stations," as endorsed by RG 1.30, Revision 0, and the exceptions in the NQAP, Appendix B, "Regulatory Guide Conformance Status." However, this criteria is not applicable for the ESP.
- In lieu of Subpart 2.5, "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Power Plants," ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition identified in SRP 17.5, TVA commits to ANSI N45.2.5 1974, "Supplementary Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations During the Construction Phase of Nuclear Power Plants," as endorsed by RG 1.94, Revision 1, and the exceptions in the NQAP, Appendix B, "Regulatory Guide Conformance Status." However, this criteria is not applicable for the ESP.
- In lieu of Subpart 2.7, "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications," ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition identified in SRP 17.5, TVA commits to the Software Quality Assurance controls established in NQAP Section 13 and supporting Nuclear Power Group procedures. These controls establish measures for the development of application software and associated documentation including software requirements specifications, design specifications, coding conventions, user documentation and changes thereto. Controls are established to verify and validate the functionality and accuracy of software applications prior to use. The controls also establish measures to assure allowable usage is defined, tracked and users are appropriately trained. TVA commits to RG 1.152, "Criteria for Programmable Digital Computer System Software in Safety-Related Systems of Nuclear Power Plants," Revision 0, and RG 1.64, "Quality Assurance Requirements for the Design of Nuclear Power Plants," Revision 2, and the exceptions in the NQAP, Appendix B, "Regulatory Guide Conformance Status." However, these criteria are not applicable for the ESP.

- In lieu of Subpart 2.8, “Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems for Nuclear Power Plants,” ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition identified in SRP 17.5, TVA commits to ANSI N45.2.8-1975, “Supplementary Quality Assurance Requirements for Installation, Inspection and Testing of Mechanical Equipment and Systems for the Construction Phase of Nuclear Power Plants,” as endorsed by RG 1.116, Revision 0, and the exceptions described in the NQAP, Appendix B, “Regulatory Guide Conformance Status.” However, this criteria is not applicable for the ESP.
- In lieu of Subpart 2.14, “Quality Assurance Requirements for Commercial Grade Items and Services,” ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition identified in SRP 17.5, TVA commits to implementing the actions and policies required by NRC GLs 89-02 and 91-05. TVA controls established in the NQAP and Nuclear Power Group implementing procedures for commercial grade dedication activities are consistent with the GLs, including the guidance in EPRI 3002002982, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications: Revision 1 to EPRI NP-5652 and TR-102260,” and are equivalent to Subpart 2.14 of NQA-1-2008/2009a.
- In lieu of Subpart 2.15, “Quality Assurance Requirements for Hoisting, Rigging, and Transporting Items for Nuclear Power Plants,” ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition identified in SRP 17.5, TVA commits to ANSI N45.2.2-1972, “Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plant,” as endorsed by RG 1.38, Revision 2, and the exceptions described in the NQAP, Appendix B, “Regulatory Guide Conformance Status.”
- SRP 17.5 identifies Subpart 2.20, “Quality Assurance Requirements for Subsurface Investigations for Nuclear Power Plants,” ASME NQA-1-1994 Edition or ASME NQA-1-2008/2009a Edition as the acceptable quality standard for the performance of such activities. The TVA NQAP does not reflect commitment to Subpart 2.20. In lieu of an NQAP commitment to subpart 2.20, TVA commits to assuring that subsurface investigations and related data usage performed and compiled by TVA contractors and subcontractors are compliant with Subpart 2.20 of NQA-1-1994 or 2008/2009a editions.
- SRP 17.5 identifies various Nuclear Information and Records Management Association (NIRMA) documents (TG-11-998, 15-1998, 16-1998, and 21-1998) as acceptable quality standards for the establishment and controls of electronic records management and software controls. The TVA NQAP does not reflect commitment to the NIRMA documents. TVA commits to ANSI N45.2.9-1974, “Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants,” as endorsed by RG 1.88, Revision 2, and the exceptions described in the NQAP, Appendix B, “Regulatory Guide Conformance Status.” TVA commits to the implementation of existing electronic record and software controls established in the NQAP and supporting Nuclear Power Group procedures.