17.0 QUALITY ASSURANCE (RELATED TO RG 1.206, SECTION C.III.1, CHAPTER 17, C.I.17, "QUALITY ASSURANCE AND RELIABILITY ASSURANCE")

The quality assurance (QA) program for design, fabrication, construction, testing, and operation, design reliability program, and maintenance rule (MR) program are discussed in this chapter.

17.1 Quality Assurance During the Design and Construction Phases

17.1.1 Introduction

The QA program related to design and construction activities is discussed in this section. It addresses the QA program implemented during combined license (COL) application development through and until COL issuance. Construction activities at Bellefonte (BLN) are not planned before the COL is issued.

17.1.2 Summary of Application

Section 17.1 of the BLN COL Final Safety Analysis Report (FSAR) incorporates by reference Section 17.1 of the AP1000 Design Control Document (DCD), Revision 17. In addition, in BLN COL FSAR Section 17.1, the applicant provided the following, which is application specific.

AP1000 COL Information Items

- BLN COL 17.5-1

The applicant provided additional information in BLN COL 17.5-1 to address AP1000 COL Information Item 17.5-1. BLN COL 17.5-1 addresses the quality assurance program (QAP) for the design and construction phases up until COL issuance. Section 17.5 of the BLN COL FSAR addresses the QA program for the design and construction phases following COL issuance.

17.1.3 Regulatory Basis

The regulatory basis of the information incorporated by reference is addressed within the Nuclear Regulatory Commission (NRC) staff's Final Safety Evaluation Report (FSER) related to the AP1000 DCD, "Final Safety Evaluation Report Related to Certification of the AP1000 Standard Design," (NUREG-1793).

In addition, the relevant requirements of the Commission regulations for the resolution of BLN COL 17.5-1 is established in Appendix B to Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," as required by 10 CFR 52.79(a)(25).

17.1.4 Technical Evaluation

The NRC staff reviewed Section 17.1 of the BLN COL FSAR and checked the referenced DCD to ensure that the combination of the DCD and the information in the COL represent the

complete scope of information relating to this review topic.[1] The NRC staff's review confirmed that the information contained in the application and incorporated by reference addresses the required information relating to QA during design and construction phases. Section 17.1 of the AP1000 DCD is being reviewed by the staff under Docket Number 52-006. The NRC staff's technical evaluation of the information incorporated by reference related to QA during design and construction phases will be documented in the staff safety evaluation report (SER) on the design certification application for the AP1000.

The staff reviewed the information contained in the BLN COL FSAR:

AP1000 COL Information Item

- BLN COL 17.5-1

The NRC staff reviewed the partial resolution of BLN COL 17.5-1 related to QA during the design and construction phases until COL issuance included under Section 17.1 of the BLN COL FSAR. The remaining information for BLN COL 17.5-1 is included in Section 17.5 of the BLN COL FSAR.

The applicant replaced information in DCD Section 17.1 with new text to address the QA program requirements for design activities implemented from COL application development through COL issuance. The applicant included additional text to BLN COL FSAR Section 17.1 to address Tennessee Valley Authority's (TVA's) responsibility for establishing and executing the QA program requirements during the design phase until COL issuance of BLN Units 3 and 4. BLN COL FSAR Section 17.1 further states that TVA maintains oversight of its contractors under its existing Appendix B to 10 CFR Part 50 QA program (Reference 204 of BLN COL FSAR, Tennessee Valley Authority, Nuclear Quality Assurance Plan, TVA-NQA-PLN-89-A).

In request for additional information (RAI) 17.5-10, the NRC staff requested clarification on the expected NuStart and Westinghouse scope of work related to the BLN COL application (COLA) design activities from the time of docketing until the time the COL might be issued. In its letters dated June 11, 2008, and October 16, 2008, the applicant stated that site-specific characterization, except for Section 2.4.4 of the BLN COL FSAR, was performed for TVA under TVA QA Program oversight by NuStart and its subcontractors. In addition, the applicant proposed to remove the reference to Westinghouse in Section 17.1 of the BLN COL FSAR since Westinghouse activities related to the standard design are not subject to oversight of TVA until Phase 5 (Engineering, Procurement, and Construction). Phase 5 activities are not planned to begin until after the receipt of a COL. The NRC staff has reviewed the applicant's proposed revision to Section 17.1 of the BLN COL FSAR and has verified that the proposed revision was incorporated into Revision 1 of the BLN COL FSAR. RAI 17.5-10 is closed.

In RAI 17.5-11, the NRC staff requested clarification as to when the Quality Assurance Program Description (QAPD) discussed in Section 17.5 of the BLN COL FSAR will be implemented. In its letters, dated June 11, 2008, and June 26, 2008, the applicant revised BLN COL FSAR Section 17.1 to state:

> Implementation of the applicable portions of the "Quality Assurance Program Description" (QAPD) discussed in Section 17.5 begins at COL issuance. The

[1] See Section 1.2.2 for a discussion of the staff's review related to verification of the scope of information to be included within a COL application that references a design certification.

> program establishes the QA program requirements for the remaining portion of the design and construction phases and for operations; however, full implementation of the Operations related requirements will be no later than indicated in Table 13.4-201.

Based on the proposed revision to Section 17.1 of the BLN COL FSAR, the NRC staff determined that the implementation schedule for the QAPD is acceptable. The NRC staff has verified that the proposed revision was incorporated into Revision 1 of the BLN COL FSAR. RAI 17.5-11 is closed.

In RAI 17.1-12, dated May 12, 2008, the NRC staff requested that the applicant perform an evaluation of the existing TVA QA program (TVA-NQA-PLN-89-A) against the acceptance criteria in Section 17.1 of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," (SRP). In its letters, dated June 11, 2008, and October 16, 2008, the applicant stated that a comparison was performed between the acceptance criteria for Section 17.1 of NUREG-0800 and TVA-NQA-PLN89-A, which demonstrated that the TVA QA program conformed to Section 17.1 of NUREG-0800. The applicant also proposed to revise Table 1.9-202 of the BLN COL FSAR to address TVA-NQA-PLN89A conformance to Section 17.1 of NUREG-0800. The NRC staff has verified that the proposed revision was incorporated into Revision 1 of the BLN COL FSAR. RAI 17.1-12 is closed.

The NRC staff also reviewed Appendix 1AA of the BLN COL FSAR, which lists BLN's conformance with NRC Regulatory Guides (RGs) and provides any exceptions to conformance with those RGs. In its application, Appendix 1AA of the BLN COL FSAR only addressed conformance of the QAPD provided in Part 11 of the BLN COL application to the QA-related RGs. In RAI 17.5-16, dated May 12, 2008, the NRC staff requested that the applicant revise Appendix 1AA to include the conformance of the existing TVA QA program to the QA-related RGs. In its letters, dated June 24, 2008, and October 16, 2008, the applicant proposed to revise Section 17.1 of the BLN COL FSAR to state:

> The TVA Bellefonte Units 3 and 4 safety related design activities conducted under the program described in FSAR Section 17.1 are performed in conformance with Regulatory Guide 1.28, Revision 3. This is the only identified applicable quality assurance Regulatory Guide for the program in place prior to COL receipt.

Based on the applicant's commitment to RG 1.28, Revision 3, the NRC staff determined that the proposed revision to Section 17.1 of the BLN COL FSAR is acceptable. The NRC staff has verified that the proposed revision was incorporated into Revision 1 of the BLN COL FSAR. RAI 17.5-16 is closed.

In addition, the applicant proposed revisions to Appendix 1AA in its letter, dated August 19, 2008, in response to the NRC staff's RAI 1-5. In its response, the applicant proposed to change the exception statements to address the version of NQA-1 instead of addressing the QAPD included in Part 11 of the BLN COL application. The NRC staff has verified that the proposed revision was incorporated into Revision 1 of the BLN COL FSAR for those RGs with QA requirements. RAI 1-5 is closed for all RGs that contain exception statement referencing NQA-1 (i.e., RG 1.28, 1.30, 1.38, 1.39, 1.94, and 1.116 except for RG 1.33.

In RAI 01-11, dated December 16, 2008, the NRC staff requested that the applicant document the mechanism for incorporation of the requirements of RG 1.33 since these requirements are not covered by NQA-1. In its letter, dated January 27, 2009, the applicant stated that conformance with RG 1.33 will be supplemented in a future amendment to include a reference to Nuclear Energy Institute (NEI) 06-14A. The NRC staff has addressed this issue with NEI since NEI 06-14A does not commit to RG 1.33. This issue will remain open until closure is reached with NEI 06-14A or the applicant. This is identified as **Open Item 17.1-1**.

In February 2008, the NRC conducted a limited scope inspection at the TVA facility in Chattanooga, Tennessee, as documented in an inspection report dated March 19, 2008. The purpose of the NRC inspection was to verify that QA processes and procedures were effectively implemented with regard to the Simulated Open Channel Hydraulics (SOCH) model for the BLN COL application. The SOCH model was used to calculate the design basis flood presented in BLN COL FSAR Sections 2.4.3, Probable Maximum Flood on Streams and Rivers, and 2.4.4, Potential Dam Failures. In this inspection, the NRC inspectors identified three violations of NRC requirements related to design control, software verification and validation, and QA records for the SOCH model. TVA responded to the Notice of Violation (NOV) by its letter, dated April 18, 2008. TVA provided its actions to correct and prevent recurrence of the violations and committed to provide a date when final compliance was achieved. TVA subsequently revised its April 18, 2008, response by letter, dated June 30, 2008. In the June 30, 2008, letter, TVA revised the completion date of the corrective actions associated with the NOV. The NRC staff intends to conduct a follow-up inspection to verify compliance once TVA notifies the NRC that compliance has been achieved. This follow-up inspection is identified as **Open Item 17.1-2**.

NRC staff intends to conduct an inspection of TVA's implementation of its Appendix B to 10 CFR Part 50 QA program, as it relates to TVA's oversight of its contractors in the near future. This inspection will be documented in an inspection report and will be described in Section 17.1.4 of the NRC staff's FSER. This inspection is identified as **Open Item 17.1-3.**

17.1.5 Post Combined License Activities

There are no post-COL activities related to this section.

17.1.6 Conclusions

The NRC staff reviewed the application and checked the referenced DCD. The NRC staff's review confirmed that the applicant addressed the required information relating to QA during the design and construction phase, and there is no outstanding information expected to be addressed in the BLN COL FSAR related to this subsection.

Section 17.1 of Revision 17 of the AP1000 DCD is identical to Section 17.1, Revision 15 of the AP1000 DCD, which is incorporated by reference into 10 CFR Part 52, Appendix D. This subsection is not affected by the changes that Westinghouse proposed in Revision 17 to the AP1000 DCD. Pursuant to 10 CFR 52.63(a)(5) and 10 CFR Part 52, Appendix D, Section VI.B.1, all nuclear safety issues relating to QA during the design phase until COL issuance that were incorporated by reference have been resolved.

However, as a result of the open items, the staff is unable to finalize its conclusions on BLN COL 17.5-1 in accordance with Appendix B to 10 CFR Part 50 and 10 CFR 52.79(a)(25).

17.2 Quality Assurance During the Operations Phase

Section 17.2 of the BLN COL FSAR, Revision 1, incorporates by reference, with no departures or supplements, Section 17.2 of Revision 17 of the AP1000 DCD. The NRC staff reviewed the application and checked the referenced DCD to ensure that no issue relating to this section remained for review.[1] The NRC staff's review confirmed that there is no outstanding issue related to this subsection.

Section 17.2 of Revision 17 of the AP1000 DCD is identical to Section 17.2, Revision 15 of the AP1000 DCD, which is incorporated by reference into 10 CFR Part 52, Appendix D. This subsection is not affected by the changes that Westinghouse proposed in Revision 17 to the AP1000 DCD. Pursuant to 10 CFR 52.63(a)(5) and 10 CFR Part 52, Appendix D, Section VI.B.1, all nuclear safety issues relating to quality assurance during the operations phase that were incorporated by reference have been resolved.

17.3 Quality Assurance During Design, Procurement, Fabrication, Inspection, and/or Testing of Nuclear Power Plant Items (Related to RG 1.206, Section C.III.1, Chapter 17, C.I.17.3, "Quality Assurance Program Description")

Section 17.3 of the BLN COL FSAR incorporates by reference, with no departures or supplements, Section 17.3 of Revision 17 of the AP1000 DCD. The NRC staff reviewed the application and checked the referenced DCD to ensure that no issue relating to this section remained for review.[1] The NRC staff's review confirmed there is no outstanding issue related to this subsection.

The Westinghouse application to amend Appendix D of 10 CFR Part 52 includes changes to Section 17.3 of the AP1000 DCD, as stated in Revision 17 of the AP1000 DCD. The staff is reviewing this information on Docket Number 52-006. The results of the NRC staff's technical evaluation of the information related to QA during design, procurement, fabrication, inspection, and/or testing of nuclear power plant items incorporated by reference in the BLN COL FSAR, Revision 1, will be documented in NUREG-1793. The supplement to NUREG-1793 is not yet complete and this is being tracked as part of Open Item 1-1. The staff will update Section 17.3 of this SER to reflect the final disposition of the design certification (DC) application.

17.4 Design Reliability Assurance Program (Related to RG 1.206, Section C.III.1, Chapter 17, C.I.17.4, "Reliability Assurance Program Guidance")

17.4.1 Introduction

This reliability assurance program (RAP) provides reasonable assurance that a plant is designed, constructed, and operated in a manner that is consistent with the assumptions and risk insights related to systems, structures, and components that are identified as being significant contributors to plant safety as determined by using probabilistic, deterministic, or other methods of analysis. The information is obtained from sources such as the plant- and site-specific probabilistic risk assessment, industry operating experience, relevant component failure data bases, and expert panels.

The RAP is implemented in two stages. The first stage, the design reliability assurance program (D-RAP), comprises the reliability assurance activities that assure that the plant is consistent

with the certified design when fuel is loaded for the first time. The second stage applies to operational phase reliability assurance activities (OPRAAs) integrated into other programs.

17.4.2 Summary of Application

Section 17.4 of the BLN COL FSAR, Revision 1, incorporates by reference Section 17.4 of the AP1000 DCD, Revision 17.

17.4.3 Regulatory Basis

The regulatory basis of the information incorporated by reference is addressed within the NRC staff's FSER related to the DCD.

In addition, the relevant requirements of the Commission regulations for the D-RAP and the associated acceptance criteria are identified in Section 17.4 of NUREG-0800. The staff requirements memorandum (SRM) on SECY 95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-safety Systems in Passive Plant Designs" states that an application for advanced reactor design certification or a combined license must contain: (1) the description of the reliability assurance program used during the design that includes, scope, purpose, and objectives; (2) the process used to evaluate and prioritize the structures, systems, and components in the design, based on their degree of risk significance; (3) a list of the structures, systems, and components designated as risk significant: and (4) for those structures, systems, and components designated as risk significant: (i) a process to determine dominant failure modes that considered industry experience, analytical models, and applicable requirements; and (ii) key assumptions and risk insights from probabilistic, deterministic, or other methods that considered operations, maintenance, and monitoring activities.

Regulatory Guide 1.206 describes an acceptable way to satisfy these requirements.

17.4.4 Technical Evaluation

The NRC staff reviewed Section 17.4 of the BLN COL FSAR and the referenced DCD to ensure that the combination of the DCD and the information in the COL represent the complete scope of information relating to this review topic.[1] Section 17.4 of the AP1000 DCD is being reviewed by the staff under Docket Number 52-006. The NRC staff's technical evaluation of the information incorporated by reference related to the D-RAP will be documented in the staff's SER on the application to revise the AP1000 design certification.

No site-specific structures, systems, and components (SSCs) have been added to the D-RAP. The applicant asserts that the AP1000 DCD and PRA bound all site-specific hazards and associated risks. The staff's evaluation of the probabilistic methods used to reach this conclusion is documented in Chapter 19 of this safety evaluation. The staff concludes that the list of SSCs incorporated by reference to the DCD is an acceptable list for the BLN COL.

The staff noted that risk metrics may change with modifications to the plant design or other new information and requested additional information on how the applicant would address risk-significant SSCs that are identified after the COL is issued (RAI 17.4-1). In its response dated September 17, 2008, the applicant stated that such changes would be captured and included in the appropriate OPRAAs in accordance with procedures developed under the QA program. In addition, the response states that the MR program is to be consistent with NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for

Plants Licensed under 10 CFR Part 52," which has been endorsed by the staff in a letter to NEI, dated January 24, 2008.

The MR program description calls for establishment of an expert panel prior to fuel load. As additional information is developed, such a panel alters the scope of OPRAAs as appropriate. Because this provides assurance that changes will receive appropriate review, the staff finds it acceptable; therefore, RAI 17.4-1 is closed.

However, the staff requested that the applicant supplement the BLN COL FSAR to describe the organizational and process aspects of the RAP that will be performed by the COL holder (RAI 17.4-2). In its response dated April 9, 2009, the applicant proposed to revise the BLN COL FSAR Section 17.4 to include a standard supplement identifying the quality assurance requirements for non-safety-related SSCs within the scope of D-RAP. This is consistent with RG 1.206 and is therefore an acceptable method for meeting the Commission's policy for RAP. The staff identifies the need for a revision to the BLN COL FSAR as Confirmatory Item 17.4-1.

17.4.5 Post Combined License Activities

There are no post-COL activities related to this section.

17.4.6 Conclusion

The NRC staff reviewed the application and checked the referenced DCD. Until Confirmatory Item 17.4-1 is resolved, the staff cannot confirm that the applicant addressed the required information related to the D-RAP.

The Westinghouse application to amend Appendix D of 10 CFR Part 52 includes changes to Section 17.4 of the AP1000 DCD, as stated in Revision 17 of the AP1000 DCD. The staff is reviewing this information on Docket Number 52-006. The results of the NRC staff's technical evaluation of the information incorporated by reference in the BLN COL FSAR will be documented in a supplement to NUREG-1793. The supplement to NUREG-1793 is not yet complete, and this is being tracked as part of Open Item 1-1. The staff will update Section 17.4 of this SER to reflect the final disposition of the DC application.

As a result of the confirmatory item, the staff is unable to finalize its conclusions on D-RAP.

17.5 Quality Assurance Program Description – New License Applicants (Related to RG 1.206, Section C.III.1, Chapter 17, C.I.17.5, "Quality Assurance Program Guidance")

17.5.1 Introduction

The QA program during the design, fabrication, construction, testing, and operation phases of a nuclear power plant is discussed in this section. Implementation of the applicable portions of the QAPD referenced in Section 17.5 begins at COL issuance with full implementation of the operations-related requirements consistent with Table 13.4-201.

17.5.2 Summary of Application

The applicant provided in Part 11 of the BLN COL application a QAPD to be in place during the design, construction, and operations phases.

License Condition

- License Condition 6, regarding QA program implementation for operations

In BLN COL FSAR Section 17.5, the applicant provided the following:

AP1000 COL Information Items

- BLN COL 17.5-1

The applicant provided additional information in BLN COL 17.5-1 to address AP1000 COL Information Item 17.5-1. BLN COL 17.5-1 addresses the QA program for the design and construction phases following COL issuance.

- STD COL 17.5-2

The applicant provided additional information in STD COL 17.5-2 to address AP1000 COL Information Item 17.5-2. STD COL 17.5-2 addresses QA programs for procurement, fabrication, installation, construction, and testing of SSCs in the plant.

- STD COL 17.5-4

The applicant provided additional information in STD COL 17.5-4 to address AP1000 COL Information Item 17.5-4. STD COL 17.5-4 addresses the QA program for operations.

- STD COL 17.5-8

The applicant provided additional information in STD COL 17.5-8 to address AP1000 COL Information Item 17.5-8. STD COL 17.5-8 addresses operational reliability assurance program integration with the QA program.

17.5.3 Regulatory Basis

The relevant requirements of the Commission regulations for the QA program description, and the associated acceptance criteria, are given in Section 17.5 of NUREG-0800.

The applicable regulatory requirements for the QA program description are as follows:

Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” to 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” requires that the application contain a description of the QA program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility and establishes QA requirements for the design, construction, and operation of those SSCs. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of the SSCs, including

designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

10 CFR 52.79(a)(17) requires that the application contain information with respect to compliance with technically relevant positions of the Three Mile Island requirements of 10 CFR 50.34(f).

10 CFR 52.79(a)(25) requires that the description of the QA program include a discussion of how the applicable requirements of Appendix B have been and will be satisfied, and also include a discussion of how the QA program will be implemented.

Further, 10 CFR 52.79(a)(27) requires that the application contain information on the managerial and administrative controls to be used for a nuclear power plant and include a discussion of how the applicable requirements of Appendix B will be satisfied.

17.5.4 Technical Evaluation

The NRC staff reviewed Section 17.5 of the BLN COL FSAR and the QAPD provided in Part 11 of the BLN COL application. In RAI 17.5-9, dated May 12, 2008, the NRC staff requested that the applicant explain why the QAPD provided in Part 11 of the BLN COL application is not referenced or incorporated by reference in the BLN COL FSAR Section 17.5. In its letters, dated June 26, 2008, and October 16, 2008, the applicant proposed to revise Section 17.5 of the BLN COL FSAR to state that the QAPD is incorporated by reference. In addition, the applicant proposed to revise Section 17.5 of the BLN COL FSAR to provide the title of the QAPD that is incorporated by reference. The NRC staff has reviewed the proposed revisions to Section 17.5 and concluded that the proposed changes are responsive to RAI 17.5-9. The NRC staff has verified that the proposed revision was incorporated into Revision 1 of the BLN COL FSAR. RAI 17.5-9 is closed.

In addition, the NRC staff reviewed the resolution of COL information items BLN COL 17.5-1, STD COL 17.5-2, 17.5-4, and 17.5-8, which are addressed in the BLN QAPD. Information for BLN COL 17.5-1, related to QA that is implemented prior to COL issuance, is reviewed in Section 17.1 of this SER. The BLN QAPD is based on NEI 06-14A, "Quality Assurance Program Description," Revision 4, which was approved by the NRC staff using Section 17.5 of NUREG-0800. The NEI 06-14A template provided generic information and format for QAPDs with bracketed areas for applicants to provide plant-specific information. The generic information in NEI 06-14A provides the information required for STD COL 17.5-2, 17.5-4, and 17.5-8. In its review of TVA QAPD, the NRC staff used Section 17.5 of NUREG-0800 and RG 1.206 as guidance. The NRC staff developed Section 17.5 of NUREG-0800 using American Society of Mechanical Engineers (ASME) standard ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," as supplemented by additional regulatory and industry guidance for nuclear operating facilities.

During its review of the TVA QAPD, the NRC staff identified two issues in the introduction of BLN's QAPD that required further clarification. In RAI 17.5-1, dated May 12, 2008, the NRC staff requested that the applicant explain how Part I, Section 1 and Section 1.1 of the QAPD are consistent in describing the scope of the QAPD. In its response dated June 26, 2008, the applicant proposed to revise BLN QAPD Part I, Section 1 to state:

> The Tennessee Valley Authority (TVA) Quality Assurance Program Description (QAPD) is the top-level policy document that establishes the quality assurance

> policy and assigns major functional responsibilities for construction/pre-operation and operations activities conducted by or for TVA.

The applicant also revised TVA QAPD Part I, Section 1.1 to state:

> This QAPD applies only to Bellefonte Units 3 and 4 Combined Operating License (COL), construction/pre-operation and operations activities affecting the quality and performance of safety-related structures, systems, and components, including, but not limited to . . .

Based on the proposed revision to TVA QAPD Part I, Sections 1 and 1.1, the NRC staff determined that the proposed revisions are acceptable because the inconsistency was resolved. The NRC staff has verified that the proposed revisions were incorporated into Revision 1 of the BLN QAPD. RAI 17.5-1 is closed.

In RAI 17.5-2, the NRC staff requested that the applicant clarify how siting activities would be subject to the provisions of the QAPD as described in Part I, Section 1.1. Siting activities would be complete at the time of COL issuance. In its response dated June 26, 2008, the applicant proposed to revise TVA QAPD Part I, Section 1.1 to delete the reference to siting activities. Based on the proposed revision to TVA QAPD Part I, Section 1.1, the NRC staff determined that the proposed revision is acceptable. The NRC staff has verified that the proposed revision was incorporated into Revision 1 of the BLN QAPD. RAI 17.5-2 is closed.

17.5.4.1 Organization

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.A. The QAPD describes and defines the responsibility and authority for planning, establishing, and implementing an effective overall QA program. The QAPD provides a description of an organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying QAPD implementation. The QAPD establishes independence between the organization responsible for checking a function and the organization that performs the function. In addition, the QAPD allows TVA management to size the QA organization commensurate with the duties and responsibilities assigned.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 1 and Supplement 1S-1.

In RAI 17.5-3, dated May 12, 2008, the NRC staff requested in that the applicant provide a description of the managerial organization for operations. In its response dated June 26, 2008, the applicant proposed to revise TVA QAPD Part II, Section I in its entirety. The applicant also made corresponding changes to BLN COL FSAR Chapter 13 with the addition of a new BLN COL FSAR Section 13.1.1.3.1.6(a). Based on the proposed revisions to TVA QAPD Part II, Section 1, the NRC staff determined that the proposed revisions to the QAPD are acceptable. The NRC staff has verified that the proposed revision was incorporated into Revision 1 of the Bellefonte QAPD. RAI 17.5-3 is closed.

In RAI 17.5-4, the NRC staff requested that the applicant revise the TVA QAPD to include the organizational charts for construction/pre-operations and operations. In its response dated June 26, 2008, the applicant proposed to revise TVA QAPD Part II, Section I to include the two organizational charts in Appendix A of the TVA QAPD. Based on the proposed revisions to TVA QAPD Part II, Section 1, the NRC staff determined that the proposed revisions to the QAPD are

acceptable. The NRC staff has verified that the proposed revision was incorporated into Revision 1 of the BLN QAPD. RAI 17.5-4 is closed.

17.5.4.2 Quality Assurance Program

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.B. The QAPD establishes measures to implement a QA program to ensure that the design, construction, and operation of a nuclear power plant are in accordance with governing regulations and license requirements. The QA program comprises those planned and systematic actions necessary to provide confidence that SSCs will perform their intended safety function, including certain non-safety-related SSCs and activities that are significant contributors to plant safety, as described in the applicant's FSAR. The QA program requires that a list or system identifying SSCs and activities to which the QAPD applies be maintained.

The QAPD provides measures to assess the adequacy of the QAPD and to ensure its effective implementation at least once each year or at least once during the life of the activity, whichever is shorter. The program allows the period for assessing the QAPD during the operations phase to be extended to once every 2 years. In addition, consistent with Section 17.5 of NUREG-0800, paragraph II.B.8, the QAPD applies a grace period of 90 days to activities that must be performed on a periodic basis. The next due date for the performance of an activity that invokes the 90-day grace period remains unchanged. The next due date for an activity performed before the scheduled due date is moved backwards so that the interval prescribed for the performance of the activity is not exceeded.

The QAPD also follows the guidance of Section 17.5 of NUREG-0800, paragraphs II.S and II.T. The QAPD describes measures to establish and maintain formal indoctrination and training programs for personnel performing, verifying, or maintaining activities within the scope of the QAPD to ensure that they achieve and maintain suitable proficiency. The plant's technical specifications delineate the minimum qualifications for plant and support staff. Personnel are required to complete the training for positions identified in 10 CFR 50.120, "Training and Qualification of Nuclear Power Plant Personnel," according to programs accredited by the National Nuclear Accrediting Board of the National Academy for Nuclear Training. The QAPD also provides the minimum training requirements for managers responsible for QAPD implementation, in addition to the minimum training requirements for the individuals responsible for planning, implementing, and maintaining the QAPD.

The QAPD also follows Section 17.5 of NUREG-0800, paragraph II.W. The QAPD provides measures for establishing an independent review program for activities occurring during the operational phase. In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3, and 2S-4, with the following alternatives:

- NQA-1-1994, Supplement 2S-1, includes NQA-1-1994, Appendix 2A-1. The QAPD proposes the following alternatives to the implementation of Supplement 2S-1 and Appendix 2A-1:
  - NQA-1-1994, Supplement 2S-1, states that the organization designate those activities that require qualified inspectors and test personnel and establish written procedures for the qualification of these personnel. As an alternative to this requirement, the QAPD proposes that a qualified engineer may plan inspections, evaluate the capabilities of an inspector, or evaluate the training program for

inspectors. For the purposes of these functions, a qualified engineer is one who has a baccalaureate degree in engineering in a discipline related to the inspection or test activity (i.e., electrical, mechanical, or civil engineering) and has at least 5 years of engineering work experience, with at least 2 years of this experience regarding nuclear facilities. The NRC staff evaluated this proposed alternative and determined that the designation of a qualified engineer to plan inspections, evaluate inspectors, or evaluate the inspector qualification programs is consistent with the training and qualification criteria of 10 CFR Part 50, Appendix B, Criterion II, "Quality Assurance Program," and NQA-1-1994, Supplement 2S-1. Therefore, the NRC staff concluded that this alternative is acceptable.

- NQA-1-1994, Appendix 2A-1 provides guidance for qualifying inspection and test personnel as Level I, II, or III. As an alternative to this guidance, the QAPD proposes that personnel performing independent quality verification inspections, examinations, measurements, or tests will be required to possess qualifications equal to or better than those required for performing the task being verified. In addition, the verification performed must be within the skills of these personnel and addressed by procedures. These personnel will not be responsible for planning quality verification inspections or tests (i.e., establishing hold points and acceptance criteria in procedures, and determining responsibility for performing the inspection), evaluating inspection training programs, or certifying inspection personnel. The NRC staff evaluated this proposed alternative and determined that it is consistent with inspection and test personnel initial qualification requirements specified in Section 17.5 of NUREG-0800, paragraph II.T.5. Therefore, the NRC staff concluded that this alternative is acceptable.

- NQA-1-1994, Supplement 2S-2, states that nondestructive examination personnel must be qualified. As an alternative to this requirement, the QAPD proposes to follow the applicable standard cited in Sections III and XI of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code. 10 CFR 50.55a, "Codes and Standards," also requires the use of the latest Edition and Addenda of Sections III and XI of the ASME Code. The NRC staff evaluated this proposed alternative and determined that it is consistent with the regulation in 10 CFR 50, Appendix B, Criterion II, "Quality Assurance Program." Therefore, the NRC staff concluded that this alternative is acceptable.

- NQA-1-1994, Supplement 2S-3, states that the prospective lead auditors must have participated in a minimum of five audits in the previous 3 years. As an alternative to this requirement, the QAPD proposes to follow the guidance provided in Section 17.5 of NUREG-0800, paragraph II.S.4.c, which states that prospective lead auditors shall demonstrate their ability to properly conduct the audit process, as implemented by the company, to effectively lead an audit team, and to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification. The NRC staff evaluated this proposed alternative and determined that it is consistent with the regulation in 10 CFR Part 50, Appendix B, Criterion II. Therefore, the NRC staff concluded that this alternative is acceptable.

In RAI 17.5-5, dated May 12, 2008, the NRC staff requested that the applicant revise the TVA QAPD Part II, Section 2.5 to cite the correct regulation of 10 CFR 52.79(a)(27) versus 10 CFR 50.34(b)(6)(ii). In its response dated June 26, 2008, the applicant proposed to revise the TVA QAPD Part II, Section 2.5 consistent with the proposed wording in NEI Technical

Report 06-14A, "Quality Assurance Program Description," Revision 5, dated May 2008. Revision 5 of NEI 06-14A has not been approved by the NRC staff; therefore, this issue will remain open until Revision 5 of NEI 06-14A is approved and TVA has incorporated the approved changes into the TVA QAPD. This is identified as **Open Item 17.5-1**.

In RAI 17.5-6, the NRC staff requested that the applicant explain how the discussion of the Independent Review Committee responsibilities in Part II, Section 2.7 of the TVA QAPD is consistent with the requirements of American National Standards Institute (ANSI) N18.7. In its response dated June 26, 2008, the applicant proposed to revise the TVA QAPD Part II, Section 2.7 consistent with the proposed wording in NEI 06-14A, Revision 5. This issue will remain open until Revision 5 of NEI 06-14A is approved and TVA has incorporated the approved changes into the TVA QAPD. This is identified as **Open Item 17.5-2.**

17.5.4.3 Design Control

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.C. The QAPD establishes the necessary measures 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 QAPD design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces with the applicant and its suppliers. These provisions ensure that the design inputs (i.e., design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (i.e., analyses, specifications, drawings, procedures, and instructions). In addition, the QAPD provides for individuals knowledgeable in QA principles to review design documents to ensure that they contain the necessary QA requirements.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 3 and Supplement 3S-1, to establish the program for design control and verification, Subpart 2.20 for the subsurface investigation requirements, and Subpart 2.7 for the standards for computer software QA controls.

17.5.4.4 Procurement Document Control

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.D. The QAPD establishes the necessary administrative controls and processes to ensure that procurement documents include or reference applicable regulatory, technical, and QA program requirements. As noted in Section 17.5 of NUREG-0800, paragraph II.D.1, applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and the regulation in 10 CFR Part 21, "Reporting of Defects and Noncompliance") are invoked for procurement of items and services.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 4 and Supplement 4S-1, with the following alternatives and commitment:

- NQA-1-1994, Supplement 4S-1, Section 2.3, states that procurement documents must require suppliers to have a documented QA program that implements NQA-1-1994, Part I.
    - As an alternative to this requirement, the QAPD proposes that suppliers have a documented QA program that meets Appendix B to 10 CFR Part 50, as applicable to

the circumstances of the procurement. The NRC staff evaluated this proposed alternative and determined that it is consistent with Appendix B, Criterion IV, "Procurement Document Control." Therefore, the NRC staff concluded that this alternative is acceptable.

- As an alternative to this requirement, the QAPD proposes that procurement documents allow suppliers to work under TVA's QAPD, including implementing procedures, if suppliers do not have their own QA program. The NRC staff evaluated this proposed alternative and determined that TVA's QAPD follows the guidance in Section 17.5 of NUREG-0800, paragraph II.G, regarding "Control of Purchased Material, Equipment, and Services." Specifically, the QAPD provides measures to evaluate prospective suppliers so that only qualified suppliers are selected, acceptance actions are performed for procured products and services, and suppliers are periodically audited and evaluated to ensure that qualified suppliers continue to provide acceptable products and services. Therefore, the NRC staff concluded that this alternative is acceptable.

- NQA-1-1994, Supplement 4S-1, Section 3, states that procurement documents are to be reviewed before award of the contract. As an alternative to this requirement, the QAPD proposes to conduct the QA review of procurement documents through review of the applicable procurement specification, including the technical and quality procurement requirements, before contract award. In addition, procurement document changes (e.g., scope, technical, or quality requirements) will also receive QA review. The NRC staff evaluated this proposed alternative and determined that it provides adequate QA review of procurement documents before awarding the contract and after any change. Therefore, the NRC staff concluded that this alternative is acceptable.

- In the QAPD, TVA commits that procurement documents prepared for commercial-grade items, procured as safety-related items, shall contain technical and quality requirements such that the procured item can be appropriately dedicated. The NRC staff evaluated this proposed commitment and determined that it is consistent with NRC staff guidance in Generic Letter (GL) 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," dated March 21, 1989, and GL 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991, as delineated in Section 17.5 of NUREG-0800, paragraphs II.U.1.d and II.U.1.e. Therefore, the NRC staff concluded that this commitment is acceptable.

In RAI 17.5-7, dated May 12, 2008, the NRC staff requested that the applicant revise TVA QAPD Part II, Section 4 to substitute "TVA's" for "licensee's" to make it clear that a supplier may work under TVA's approved QA program. In its response dated June 26, 2008, the applicant stated that current use of "licensee's" is consistent with the wording in NEI 06-14A, Revision 4, which has been approved by the NRC staff. In a letter, dated September 17, 2008, the NRC staff requested NEI to address this question as part of a future revision to NEI 06-14A. This issue will remain open until Revision 5 of NEI 06-14A is approved and TVA has incorporated the approved changes into the TVA QAPD. This is identified as **Open Item 17.5-3.**

17.5.4.5 Instructions, Procedures, and Drawings

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.E. The QAPD establishes 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.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 5, to establish procedural controls.

17.5.4.6 Document Control

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.F. The QAPD establishes the necessary measures and governing procedures to control the preparation, review, approval, issuance, and changes of documents that specify quality requirements or prescribe measures for controlling activities affecting quality, including organizational interfaces. The QAPD provides measures to ensure that the same organization that performed the original review and approval also review and approve revisions or changes to documents, unless other organizations are specifically designated.

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. To ensure effective and accurate procedures during the operational phase, applicable procedures are reviewed and updated as necessary, consistent with NRC staff guidance provided in Section 17.5 of NUREG-0800, paragraph II.F.8.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 6 and Supplement 6S-1, to establish provisions for document control.

17.5.4.7 Control of Purchased Material, Equipment, and Services

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.G. The QAPD establishes the necessary measures and governing procedures to control the procurement of items and services to ensure conformance with specified requirements. The program provides measures to evaluate prospective suppliers so that only qualified suppliers are selected. In addition, the program requires that suppliers be periodically audited and evaluated to ensure that qualified suppliers continue to provide acceptable products and services.

The program provides for acceptance actions, such as source verification, receipt inspection, pre- and post-installation tests, and review of documentation, such as certificates of conformance, to ensure that procurement, inspection, and test requirements have been satisfied before relying on the item to perform its intended safety function. Purchased items (such as components, spares, and replacement parts necessary for plant operation, refueling, maintenance, and modifications) and services are subject to quality and technical requirements at least equivalent to those specified for original equipment or by properly reviewed and approved revisions to ensure that the items are suitable for the intended service and are of acceptable quality, consistent with their effect on safety.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 7 and Supplement 7S-1, to establish procurement verification control, with the following exceptions and alternatives:

- NQA-1-1994, Basic Requirement 7 and Supplement 7S-1, state that procurement sources and suppliers' performance are to be evaluated. As an exception to these requirements, the QAPD proposes that other 10 CFR Part 50 licensees (other than

TVA), authorized nuclear inspection agencies, the National Institute of Standards and Technology (NIST), and other State and Federal agencies that may provide items or services to TVA are not required to be evaluated or audited.

The NRC staff acknowledges that 10 CFR Part 50 licensees, authorized nuclear inspection agencies, the National Voluntary Laboratory Accreditation Program (NVLAP) administered by NIST, and other state and federal agencies perform work under quality programs acceptable to the NRC, and that no additional audits or evaluations are required. However, TVA remains responsible for ensuring that procured items or services conform to its Appendix B program, applicable ASME Boiler and Pressure Vessel Code requirements, and other regulatory requirements and commitments. TVA also remains responsible for ensuring that the items or services are suitable for the intended application and for documenting the evaluation that supports this conclusion. The proposed exception provides an appropriate level of quality and safety. The NRC staff determined that this exception is acceptable as documented in a previous SE.

- Section 17.5 of NUREG-0800, paragraph II.L.8, establishes provisions for the procurement of commercial-grade calibration services for safety-related applications. As an exception to these provisions, the QAPD proposes that procurement source evaluation and selection measures not be required, provided all of the following conditions are met:

  - Purchase documents impose additional technical and administrative requirements to satisfy any licensee-specific QAPD and technical requirements.

  - Purchase documents require reporting as-found calibration data when calibrated items are found to be out of tolerance.

  - A documented review of the supplier's accreditation will be performed and will include a verification of the following:

    - The calibration laboratory holds a domestic accreditation by any one of the following accrediting bodies, which are recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA):

      - National Voluntary Laboratory Accreditation Program (NVLAP), administered by the National Institute of Standards & Technology,

      - American Association for Laboratory Accreditation (A2LA).

    - The accreditation encompasses ANS/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."

    - The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, range, and uncertainties.

The NRC staff evaluated and found to be acceptable the NVLAP and A2LA accreditation programs. In RAI 17.5-13, dated May 12, 2008, the NRC staff requested that the applicant justify the wording discrepancy between TVA QAPD Part II, Section 7.2 and Section 17.5 of NUREG-0800, Section II.L.8.c, regarding the NRC approved alternative for commercial grade

calibration services. In its response dated June 24, 2008, the applicant stated that wording is consistent with the wording in NEI 06-14A, Revision 4, which has been approved by the NRC staff. In a letter, dated September 17, 2008, the NRC staff requested NEI to address this question as part of Revision 5 to NEI 06-14A. This issue will remain open until Revision 5 of NEI 06-14A is approved and TVA has incorporated the approved changes into the TVA QAPD. This is identified as **Open Item 17.5-4**.

- NQA-1-1994, Supplement 7S-1, Section 8.1, states that documentary evidence that items conform to procurement documents shall be available at the nuclear facility site prior to installation or use. As an alternative to the requirement for procurement documentary evidence to be available at the nuclear facility site during construction. The QAPD proposes that documentary evidence may be stored in physical form or in electronic media, under the control of TVA or its supplier(s), at a location(s) other than the nuclear facility site, as long as the documents can be accessed at the nuclear facility site during construction. After completion of construction, TVA will have sufficient documentary evidence to support operations. The NRC staff determined that implementation of this alternative would allow access to and review of the necessary procurement documentary evidence at the nuclear facility site, both before installation and use. Therefore, the NRC staff concluded that this alternative is acceptable.

- As an alternative to the requirements for the control of commercial-grade items and services in NQA-1-1994, Supplement 7S-1, Section 10, TVA commits in the QAPD to follow NRC guidance discussed in GL 89-02 and GL 91-05. In addition, TVA commits to establish and describe special quality verification requirements in applicable documents to assure that the commercially procured items will perform satisfactorily in service. In addition, the documents should provide for determining critical characteristics, technical evaluation, receipt requirements, and quality evaluation of the items to ensure that the items are suitable for their intended use. The NRC staff determined that this alternative will improve detection of counterfeit and fraudulently marked products and will improve the commercial-grade dedication programs. This alternative is consistent with the guidance of Section 17.5 of NUREG-0800, paragraphs II.U.1.d and II.U.1.e. Therefore, the NRC staff concluded that this alternative is acceptable.

- As an alternative to the requirements for the control of commercial-grade items and services in NQA-1-1994, Supplement 7S-1, Section 10, TVA commits to use other appropriate approved regulatory means and controls to support TVA commercial grade dedication activities. One example of this is NRC Regulatory Issue Summary (RIS) 2002-22, "Use of EPRI/NEI Joint Task Force Report, 'Guideline on Licensing Digital Upgrades: EPRI TR-102348, Revision 1, NEI 01-01: A Revision of EPRI TR-102348 to Reflect Changes to the 10 CFR 50.59 Rule.'" TVA will assume 10 CFR Part 21 reporting responsibility for all items that TVA dedicates as safety-related.

In RAI 17.5-14, the NRC staff requested that the applicant provide an explanation as to how RIS 2002-22 represents an example of other approved regulatory means for commercial grade dedication activities. In its response dated June 24, 2008, the applicant stated that wording is consistent with the wording in NEI 06-14A, Revision 4, which has been approved by the NRC staff. In a letter, dated September 17, 2008, the NRC staff requested NEI to address this question as part of Revision 5 to NEI 06-14A. This issue will remain open until Revision 5 of NEI 06-14A is approved and TVA has incorporated the approved changes into the TVA QAPD. This is identified as **Open Item 17.5-5**.

17.5.4.8 Identification and Control of Materials, Parts, and Components

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.H. The QAPD establishes 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, consistent with the item's effect on safety.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 8 and Supplement 8S-1, to establish provisions for identification and control of items.

17.5.4.9 Control of Special Processes

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.I. The QAPD establishes programs, procedures, and processes to ensure that special processes requiring interim process controls to ensure quality, such as welding, heat treating, chemical cleaning, and nondestructive examinations are implemented and controlled in accordance with applicable codes, specifications, and standards.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 9 and Supplement 9S-1, to establish measures for the control of special processes.

17.5.4.10 Inspection

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.J. The QAPD establishes the necessary measures to implement inspections that ensure items, services, and activities affecting safety meet established requirements and conform to applicable documented 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. Properly qualified personnel independent of those who performed or directly supervised the work are required to perform the inspections.

In the QAPD, TVA commits to comply with NQA-1-1994, Basic Requirement 10, Supplement 10S-1, and Subparts 2.4, 2.5, and 2.8, to establish inspection requirements, with the following commitment and alternative:

- NQA-1-1994, Subpart 2.4, requires the use of the Institute of Electrical and Electronic Engineers (IEEE) Standard 336-1985, "IEEE Standard Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities." IEEE Standard 336-1985 refers to IEEE 498-1985, "IEEE Standard Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities." Each of these standards uses the definition of safety systems equipment from IEEE Standard 603-1980, "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations." IEEE Standard 603-1980 defines "safety system" as:

Those systems (the reactor trip system, an engineered safety feature, or both, including all their auxiliary supporting features and other auxiliary feature) which provide a safety function. A safety system is comprised of more than one safety group of which any one safety group can provide the safety function.

The QAPD must commit to the definition of safety systems equipment from IEEE Standard 603-1980 to appropriately implement NQA-1-1994, Subpart 2.4. In the QAPD, TVA commits to the definition of safety systems equipment from IEEE Standard 603-1980, but does not commit to the balance of IEEE Standard 603-1980. This definition applies only to equipment in the context of Subpart 2.4. The NRC staff determined that the use of the definition of safety systems equipment is acceptable because it is consistent with the requirements of NQA-1-1994, Subpart 2.4.

- NQA-1-1994, Supplement 10S-1, Section 3.1, states that inspection personnel shall not report to the immediate supervisor who is responsible for performing the work being inspected. As an alternative to this requirement, the QAPD proposes that QA inspectors will report to quality control management while performing such inspections. The NRC staff determined that the use of this alternative is consistent with guidance provided in Section 17.5 of NUREG-0800, paragraph II.J.1. Therefore, the NRC staff concluded that this alternative is acceptable.

In RAI 17.5-8, dated May 12, 2008, the NRC staff noted that the third alternative in Part II, Section 10.1 of the TVA QAPD was bracketed and requested that the applicant explain whether TVA intends to implement the wording in brackets. In its response dated June 26, 2008, the applicant stated that the brackets were inadvertently left in the QAPD. The applicant proposed revising the TVA QAPD to remove the brackets. Based on the proposed revisions to TVA QAPD Part II, Section 10, the NRC staff determined that the proposed revisions to the QAPD are acceptable. The NRC staff has verified that the proposed revision was incorporated into Revision 1 of the BLN QAPD. RAI 17.5-8 is closed.

17.5.4.11 Test Control

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.K. The QAPD establishes the necessary measures and governing provisions to demonstrate that items subject to the provisions of the QAPD 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.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 11 and Supplement 11S-1, to establish provisions for testing.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Supplement 11S-2 and Subpart 2.7, to establish provisions to ensure that computer software used in applications affecting safety be prepared, documented, verified, tested, and used such that the expected outputs are obtained and configuration control maintained.

17.5.4.12 Control of Measuring and Test Equipment

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.L. The QAPD establishes the necessary measures to control the calibration, maintenance, and use of measuring and test equipment that provide information important to safe plant operation.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 12 and Supplement 12S-1, to establish provisions for control of measuring and test equipment, with the following clarification and exception:

- The QAPD clarifies that the out-of-calibration conditions, described in paragraph 3.2 of Supplement 12S-1 of NQA-1-1994, refer to cases where the measuring and test equipment are found to be out of the required accuracy limits (i.e., out of tolerance) during calibration. The NRC staff determined that the clarification for the out-of-calibration conditions is consistent with Supplement 12S-1. Therefore, the NRC staff concluded that this clarification is acceptable.

- As an alternative to the NQA-1-1994, Subpart 2.4, Section 7.2.1, calibration labeling requirements, the QAPD proposes that, when it is impossible or impractical to mark equipment with required calibration information because of equipment size or configuration, the required calibration information will be documented and traceable to the equipment. The NRC staff determined that this alternative is consistent with NRC staff guidance provided in Section 17.5 of NUREG-0800, paragraph II.L.3. Therefore, the NRC staff concluded that this alternative is acceptable.

17.5.4.13 Handling, Storage, and Shipping

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.M. The QAPD establishes the necessary measures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss and to minimize deterioration.

In the QAPD, TVA commits to comply with NQA-1-1994, Basic Requirement 13 and Supplement 13S-1, and to establish provisions for handling, storage, and shipping. In the QAPD, TVA also commits to comply with NQA-1-1994, Subparts 2.1 and 2.2, during the construction and pre-operations phase of the plant, as applicable, with the following alternative:

- NQA-1-1994, Subpart 2.2, Section 6.6, states that the preparation of records must include information on personnel access to QA records. The QAPD establishes the necessary measures to document personnel authorized to access storage areas and recording personnel access. However, the QAPD proposes to not consider these documents as quality records. As an alternative, TVA will retain these documents in accordance with plant administrative controls. The NRC staff determined that these records do not meet the classification of a quality record as defined in NQA-1-1994, Supplement 17S-1, Section 2.7. Therefore, the NRC staff concluded that this alternative is acceptable.

- NQA-1-1994, Subpart 2.2, Section 7.1, refers to Subpart 2.15 for requirements related to handling of items. The QAPD clarifies that the scope of Subpart 2.15 includes hoisting, rigging and transporting of items for nuclear power plants during construction. The NRC staff has determined that this clarification is acceptable because it distinguishes between the requirements for construction and operation.

17.5.4.14 Inspection, Test, and Operating Status

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.N. The QAPD establishes the necessary measures to identify the inspection, test, and operating status of items and components subject to the provisions of the QAPD to maintain personnel and reactor safety and avoid inadvertent operation of equipment.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 14, for identifying inspection, test, and operating status.

17.5.4.15 Nonconforming Materials, Parts, or Components

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.O. The QAPD establishes the necessary measures to control items, including services that do not conform to specified requirements to prevent inadvertent installation or use. Nonconformances are evaluated for their impact on operability of quality SSCs to ensure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. The results of evaluations of conditions adverse to quality are analyzed to identify quality trends, documented, and reported to upper management in accordance with applicable procedures.

In addition, the QAPD provides for establishing the necessary measures to implement the requirements of Subparts A and C of 10 CFR Part 52, 10 CFR 50.55(e), and 10 CFR Part 21, as applicable.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 15 and Supplement 15S-1, to establish measures for nonconforming material.

17.5.4.16 Corrective Action

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.P. The QAPD establishes the necessary measures to promptly identify, control, document, classify, and correct conditions adverse to quality. The QAPD requires personnel to identify known conditions adverse to quality. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality are documented and reported to responsible management. In the case of suppliers working on safety-related activities or similar situations, TVA may delegate specific responsibility for the corrective action program, but TVA maintains responsibility for the program's effectiveness.

In addition, the QAPD provides for establishing the necessary measures to implement a reporting program in accordance with the requirements of 10 CFR Part 21.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 16, to establish a corrective action program.

17.5.4.17 Quality Assurance Records

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.Q. The QAPD establishes the necessary measures to ensure that sufficient records of items and activities affecting quality are generated, identified, retained, maintained, and retrievable.

Concerning the use of electronic records storage and retrieval systems, the QAPD complies with the NRC guidance given in RIS 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," dated October 23, 2000, and associated Nuclear Information and Records Management Association (NIRMA) guidelines TG 11-1998, TG 15-1998, TG 16-1998 and TG 21-1998.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 17 and Supplement 17S-1, to establish provisions for records, with the following alternative:

- NQA-1-1994, Supplement 17S-1, Section 4.2(b) states that records must be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. As an alternative to this requirement, the QAPD proposes that hard-copy records be stored in steel cabinets or on shelving in containers, except that methods other than binders, folders, or envelopes may be used to organize records for storage. The NRC staff determined that this alternative is acceptable as documented in an SER dated September 1, 2005 for Nuclear Management Company.

17.5.4.18 Quality Assurance Audits

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.R. The QAPD establishes the necessary measures to implement audits to verify that activities covered by the QAPD are performed in conformance with documented requirements. The audit program is reviewed for effectiveness as part of the overall audit process.

The QAPD provides for the applicant or holder to conduct periodic internal and external audits. Internal audits are conducted to determine that the program and procedures being audited comply with the QAPD. Internal audits, conducted after placing the facility in operation, are performed with a frequency commensurate with safety significance and in such a manner as to ensure that an audit of all applicable QA program elements is completed for each functional area within a period of 2 years. External audits determine the adequacy of a supplier's or contractor's QA program.

TVA ensures that audits are documented and reviews audit results. TVA responds to all audit findings and initiates appropriate corrective actions. In addition, where corrective actions are indicated, TVA documents follow-up of applicable areas through inspections, review, re-audits, or other appropriate means to verify implementation of assigned corrective actions.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 18 and Supplement 18S-1, to establish the independent audit program.

17.5.4.19 Non-safety-Related SSC Quality Assurance Control

17.5.4.19.1 Non-safety-Related SSCs - Significant Contributors to Plant Safety

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.V.1. The QAPD establishes program controls applied to non-safety-related SSCs that are significant contributors to plant safety and to which Appendix B does not apply. The QAPD applies specific controls to these items in a selected manner, targeting the characteristics or critical attributes that render the SSC a significant contributor to plant safety consistent with applicable sections of the QAPD.

17.5.4.19.2 Non-safety-Related SSCs Credited for Regulatory Events

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.V.2, to establish the quality requirements for non-safety-related SSCs credited for regulatory events. In the QAPD, TVA commits to comply with the following regulatory guidance:

- TVA shall implement quality provisions for the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in RG 1.189, "Fire Protection for Operating Nuclear Power Plants," issued April 2001.

- TVA shall implement quality provisions for anticipated transient without scram (ATWS) equipment in accordance with GL 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related," issued January 1985.

- TVA shall implement quality provisions for station blackout (SBO) equipment in accordance with Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Non-Safety Systems and Equipment," in RG 1.155, "Station Blackout," issued August 1988.

17.5.4.20 Regulatory Commitments

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.U. The QAPD establishes QA program commitments. In the QAPD, TVA commits to comply with the following NRC regulatory guides and other QA standards to supplement and support the QAPD:

- RG 1.26, Revision 4, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," issued March 2007. In the QAPD, TVA commits to comply with the regulatory positions of this guidance, with the exception of Criteria C.1, C.1.a, C.1.b, and C.3. As documented in the NRC staff's FSER (NUREG-1793), issued September 2000, and Supplement 1 to NUREG-1793, issued December 2005, the NRC staff determined that the proposed exceptions are acceptable for use with the AP1000 design.

- RG 1.29, Revision 4, "Seismic Design Classification," issued March 2007. In the QAPD, TVA commits to comply with the regulatory positions of this guidance, with the exception of Criteria C.1.d, C.1.g, and C.1.n. As documented in NUREG-1793 and Supplement 1 to NUREG-1793, the NRC staff determined that the proposed exceptions are acceptable for use with the AP1000 design.

- ASME NQA-1-1994, “Quality Assurance Requirements for Nuclear Facility Applications,” Parts I and II, as described in the TVA QAPD.

- NIRMA technical guides, as described in Part II, Section 17 of the QAPD.

In RAI 17.5-15 dated May 12, 2008, the NRC staff requested that the applicant revise the TVA QAPD Part IV to commit to RG 1.37 Revision 1, “Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants,” issued March 2007. In its response dated June 24, 2008, the applicant stated that Part IV of the TVA QAPD is consistent with Revision 4 of NEI 06-14A. In a letter, dated September 17, 2008, the NRC staff requested NEI to address this question as part of Revision 5 to NEI 06-14A. However, the applicant committed to RG 1.37, Revision 1, in Revision 1 of the BLN QAPD. RAI 17.5-15 is closed.

The NRC staff also reviewed Appendix 1AA of the BLN COL FSAR, which lists BLN’s conformance with NRC RGs and provides any exceptions to conformance with those RGs. In RAI 17.5-17, the NRC staff requested that the applicant explain how the QAPD provides an acceptable exception to the RGs described in Appendix 1AA. In its response (ML081780171), the applicant stated that Part IV of the TVA QAPD is consistent with Revision 4 of NEI 06-14A. Additionally, the applicant provided further information addressing these RGs in response to RAIs 17.5-15 and 17.5-17. The response to RAI 17.5-15 proposed revisions to Appendix 1AA and Parts II and IV of the QAPD, whereas the response to RAI 17.5-17 provided further justification. The applicant provided a response to RAI 1-5 in a letter dated August 19, 2008, to address the discrepancies between the revisions of the RGs addressed in Appendix 1AA and those addressed in Westinghouse DCD Appendix 1A. The information in this letter appears to have superseded the changes that were proposed and acceptable to the NRC staff in the applicant’s June 24, 2008 letter, thereby reopening the issue identified in RAI 17.5-17. This is identified as **Open Item 17.5-6.**

In RAI 17.5-18, the NRC staff requested that the applicant address the proposed AP1000 DCD, Revision 17 change of Table 1.9-1 with regard to RG 1.33, which would make it inconsistent with BLN COL FSAR Appendix 1AA. In its letter, dated June 24, 2008, the applicant stated that Westinghouse was considering processing a change to the DCD that may revise the Table 1.9-1 reference to be consistent with the RG 1.33 reference in DCD Appendix 1A. The NRC staff noted that this change was documented in Westinghouse TF-134, Revision 5 resulting in consistency between the AP1000 DCD and the BLN COL FSAR for RG 1.33. RAI 17.5-18 is closed.

17.5.5 Post Combined License Activities

The following items were identified as the responsibility of the COL holder:

License Condition 6, “Operational Program Readiness,” in Part 10 of the BLN COL application will require the licensee to develop a schedule that supports planning for and conduct of NRC inspections of the operational programs listed in BLN COL FSAR Table 13.4-201, "Operational Programs Required by NRC Regulations." This schedule must be available to the NRC staff 12 months after issuance of the COL. The condition will also require that the schedule be updated every 6 months until 12 months before scheduled fuel load, and every month thereafter until either the operational programs listed in the BLN COL FSAR Table 13.4-201 table have

been fully implemented or the plant has been placed in commercial service, whichever comes first.

17.5.6 Conclusion

The NRC staff used the requirements of Appendix B to 10 CFR Part 50 and the guidance of Section 17.5 of NUREG-0800 as the basis for evaluating the acceptability of TVA's QAPD and concludes that:

- The QAPD provides adequate guidance for TVA to describe the authority and responsibility of management and supervisory personnel, performance/verification personnel, and self-assessment personnel.

- The QAPD provides adequate guidance for TVA to provide for organizations and persons to perform verification and self-assessment functions with the authority and independence to conduct their activities without undue influence from those directly responsible for costs and schedules.

- The QAPD provides adequate guidance for TVA to apply a QAPD to activities and items that are important to safety.

- The QAPD provides adequate guidance for TVA to establish controls that, when properly implemented, comply with 10 CFR Part 52, Appendix B, to 10 CFR Part 50, 10 CFR Part 21, and 10 CFR 50.55(e), with the acceptance criteria in Section 17.5 of NUREG-0800, and with the commitments to applicable regulatory guidance.

The TVA QAPD addresses BLN COL 17.5-1 and STD COL 17.5-2, 17.5-4, and 17.5-8.

However, as a result of the open items, the staff is unable to finalize its conclusions on Section 17.5 of the BLN COL FSAR and the TVA QAPD in accordance with the requirements of Appendix B to 10 CFR Part 50, 10 CFR 52.79(a)(17), 10 CFR 52.79(a)(25) and 10 CFR 52.79(a)(27).

17.6 Maintenance Rule Program (Related to RG 1.206, Section C.III.1, Chapter 17, C.I.17.6, "Description of the Applicant's Program for Implementation of 10 CFR 50.65, The Maintenance Rule")

17.6.1 Introduction

This section addresses the program for maintenance rule (MR) implementation. It is based on the requirements of 10 CFR Part 52 and the guidance provided to the industry by the Nuclear Management and Resources Council (NUMARC) and its successor, the Nuclear Energy Institute (NEI). NUMARC 93-01, "Industry Guidance for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," is endorsed by the staff in RG 1.160. Section 11.0 of NUMARC 93-01 was later revised; the revision, as modified by RG 1.182, is also endorsed by the staff. NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," provides a template for presenting this information that has also been endorsed by the staff in a letter to NEI, dated January 24, 2008.

17.6.2 Summary of Application

Section 17.6 of the BLN COL FSAR contains the following:

Supplemental Information

- STD SUP 17.6-1, which incorporates, by reference, NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52." It also identified where operational programs are described in the BLN COL FSAR, including a description of and milestones for the MR program.

License Conditions

Proposed License Condition 6, "Operational Program Readiness" requires submittal of a schedule to support NRC inspections of operational programs consistent with SECY-05-0197.

17.6.3 Regulatory Basis

Commission regulations for the MR program include the requirements of 10 CFR 50.65 and 10 CFR 52.79(a)(15). The staff reviews this part of the application in accordance with Section 17.6 of NUREG-0800.

The regulatory basis for the information incorporated by reference is documented in the FSER for topical report NEI 07-02, Revision 3, transmitted to NEI in a letter from the staff, dated January 24, 2008.

SECY-05-0197, "Review of Operational Programs in a Combined License Application and Generic Emergency Planning Inspections, Tests, Analyses, and Acceptance Criteria," identifies schedule requirements and proposes a license condition to be satisfied by COL holders.

17.6.4 Technical Evaluation

The NRC staff reviewed conformance of Section 17.6 of the BLN COL FSAR, including the COL standard information item identified in Subsection 17.6.2, with the guidance in NUREG-0800, Section 17.6. The staff also compared it with RG 1.206, Section C.III.1, Chapter 17, C.I.17.6, "Description of the Applicant's Program for Implementation of 10 CFR 50.65, the Maintenance Rule."

In addition, the NRC staff reviewed the COL standard information item identified in Subsection 17.6.2 above. In its review, the staff used NUREG-0800, Section 17.6, "Maintenance Rule," as guidance.

Supplemental Information

- STD SUP 17.6-1, which incorporated NEI 07-02A and identified where operational programs are described in the BLN COL FSAR, including a description of the MR program

The applicant added the following text to Section 17.6 of the BLN COL FSAR:

> This section incorporates by reference NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed under 10 CFR Part 52," with the following supplemental information. See Table 1.6-201.
>
> Table 13.4-201 provides milestones for maintenance rule [MR] program implementation.

The applicant indicated where, in the BLN COL FSAR, the programs listed in Subsection 17.X.3 of NEI 07-02A are described:

- MR program (Section 17.6)
- QA program (Section 17.5)
- inservice inspection program (Sections 5.2 and 6.6)
- inservice testing program (Section 3.9)
- technical specifications surveillance test program (Chapter 16)

The NRC staff endorsed NEI 07-02A, stating that it provides an acceptable method:

- for complying with the requirement in 10 CFR 52.79(a)(15) that FSARs contain a description of the program and its implementation

- for monitoring the effectiveness of maintenance to meet the requirements of Section 50.65

- for satisfying the acceptance criteria of NUREG-0800, Section 17.6

Because STD SUP 17.6-1 incorporates NEI 07-02A by reference and identifies the relevant operational programs and milestones, the staff finds that the applicant has provided sufficient information to fully describe the maintenance rule program. This provides reasonable assurance that the program, when implemented, satisfies the requirements of 10 CFR 50.65.

17.6.5 Post Combined License Activities

In accordance with the SRM for SECY-05-0197, each COL will contain a license condition regarding operational programs. The NEI 07-02A template specifies that the MR program documents will be developed and maintained and the MR program implemented by the time that fuel load is authorized, that is, by the time the Commission is asked to make the finding required in 10 CFR 52.103(g).

The NRC staff's position is that implementation of an acceptable MR program may occur in advance of the Commission's 10 CFR 52.103(g) finding, with components being monitored or tracked as they become available.

License Condition 6, "Operational Program Readiness," in Part 10 of the BLN COL application will require the licensee to develop a schedule that supports planning for and conduct of NRC inspections of the operational programs listed in BLN COL FSAR Table 13.4-201, "Operational Programs Required by NRC Regulations." This schedule must be available to the NRC staff

12 months after issuance of the COL. The condition will also require that the schedule be updated every 6 months until 12 months before scheduled fuel load, and every month thereafter until either the operational programs listed in the BLN COL FSAR Table 13.4-201 table have been fully implemented or the plant has been placed in commercial service, whichever comes first.

The staff finds this to be an acceptable basis for the MR program and its schedule.

17.6.6 Conclusion

The NRC staff reviewed the application and confirmed that the applicant addressed the required information relating to the maintenance rule program. STD SUP 17.6-1 incorporated NEI 07-02A by reference; identified where operational programs are described in the BLN COL FSAR, including a description of the MR program; and provided a schedule for implementation of the maintenance rule program. The staff concludes that the relevant information presented within Section 17.6 of the COL FSAR meets the requirements of 10 CFR 50.65 and 10 CFR 52.79(a)(15) and is therefore acceptable.

12 months after issuance of the COL. The condition will also require that the schedule be updated every 6 months until 12 months before scheduled fuel load, and every month thereafter until either the operational programs listed in the BLN COL FSAR Table 13.4-201 table have been fully implemented or the plant has been placed in commercial service, whichever comes first.

The staff finds this to be an acceptable basis for the MR program and its schedule.

17.6.6 Conclusion

The NRC staff reviewed the application and confirmed that the applicant addressed the required information relating to the maintenance rule program. STD SUP 17.6-1 incorporated NEI 07-02A by reference; identified where operational programs are described in the BLN COL FSAR, including a description of the MR program; and provided a schedule for implementation of the maintenance rule program. The staff concludes that the relevant information presented within Section 17.6 of the COL FSAR meets the requirements of 10 CFR 50.65 and 10 CFR 52.79(a)(15) and is therefore acceptable.

PKG No.: ML091530609
Accession No.: ML091190346

NAME	DNRL/NWE1/LA	DNRL/NWE1/PM	DCIP/CQVP:PM	DCIP/CQVP/BC	DSRA/SPLA:PM	DSRA/SPLA/BC
OFFICE	KGoldstein	MComar	KKavanagh	JPeralta	MPatterson	LMrowca
DATE	4/15/09	4/16/09	06/02/09	06/02/09	06/02/09	06 /02/09
NAME	OGC	DNRL/NWE1/BC				
OFFICE	AHodgdon	SCoffin				
DATE	6/15/09	06/17/09				

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