17.0 QUALITY ASSURANCE

This chapter of the Combined License (COL) Final Safety Analysis Report (FSAR) describes the Quality Assurance (QA) Program for the design, fabrication, construction, testing, and operation of the South Texas Project (STP), Units 3 and 4, Advanced Boiling Water Reactors (ABWRs).

17.0 Introduction

This section of the FSAR addresses COL Information Item 17.1, by referencing the various sections in Chapter 17 where the applicant's QA Program for the construction and operation phases are discussed. The U.S. Nuclear Regulatory Commission (NRC) staff's review of the applicant's QA Program is in Section 17.5S of this safety evaluation report (SER).

Section 17.0 of the STP, Units 3 and 4, COL FSAR incorporates by reference Section 17.0 of the certified ABWR design control document (DCD), Revision 4, referenced in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," Appendix A, "Design Certification Rule for the U.S. Advanced Boiling Water Reactor," with no departures. Section 17.0 also incorporates by reference Section 17.0 of the STP Nuclear Operating Company application to amend the design certification (DC) rule for the U.S. ABWR, "ABWR STP Aircraft Impact Assessment (AIA) Amendment," Revision 3, dated September 2010 (the AIA Amendment). On December 16, 2011, the AIA Amendment was certified by a final rule amending 10 CFR Part 52, Appendix A (76 FR 78096). The staff reviewed the application and checked the referenced DCD and the AIA Amendment to ensure that no issue relating to this section remains for review.[1] The staff's review confirmed that there is no outstanding issue related to this section. Pursuant to 10 CFR 52.63(a)(5) and 10 CFR Part 52, Appendix A, Section VI.B.1, all nuclear safety issues relating to the introduction that were incorporated by reference have been resolved.

17.1 Quality Assurance During Design and Construction

17.1.1 Introduction

This section of the FSAR addresses the QA Program during the design and construction phases of the STP, Units 3 and 4. In addition, this section addresses the QA Program implemented during the COL application development.

17.1.2 Summary of Application

Section 17.1 of the STP, Units 3 and 4, COL FSAR Revision 12 incorporates by reference Section 17.1 of the certified ABWR DCD Revision 4, referenced in 10 CFR Part 52, Appendix A, with no departures. Section 17.1 also incorporates by reference Section 17.1 of the AIA Amendment. In addition, in FSAR Section 17.1, the applicant provides the following:

[1] See *"Finality of Referenced NRC Approvals"* in SER Section 1.1.3, for a discussion on the staff's review related to verification of the scope of information to be included in a COL application that references a design certification

COL License Information Item

- COL License Information Item 17.1 QA Programs for Construction and Operation

This COL license information item requires the applicant to prepare and implement a QA Program for the construction phase (Section 17.1) and the operations phase (Section 17.2) that meets the requirements of the American National Standards Institute (ANSI)/American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1–1983, "Quality Assurance Requirements for Nuclear Facility Applications," and NQA-1a–1983, "Addenda to ANSI/ASME NQA 1-1983 Edition Quality Assurance Program Requirements for Nuclear Facilities," and the quality-related Regulatory Guides (RGs) listed in Table 17.0-1, "ABWR Compliance with Quality Related Regulatory Guides," of the DCD. The applicant states that the STP, Units 3 and 4, QA Program Description (QAPD) is in Section 17.5S, "Quality Assurance Program Guidance."

17.1.3 Regulatory Basis

The regulatory basis of the information incorporated by reference is in NUREG–1503, "Final Safety Evaluation Report Related to the Certification of the Advanced Boiling-Water Reactor Design," (July 1994) ((FSER) related to the ABWR DCD). The regulatory basis of the AIA Amendment information incorporated by reference is in NUREG–1948, "Final Safety Evaluation Report Related to the Aircraft Impact Amendment to the U.S. Advanced Boiling Water Reactor (ABWR) Design Certification," dated June 2011, (the SER related to the AIA Amendment). In addition, the relevant requirements of the Commission regulations for QA, and the associated acceptance criteria, are in Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," of NUREG–0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants, (LWR Edition)," (the Standard Review Plan [SRP]).

The first part of COL License Information Item 17.1, which pertains to QA Programs for the design and construction phases, is satisfied based on meeting the requirements of Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." COL License Information Item 17.1, is satisfied based on following the guidance in RG 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," and is addressed in Section 17.5S of the STP, Units 3 and 4, COL FSAR.

The second part of COL License Information Item 17.1, which pertains to QA during the operations phase, is discussed in Section 17.2.

17.1.4 Technical Evaluation

As documented in NUREG–1503 and NUREG–1948, the staff reviewed and approved Section 17.1 of the certified ABWR DCD and AIA Amendment. The staff reviewed Section 17.1 of the STP, Units 3 and 4, COL FSAR and checked the referenced ABWR DCD and AIA Amendment to ensure that the combination of the information in the COL FSAR and the information in the ABWR DCD and AIA Amendment appropriately represents the complete scope of information relating to this review topic.[1] The staff's review confirmed that the information in the application

[1] See *"Finality of Referenced NRC Approvals"* in SER Section 1.1.3, for a discussion on the staff's review related to verification of the scope of information to be included in a COL application that references a design certification

and the information incorporated by reference address the required information relating to the QA during the design and construction phases.

The staff reviewed the following information in the COL FSAR:

COL License Information Item

- COL License Information Item 17.1 QA Programs for Construction and Operation

The staff reviewed the reference to Section 17.5S of the STP, Units 3 and 4, COL FSAR. The staff concluded that the referenced section contains the description of the QA Program applied during the construction, operation, and preparation of site-specific design activities (see Section 17.5S of this SER).

The staff conducted an inspection of the applicant's implementation of the QA Program from January 13, 2009, through January 15, 2009. The limited scope of the inspection focused on the applicant's quality activities during the due diligence assessment to determine whether Toshiba Corporation is qualified to supply the design of the ABWR for STP, Units 3 and 4, in accordance with 10 CFR Part 52, Appendix A. The results of the inspection are documented in NRC Inspection Report Nos. 0520012/2009201 and 0520013/2009201 and Notice of Violation, dated March 2, 2009 (ML090560120).

As a follow-up to the January 2009, inspection of the applicant, the staff issued Request for Additional Information (RAI) 01-9 because STP applied the operational QAPD (OQAPD) to activities performed during the COL application phase, but the applicant did not provide a reference to the OQAP in the COL application. Section 17.1 of the STP COL application stated only that "the Quality Assurance Program Description [QAPD] has been submitted as a separate document titled 'STP 3 & 4 Quality Assurance Program Description.'" In RAI 01-9, the staff requested the applicant to incorporate the OQAP as a reference in the COL application. In RAI 01-9, the staff also asked the applicant to identify and justify any differences between the OQAP and the acceptance criteria included in SRP 17.5 that were in effect six months before docketing the STP COL application, for the activities being implemented under the OQAP.

In its response to RAI 01-9, dated April 2 of 2009 (ML090960321), the applicant included a commitment to revise Section 17.1 of the FSAR to incorporate by reference the OQAP. The response also clarified that in place of an earlier indication that a transition to full implementation of the STP, Units 3 and 4, QAPD would be completed within 60 days of the NRC's approval of the QAPD. The applicant stated that it would complete the transition to full implementation of the QAPD by September 30, 2009. The response also summarized the gap analysis the applicant performed to identify and justify the differences between the OQAP and the acceptance criteria in SRP Section 17.5 for STP, Units 3 and 4, activities conducted under the OQAP. The gap analysis compared the items listed in the SRP dated March 2007, to the corresponding sections of the OQAP. The staff found that the proposed changes adequately satisfy the guidance of SRP Section 17.5 and are therefore acceptable. The staff verified that the proposed revision was incorporated into Revision 4 of the STP, Units 3 and 4, FSAR. Therefore, RAI 01-09 is resolved and closed.

17.1.5 Post Combined License Activities

There are no post COL activities related to this section.

17.1.6 Conclusion

The staff's finding related to information incorporated by reference is in NUREG–1503 and NUREG–1948. The staff reviewed the application and checked the referenced DCD and AIA Amendment. The staff's review confirmed that the applicant has addressed the required information, and no outstanding information is expected to be addressed in the COL FSAR related to this section. Pursuant to 10 CFR 52.63(a)(5) and 10 CFR Part 52, Appendix A, Section VI.B.1, all nuclear safety issues relating to the QA Program during the design and construction phases that were incorporated by reference, have been resolved.

The staff found the applicant's response to COL License Information Item 17.1, acceptable because it adequately provides a reference to Section 17.5S of the STP, Units 3 and 4, COL FSAR, for the description of the QA Program applied during the design, construction, and operation activities for STP, Units 3 and 4 (see Section 17.5S of this SER). In addition, Section 17.1 of the STP, Units 3 and 4, COL FSAR, addresses that during design and construction of STP, Units 3 and 4, prior to full implementation of the STP, Units 3 and 4 QAPD, the approved STP, Units 1 and 2 OQAP has been incorporated by reference for use on STP, Units 3 and 4.

17.2 Quality Assurance During the Operations Phase

17.2.1 Introduction

This section of the FSAR addresses the QA Program during the operations phase of the STP, Units 3 and 4.

17.2.2 Summary of Application

Section 17.2 of the STP, Units 3 and 4, COL FSAR Revision 12 incorporates by reference Section 17.2 of the certified ABWR DCD Revision 4, referenced in 10 CFR Part 52, Appendix A, with no departures. In addition, in FSAR Section 17.2, the applicant provides the following:

COL License Information Item

- COL License Information Item 17.1 QA Programs for Construction and Operation

COL License Information Item 17.1, relates to QA Programs for construction and operation and is addressed in Section 17.5S of the STP, Units 3 and 4, COL FSAR.

17.2.3 Regulatory Basis

The regulatory basis of the information incorporated by reference is in NUREG–1503. In addition, the relevant requirements of the Commission regulations for the QA Program during the operations phase, and the associated acceptance criteria, are in Section 17.5 of NUREG-0800.

17.2.4 Technical Evaluation

As documented in NUREG–1503, the staff reviewed and approved Section 17.2 of the certified ABWR DCD. The staff reviewed Section 17.2 of the STP, Units 3 and 4, COL FSAR and checked the referenced ABWR DCD to ensure that the combination of the information in the COL FSAR and the information in the ABWR DCD appropriately represents the complete scope

of information relating to this review topic[1]. The staff's review confirmed that the information in the application and the information incorporated by reference address the required information relating to the QA during the operations phase.

In addition, the applicant provides specific information to address a QA Program and implementation plan for the operations phase that meets the requirements of Appendix B to 10 CFR Part 50.

The staff's review of the QA Program implemented during the operations phase is described in Section 17.5S of this SER.

17.2.5 Post Combined License Activities

There are no post COL activities related to this section.

17.2.6 Conclusion

The staff's finding related to information incorporated by reference is in NUREG–1503. The staff reviewed the application and checked the referenced DCD. The staff's review confirmed that the applicant has addressed the required information, and no outstanding information is expected to be addressed in the COL FSAR related to this section. Pursuant to 10 CFR 52.63(a)(5) and 10 CFR Part 52, Appendix A, Section VI.B.1, all nuclear safety issues relating to the QA Program during the operations phase that were incorporated by reference, have been resolved.

The staff's review of the applicant's response to COL license information item 17.1 is in Section 17.5S of this SER.

17.3 Reliability Assurance Program During Design Phase

17.3.1 Introduction

This section of the FSAR addresses the Commission's direction in the Staff Requirements Memorandum (SRM) dated June 28, 1995, for Item E, "Reliability Assurance Program," of SECY-95–132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs," dated May 22, 1995. The Reliability Assurance Program (RAP) is implemented using the guidance in Item E of SECY-95–132. The purposes of the RAP are to provide reasonable assurance that:

- A reactor is designed, constructed, and operated consistent with the assumptions and risk insights of the risk-significant SSCs.
- These SSCs do not degrade to an unacceptable level of reliability, availability, or condition during plant operations.
- The frequency of transients that challenge these SSCs is minimized.

[1] See *"Finality of Referenced NRC Approvals"* in SER Section 1.1.3, for a discussion on the staff's review related to verification of the scope of information to be included in a COL application that references a design certification

- These SSCs will function reliably when challenged.

The purposes of the RAP can be achieved by implementing the program in two stages. The first stage applies to RAP activities that occur before the initial fuel loading and is referred to as the design RAP (D-RAP). The goal of the D-RAP is to ensure that the reactor design meets the considerations identified earlier through the reactor design, procurement, fabrication, construction, and preoperational testing activities and programs. The second stage applies to RAP activities for the operations phase of the plant's life cycle and was previously referred to as the operational RAP (O-RAP). The objective during this stage is to ensure that the reliability of the risk-significant SSCs is maintained during plant operations. The staff verifies the RAP during the COL application phase through the agency's SER process. Implementation of the D-RAP by the COL licensee is verified using the inspections, tests, analyses, and acceptance criteria (ITAAC) process, as well as conducting inspections during the detailed design and construction phases before initial fuel loading.

17.3.2 Summary of Application

Section 17.3 of the STP, Units 3 and 4, COL FSAR Revision 12 incorporates by reference Section 17.3 of the certified ABWR DCD Revision 4, referenced in 10 CFR Part 52, Appendix A. In addition, in FSAR Section 17.3, the applicant provides the following:

COL License Information Items

The applicant provides site-specific supplemental information in Section 17.3 of the COL FSAR stating that the following COL license information items are discussed in Section 17.4S ("Reliability Assurance Program") of the FSAR:

- COL License Information Item 17.2 Policy and Implementation Procedures for D-RAP

The applicant specifies the policy and implementation procedures for using the D-RAP information.

- COL License Information Item 17.3 D-RAP Organization

The applicant describes the D-RAP organization and the programmatic controls of the D-RAP that are applied during the design and construction phases.

- COL License Information Item 17.4 Provision for O-RAP

The applicant describes the operational RAP activities that are applied during the operations phase.

17.3.3 Regulatory Basis

The regulatory basis of the information incorporated by reference is in NUREG–1503.

In addition, the relevant guidance for the RAP is in the following sources:

- Item E, "Reliability Assurance Program," of SECY-95–132.
- Section 17.4, "Reliability Assurance Program," of NUREG–0800.

17.3.4 Technical Evaluation

As documented in NUREG–1503, the staff reviewed and approved Section 17.3 of the certified ABWR DCD. The staff reviewed Section 17.3 of the STP, Units 3 and 4, COL FSAR and checked the referenced ABWR DCD to ensure that the combination of the information in the COL FSAR and the information in the ABWR DCD appropriately represents the complete scope of information relating to this review topic.[1] The staff's review confirmed that the information in the application and the information incorporated by reference address the required information relating to the RAP during design and construction phases.

The staff reviewed the following information in the COL FSAR:

COL License Information Items

- COL License Information Item 17.2 Policy and Implementation Procedures for D-RAP
- COL License Information Item 17.3 D-RAP Organization
- COL License Information Item 17.4 Provision for O-RAP

The applicant addresses COL License Information Items 17.2, 17.3, and 17.4 in Section 17.4S of the FSAR. The staff's review of the applicant's response to these COL license information items is described in Section 17.4S of this SER.

17.3.5 Post Combined License Activities

There are no post COL activities related to this section.

17.3.6 Conclusion

The staff's finding related to information incorporated by reference is in NUREG–1503. The staff reviewed the application and checked the referenced DCD. The staff's review confirmed that the applicant has addressed the required information, and there are no outstanding issues related to this section. Pursuant to 10 CFR 52.63(a)(5) and 10 CFR Part 52, Appendix A, Section VI.B.1, all nuclear safety issues relating to the RAP that were incorporated by reference have been resolved.

The staff's review of the relevant information relating to the RAP is in Section 17.4S of this SER.

17.4S Reliability Assurance Program

17.4S.1 Introduction

This section of the FSAR addresses the Commission's direction in the SRM dated June 28, 1995, for Item E of SECY-95–132. The purposes of the RAP are to provide reasonable assurance that:

[1] See *"Finality of Referenced NRC Approvals"* in SER Section 1.1.3, for a discussion on the staff's review related to verification of the scope of information to be included in a COL application that references a design certification

- A reactor is designed, constructed, and operated consistent with the assumptions and risk insights of the risk-significant SSCs.

- These SSCs do not degrade to an unacceptable level of reliability, availability, or condition during plant operations.

- The frequency of transients that challenge these SSCs is minimized.

- These SSCs will function reliably when challenged.

The purposes of the RAP can be achieved by implementing the program in two stages. The first stage applies to RAP activities that occur before the initial fuel loading (D-RAP). The goal of the D-RAP is to ensure that the reactor design meets the considerations identified earlier through the reactor design, procurement, fabrication, construction, and preoperational testing activities and programs. The second stage applies to RAP activities for the operations phase of the plant's life cycle. The objective during this stage is to ensure that the reliability of the risk-significant SSCs is maintained during plant operations. The staff verifies the RAP during the COL application phase through the agency's SER process. Implementation of the D-RAP by the COL licensee is verified using the ITAAC process as well as conducting inspections during detailed design and construction phases before initial fuel loading.

17.4S.2 Summary of Application

Section 17.3 of the STP, Units 3 and 4, FSAR Revision 12 incorporates by reference Section 17.3 of the certified ABWR DCD Revision 4, referenced in 10 CFR Part 52, Appendix A. Section 17.4S of the FSAR addresses COL License Information Items 17.2, 17.3, and 17.4, which are associated with Section 17.3. Specifically, in FSAR Section 17.4S, the applicant provides the following:

COL License Information Items

- COL License Information Item 17.2 Policy and Implementation Procedures for D-RAP

The applicant provides site-specific supplemental information in FSAR Section 17.4S that addresses COL License Information Item 17.2. This supplemental information specifies the applicant's policy and implementation procedures for using D-RAP information.

- COL License Information Item 17.3 D-RAP Organization

The applicant provides site-specific supplemental information in FSAR Section 17.4S that addresses COL License Information Item 17.3. This supplemental information describes the applicant's D-RAP organization and the programmatic controls of the D-RAP during the design and construction phases.

- COL License Information Item 17.4 Provision for O-RAP

The applicant provides site-specific supplemental information in FSAR Section 17.4S that addresses COL License Information Item 17.4. This supplemental information describes the applicant's RAP activities during the operations phase.

17.4S.3 Regulatory Basis

The regulatory basis of the information incorporated by reference is in NUREG–1503.

In addition, the relevant guidance for the RAP is in the following sources:

- Item E of SECY-95–132.
- Section 17.4 of NUREG–0800.

17.4S.4 Technical Evaluation

The staff reviewed the following supplemental information in Section 17.4S of the STP, Units 3 and 4, FSAR:

COL License Information Items

- COL License Information Item 17.2 Policy and Implementation Procedures for D-RAP
- COL License Information Item 17.3 D-RAP Organization
- COL License Information Item 17.4 Provision for O-RAP

The staff reviewed this supplemental information in accordance with Item E of SECY-95–132 and SRP Section 17.4 (dated March 2007) to ensure that the supplemental information meets the guidance in these documents. The staff's review of the supplemental information included RAIs to the applicant followed by the evaluation of the applicant's responses to the RAIs. The following discussion describes the staff's technical evaluation of the information in FSAR Section 17.4S. The review and resolution of COL License Information Items 17.2 and 17.3 are addressed in Subsections 17.4S.4.1, 17.4S.4.2, 17.4S.4.3, 17.4S.4.4, and 17.4S.4.6 of this SER. The review and resolution of COL License Information Item 17.4 are in Subsection 17.4S.4.5 of this SER.

17.4S.4.1 Programmatic Controls of the D-RAP

The staff reviewed the programmatic controls of the D-RAP for developing and implementing an effective site-specific D-RAP during the COL design and construction phases before initial fuel loading, which are described in FSAR Section 17.4S. This review was performed in accordance with Item E of SECY-95–132 and SRP Section 17.4 to ensure that this subject review area meets the guidance in these documents. Based on Item E of SECY-95–132 and SRP Section 17.4, the applicant should establish and apply the appropriate programmatic controls of the D-RAP to support the COL design and construction activities. These programmatic controls ensure that the key assumptions and risk insights are consistent with the design and that the list of risk-significant SSCs is appropriately developed, maintained, and communicated to the appropriate organizations. The application should adequately address the following programmatic controls of the D-RAP, which are described in SRP Section 17.4:

- Organization.
- Design control.
- Controls for procedures and instructions.
- Controls for records of activities.

- Corrective action process.
- Audit plans.

The staff's findings from the review of the supplemental information related to this subject area are as follows:

(a) FSAR Subsection 17.4S.1.1, identifies the organizations responsible for establishing the scope of the STP D-RAP and for developing, coordinating, and implementing the D-RAP activities. This section also describes how these organizations interface to ensure that the plant will be designed and constructed to be consistent with the key assumptions and risk insights. However, the staff identified the following additional information as necessary to complete the review of organizational interfaces for the D-RAP. Revision 2 of FSAR Section 17.4S.1 states that the scope of the D-RAP will also include risk-significant SSCs not modeled in the probabilistic risk assessment (PRA). This statement is consistent with the recommendations in SECY-95–132. However, the interface responsibilities of the expert panel described under FSAR Subsection 17.4S.1.1.2 appear to only address risk-significant SSCs modeled in the PRA. The staff issued RAI 17.04-5, requesting the applicant to also address in FSAR Subsection 17.4S.1.1.2 the interface responsibilities of the expert panel related to risk-significant SSCs within the scope of the D-RAP that are not modeled in the PRA.

In its response to RAI 17.04-5, dated September 28, 2009 (ML092730239), the applicant specified that: (1) the interface responsibilities of the expert panel will include ensuring that any proposed changes resulting in an increase in the deterministically established risk of an SSC not modeled in the PRA, are identified and periodically reviewed with the expert panel at a frequency determined by the panel; and (2) FSAR Section 17.4S will be revised, accordingly. The staff found that the applicant's response to RAI 17.04-5, sufficiently addresses the concerns associated with this RAI. The staff confirmed that the proposed revision is incorporated into Revision 4 of FSAR Section 17.4S. Based on the above discussion, RAI 17.04-5 is resolved and closed.

(b) FSAR Subsections 17.4S.1.1 and 17.4S.1.2, provide adequate details on the use of the D-RAP in the design control process. These subsections also discuss the quality controls used for identifying the risk-significant SSCs, including quality controls for the analyses. The configuration control process for maintaining the list of risk-significant SSCs is adequate. In addition, the applicant sufficiently describes how the design control and change process provides a feedback mechanism for notifying the appropriate organizations of changes (e.g., design changes or PRA changes) that could affect the risk-significant SSCs and other D-RAP-related inputs.

(c) FSAR Section 17.4S.6, describes the controls for procedures and instructions used for developing, coordinating, and implementing the D-RAP activities. These controls are specified in Part II (safety-related) and Part III (nonsafety-related, risk-significant) of the applicant's QAPD, as described in FSAR Section 17.5S. In general, where a procedure describes the process for an activity that applies to both safety-related and nonsafety-related SSCs, that procedure will meet the full quality program requirements of Part II. However, the staff identified the following additional information as necessary to complete the review of procedural controls for the D-

RAP. The staff issued RAI 17.04-8, requesting the applicant to provide a plan for the development of the D-RAP implementation procedures.

In its response to RAI 17.04-8, dated September 28, 2009 (ML092730239), the applicant stated that it would develop a D-RAP coordinating procedure to identify the organizational responsibilities, interfaces, and total set of procedures necessary to collectively implement the D-RAP. The staff found that the applicant's response to RAI 17.04-8 sufficiently addresses the staff's concerns associated with this RAI. The staff performed an audit from September 22, 2009, through September 23, 2009 (ML120110172), and verified that the applicant has appropriately implemented the D-RAP activities described above. Based on the above discussion, RAI 17.04-8 is resolved and closed.

(d) FSAR Section 17.4S.7 describes the controls for the D-RAP records. Implementation of the D-RAP is considered to be an activity that will affect quality. Therefore, the generation of records associated with D-RAP activities will meet the requirements in Part II and Part III of the QAPD, which the staff finds acceptable.

(e) FSAR Sections 17.4S.5 and 17.4S.8, describe the process for corrective action applied to the RAP. The corrective action process discussed in the QAPD (see FSAR Section 17.5S) is used to implement corrective actions related to D-RAP activities, including failures of RAP SSCs. The discussion of the review of the QAPD is in Section 17.5S of this SER. In addition, if any RAP SSC, including nonsafety-related RAP SSCs, experience a maintenance rule functional failure, the STP maintenance rule program (see FSAR Section 17.6S) requires the use of the corrective action process to document the failure; determine its cause; and identify the actions taken to preclude a recurrence. Other failures of SSCs that are not maintenance rule functional failures will be documented and corrected as described by the QAPD (see FSAR Section 17.5S)

(f) FSAR Section 17.4S.9 describes the plan for conducting audits of RAP activities. The RAP is collectively accomplished using programs related to the design, procurement, fabrication, construction, and preoperational testing; PRA modeling and risk assessment; deterministic evaluations from the expert panel; the corrective action program; the maintenance rule; technical specifications (TS); and other operational programs. These programs are subject to audits as described in the QAPD.

The staff reviewed the application and checked the referenced DCD. The staff's review confirmed that the applicant has addressed the required information relating to the programmatic controls of the D-RAP, and no outstanding information is expected to be addressed in the COL FSAR related to this section. The staff's review confirmed that the relevant information in the COL FSAR is acceptable and meets the applicable requirements and guidance described in Section 17.4S.3 of this SER.

17.4S.4.2 Methodology for Identifying the Risk-Significant SSCs

The staff reviewed the applicant's detailed process used to maintain, update, and revise the list of risk-significant SSCs. This process is described in FSAR Subsection 17.4S.1.4. The staff performed this review in accordance with Item E of SECY-95–132 and SRP Section 17.4 to

ensure that this subject review area meets the guidance in these documents. Based on Item E of SECY-95–132 and SRP Section 17.4, the application should describe an acceptable methodology for evaluating; identifying; and prioritizing SSCs according to their degree of risk significance; as determined by using a combination of probabilistic, deterministic, or other methods of analysis used to identify and quantify risk. The roles and responsibilities of the expert panel should be described, because the panelists play an important role in reviewing the information associated with determinations of risk significance.

The staff's findings from the review of the supplemental information related to this subject area are as follows:

(a) The initial identification of the site-specific, risk-significant SSCs during the STP, Units 3 and 4, COL FSAR preparations is based on the process described in Appendix 19K of the referenced ABWR DCD. The applicant's process for maintaining, revising, and establishing new risk rankings for a modified design is based on the methodology described in FSAR Subsection 17.4S.1.4; which includes the use of the PRA (FSAR Subsection 17.4S.1.4.1) and deterministic techniques (FSAR Subsection 17.4S.1.4.2). However, the staff identified the following additional information as necessary to complete the review of this methodology. In Revision 2 of FSAR Subsection 17.4S.1.4, SSCs within the scope of the D-RAP are categorized as having either a “High” or “Medium” risk significance, but the FSAR did not provide the PRA criteria for these risk categories. Therefore, the staff issued RAIs 17.04-6 and 17.04-11, requesting the applicant to clarify the criteria for the “High” and “Medium” risk categories.

In its responses to RAI 17.04-6, dated September 28, 2009 (ML092730239), and RAI 17.04-11, dated February 3, 2010 (ML100360834), the applicant stated that the “Medium” risk category will be subsumed within the “High” risk category. Therefore, for the PRA risk ranking of SSCs in FSAR Subsection 17.4S.1.4.1, the applicant proposed to delete the “Medium” risk category and define the “High” risk category by a Fussell-Vessely importance greater than or equal to 0.005; or by a risk achievement worth greater than or equal to 2.0. For the deterministic risk ranking of SSCs in FSAR Subsection 17.4S.1.4.2, the applicant proposed to delete the “Medium” risk category and define the ”High” risk category by a score ranging between 41 and 100; or by a weighted score of 15 or more on any one question.

The staff found the applicant’s proposed changes acceptable. The applicant’s methodology for determining risk-significant SSCs using the PRA, as described in FSAR Subsection 17.4S.1.4.1, is consistent with industry practices and NRC guidance (e.g., RG 1.160, “Monitoring the Effectiveness of Maintenance at Nuclear Power Plants”). The deterministic categorization described in FSAR Subsection 17.4S.1.4.2 is directly attributable to the importance of the system function supported by the components. The deterministic categorization process is implemented by the expert panel and can only result in an increase in a component’s categorization—but not a decrease—relative to the PRA categorization.

The staff found that the applicant’s responses to RAIs 17.04-6 and 17.04-11, sufficiently address the concerns associated with these RAIs. The staff confirmed that the proposed revisions are incorporated into Revision 4 of FSAR Section 17.4S. Based on the above discussion, RAIs 17.04-6 and 17.04-11 are resolved and closed.

(b) FSAR Section 17.4S.1 describes the use of an expert panel in the identification of risk-significant SSCs. To augment PRA techniques for the risk ranking of SSCs, the expert panel implements the deterministic categorization process and evaluates operating experience. The expert panel also acts as a final approver of the list of risk-significant SSCs. FSAR Subsection 17.4S.1.3, describes the qualification requirements for members of the expert panel. At a minimum, the combined expert panel and designated working group (or groups) should include at least three individuals with a minimum of five years of experience at a similar nuclear plant in the areas of operations, maintenance, engineering, QA, and licensing. There should also be at least one individual with a minimum of three years of experience modeling and updating the PRA for a similar nuclear plant. When utilized, expert panel representatives from contracting design organizations are required to have a minimum of three years of experience establishing risk rankings for nuclear plant SSCs using the PRA or deterministic techniques that may include failure modes and effects analyses.

The staff reviewed the application and checked the referenced DCD. The staff's review confirmed that the applicant has addressed the required information relating to the methodology for identifying the risk-significant SSCs, and no outstanding information is expected to be addressed in the COL FSAR related to this section. Based on the above discussion on the methodology for identifying the risk-significant SSCs, the staff concluded that the relevant information in the COL FSAR is acceptable and meets the applicable requirements and guidance described in Section 17.4S.3 of this SER.

17.4S.4.3 List of Risk-Significant SSCs in Scope of the Site-Specific D-RAP

The staff reviewed the list of risk-significant SSCs within the scope of the site-specific D-RAP, which is in Appendix 19K of FSAR Chapter 19. This review was performed in accordance with Item E of SECY-95–132 and SRP Section 17.4 to ensure that this subject review area meets the guidance in these documents. Based on Item E of SECY-95–132 and SRP Section 17.4, the application should identify the risk-significant SSCs within the scope of the site-specific D-RAP based on an acceptable methodology that uses a combination of probabilistic, deterministic, or other methods of analysis used to identify and quantify risk.

The staff's findings from the review of the supplemental information related to this subject area are as follows.

(a) In accordance with 10 CFR 52.79(d)(1), the initial identification of the site-specific, risk-significant SSCs during the FSAR preparation incorporates by reference Appendix 19K of the certified ABWR DCD and includes updates to account for site-specific design information and design departures. This process meets the regulatory requirements and guidance. The completeness of the list of risk-significant SSCs in Appendix 19K of FSAR Chapter 19 is directly attributed to the adequacy of the ABWR DCD PRA and the list of risk-significant SSCs in Appendix 19K of the ABWR DCD, which is subject to 10 CFR 52.63, “Finality of standard design certifications.” As the D-RAP enters the detailed design, procurement, fabrication, and construction phases, the applicant will update and maintain the list of risk-significant SSCs in FSAR Section 17.4S using the methodology described in FSAR Subsection 17.4S.1.4. This methodology augments standard PRA techniques described in FSAR Subsection 17.4S.1.4.1 by employing:

(1) an expert panel, (2) the deterministic technique described in FSAR Subsection 17.4S.1.4.2, and (3) industry operating experience (IOE).

The staff issued RAI 17.04-7, requesting the applicant to provide a plan for updating the list of site-specific, risk-significant SSCs in accordance with the methodology described in FSAR Subsection 17.4S.1.4. The staff also issued RAI 17.04-9, requesting the applicant to evaluate for inclusion in the scope of the D-RAP those SSCs of the high-pressure core flooder (HPCF) system, residual heat removal (RHR) system, reactor building cooling water (RCW) system, and reactor service water (RSW) system, whose common cause failures (CCFs) are not modeled in the ABWR DCD PRA. These RAIs were posed to ensure that the list of risk-significant SSCs is sufficiently complete to support the D-RAP activities during the detailed design, procurement, fabrication, and construction phases.

In its responses to RAIs 17.04-7 and 17.04-9, dated September 28, 2009; April 14, 2010; and May 19, 2010 (ML092730239, ML101090144, and ML101410206, respectively), the applicant stated that the SSCs in the HPCF, RHR, RCW, and RSW systems whose CCFs are not modeled in the ABWR DCD PRA will be evaluated by the D-RAP expert panel. The panel will use a detailed process described in FSAR Subsection 17.4S.1.4. The applicant also stated that the plan calls for developing a D-RAP coordinating procedure to identify the organizational responsibilities, interfaces, and total set of procedures necessary to collectively implement the D-RAP. As stated above, the staff audited the D-RAP coordinating procedure and found it acceptable. The applicant included Commitment 17.4-1 in FSAR Section 17.4S Revision 4 to: (1) complete all of the expert panel system reviews, (2) provide an updated list of the set of D-RAP SSCs, and (3) have the program elements in place to control future D-RAP activities.

The staff found that the applicant's responses to RAIs 17.04-7 and 17.04-9, sufficiently address the staff's concerns associated with these RAIs.

The staff performed several audits to review the records and procedures associated with the applicant's implementation of the D-RAP (ML120110172). The audits also reviewed the list of risk-significant systems within the scope of the D-RAP that were identified using the risk ranking methodology described in FSAR Subsection 17.4S.1.4. Numerous non-PRA modeled systems were added to the D-RAP based on the deterministic method described in FSAR Subsection 17.4S.1.4.2. Although there are subjective elements in the deterministic method (such as the weighting factors and the deterministic criteria), the applicant appears to have applied sound and reasonable judgment in implementing the methodology. Based on the audit findings, the staff concludes that the process for identifying the list of risk-significant systems within the scope of the D-RAP was appropriately implemented and that the list is comprehensive. Therefore, RAIs 17.04-7 and 17.04-9 are resolved and closed.

In FSAR Revision 7 Section 17.4S.1, the applicant closed Commitment 17.4-1. The staff found this action acceptable based on the audit findings (ML120110172) where the applicant has: (1) completed all of the expert panel system reviews; (2) provided a comprehensive list of site-specific risk-significant SSCs; and (3) established program elements to control future D-RAP activities. The site-specific risk-significant SSCs are designated at the system level and supplement the initial list included in

FSAR Appendix 19K. In general, the categorization of a system is determined by the highest categorized system function and the same categorization is given to all components in the system. The list of risk-significant SSCs is documented for use in a quality record ("D-RAP Systems Review," May 25, 2011, STI No. 32962928).

(b) In FSAR Revision 2, Appendix 19K, the description of the risk significance of the circulating water system (CWS) pump circuit breakers was inconsistent. For example, the CWS pump circuit breakers were identified as risk significant in FSAR Section 19K.7 and FSAR Table 19K-4, which incorporate by reference the CWS pump circuit breakers, although they are not identified as risk significant in FSAR Section 19K.11.13. Therefore, the staff issued RAI 17.04-3, requesting the applicant to clarify whether the CWS pump circuit breakers are risk significant and to revise FSAR Appendix 19K.

In its response to RAI 17.04-3, dated September 28, 2009 (ML092730239), the applicant stated that tripping the CWS pumps upon detection of turbine building flooding is not required for flood control. As such, the applicant identified the changes to be made in FSAR Section 19K.7. The staff agreed with these changes. However, the applicant did not address the necessary changes to FSAR Table 19K-4, Revision 2, which identified the CWS pump circuit breakers as risk significant through incorporation by reference of the ABWR DCD. Therefore, the staff issued supplemental RAI 17.04-10, requesting the applicant to revise Table 19K-4 of the STP FSAR accordingly. In its response to RAI 17.04-10, dated February 3, 2010 (ML100360834), the applicant stated that Table 19K-4 of FSAR Chapter 19 would be revised to remove the CWS pump circuit breakers. The staff found that the applicant's response to RAI 17.04-10 sufficiently addresses the concerns associated with this RAI. The staff verified that the applicant has appropriately revised Table 19K-4 in Revision 6 of STP, Units 3 and 4. Based on the above discussion, RAIs 17.04-3 and 17.04-10 are resolved and closed.

(c) In FSAR Revision 2, Appendix 19K, the applicant deleted the following components from Tables 19K-1 and 19K-2; which suggested that these components may no longer be within the scope of the D-RAP:

- Reactor core isolation cooling (RCIC) system pressure sensor PIS-Z605 miscalibrated.
- RCIC Flow Sensor FT-007-2 miscalibrated.
- RHR flow transmitters miscalibrated.
- Level 8 sensors miscalibrated.

However, these deletions are inconsistent with Table 19K-4, "Failure Modes and RAP Activities," of the STP FSAR, which includes these components in the D-RAP through incorporation by reference of Table 19K-4 of the ABWR DCD. Therefore, the staff issued RAI 17.04-2, requesting the applicant to clarify whether these components are within the scope of the D-RAP and, if necessary, to revise FSAR Appendix 19K.

In its response to RAI 17.04-2, dated February 22, 2010 (ML100560112), the applicant stated that the above-mentioned SSCs are considered risk-significant because of the modifications made to the STP plant-specific PRA. These SSCs will

be included in Table 19K-2 and remain in Table 19K-4 of the STP FSAR. The next revision of the FSAR will be revised accordingly. The staff found that the applicant's response to RAI 17.04-2, sufficiently addresses the concerns associated with this RAI. An audit (ML120110172) of the STP plant-specific PRA verified the risk significance of these SSCs. The staff confirmed that the proposed changes are incorporated into FSAR Revision 6. Based on the above discussion, RAI 17.04-2 is resolved and closed.

(d) In FSAR Revision 6, Table 19K-4, the applicant added the portable diesel-driven fire pump to the scope of the RAP, which is an important SSC for reducing risk during hurricane events. A detailed discussion of the importance of the portable diesel-driven fire pump is in Section 19Q.4 of this SER.

The staff reviewed the application and checked the referenced DCD. The staff's review confirmed that the applicant has addressed the required information relating to the list of risk-significant SSCs, and no outstanding information is expected to be addressed in the COL FSAR related to this section. Based on the above discussion on the list of risk-significant SSCs, the staff concluded that the relevant information in the COL FSAR is acceptable and meets the applicable requirements and guidance described in Section 17.4S.3 of this SER.

17.4S.4.4 Quality Assurance for Non-Safety-Related, Risk-Significant SSCs

For the nonsafety-related risk-significant SSCs, the applicant's QAPD related to COL design and construction activities provides QA controls, as described in FSAR Section 17.5S. The controls include establishing appropriate corrective actions for potential design and operational errors that degrade these SSCs. The staff reviewed these QA controls in accordance with Part V, “Non-safety Related SSC Quality Controls,” of SRP Section 17.5. The discussion of this review is in Subsection 17.5S.4.19 of this SER.

17.4S.4.5 Integration of the RAP into Operational Programs

The staff reviewed the proposed process for integrating the RAP into operational programs, which is in FSAR Sections 17.4S.4, 17.4S.5, and 17.4S.8 and addresses COL License Information Item 17.4. The staff performed this review in accordance with Item E of SECY-95-132 and SRP Section 17.4 to ensure that this subject area meets the guidance in these documents. Based on Item E of SECY-95–132 and SRP Section 17.4, the application should propose an acceptable process for integrating reliability assurance activities for risk-significant SSCs into operational programs to meet the objectives of the RAP during plant operations.

The following discussion provides the staff's findings from the review of the supplemental information related to this subject area. The applicant describes the RAP activities during the operations phase through the integration of the RAP into the following programs: maintenance rule, QA, surveillance testing, inservice inspection, and inservice testing. The applicant's proposed process also addresses the establishment of: (1) reliability, availability, or condition performance goals for the risk-significant SSCs; (2) performance and condition monitoring requirements to provide reasonable assurance that risk-significant SSCs do not degrade to an unacceptable condition or level of reliability or availability during plant operations; and (3) QA controls for the nonsafety-related, risk-significant SSCs that include establishing

appropriate corrective actions for potential design and operational errors that degrade these SSCs.

The staff reviewed the application and checked the referenced DCD. The staff's review confirmed that the applicant has addressed the required information relating to the integration of the RAP into operational programs, and no outstanding information is expected to be addressed in the COL FSAR related to this section. On the basis of the above discussion on integrating the RAP into operational programs, the staff concluded that the relevant information in the COL FSAR is acceptable and meets the applicable requirements and guidance described in Section 17.4S.3 of this SER.

17.4S.4.6 D-RAP ITAAC

In accordance with SRP Section 14.3, “Inspections, Tests, Analyses, and Acceptance Criteria,” the application incorporates by reference the D-RAP ITAAC of the ABWR DCD and is therefore acceptable.

17.4S.5 Post Combined License Activities

There are no post COL activities related to this section.

17.4S.6 Conclusion

The staff reviewed Section 17.4S of the STP, Units 3 and 4, COL FSAR in accordance with SECY-95–132 and SRP Section 17.4 and checked the referenced ABWR DCD, Section 17.3. In FSAR Section 17.4S, the applicant addresses COL License Information Items 17.2, 17.3, and 17.4. The staff’s review confirmed that the applicant has adequately addressed the COL license information items relating to the RAP in accordance with SECY-95-132 and SRP Section 17.4, and no outstanding information is expected to be addressed in the COL FSAR related to this section.

17.5S Quality Assurance Program Guidance

17.5S.1 Introduction

This FSAR section of the FSAR addresses the establishment and implementation of a QA Program applicable during the design, fabrication, construction, testing, and operation of nuclear power plants.

17.5S.2 Summary of Application

In Section 17.5S of the STP, Units 3 and 4, COL FSAR Revision 12, the applicant provides a reference to the STP QAPD that is submitted as a separate document. The staff received “Submittal of Quality Assurance Program Description, Revision 6,” dated March 23, 2011 (ML110840628). In STP, Units 3 and 4, FSAR Section 17.5S, the applicant provides the following supplemental information to address the ABWR DCD COL license information items related to the QA Program, as discussed in Sections 17.1 and 17.2 of the STP, Units 3 and 4, COL FSAR:

COL License Information Item

- COL License Information Item 17.1 QA Programs for Construction and Operation

As stated in Sections 17.0, 17.1, and 17.2, this COL license information item addresses QA Programs for construction and operation that meet the requirements of ANSI/ASME NQA-1-1983; NQA-1a–1983; and the quality-related regulatory guides listed in Table 17.0-1 of the DCD.

17.5S.3 Regulatory Basis

The regulatory basis for accepting the resolution to STP, Units 3 and 4, COL Supplemental Information 17.5S is in the Commission's regulatory requirements related to QA Programs, which are set forth in 10 CFR 52.79(a)(25) and 10 CFR Part 50, Appendix B.

In 10 CFR 52.79(a)(25), an application for a COL is required to contain a description of the QA Program applied to the design that will also be applied to the fabrication, construction, and testing of the SSCs of the facility. Furthermore, the description of the QA Program must include a discussion of how the applicable requirements of Appendix B have been and will be satisfied, including a discussion of how the QA Program will be implemented.

Appendix B sets forth the Commission's regulatory requirements related to QA Programs and establishes QA requirements for the design, fabrication, construction, and testing of the facility's SSCs. The pertinent requirements in Appendix B apply to all activities affecting the safety-related functions of these SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying these activities.

17.5S.4 Technical Evaluation

The staff reviewed the conformance of Section 17.5S of the STP, Units 3 and 4, COL FSAR to the guidance in RG 1.206, Regulatory Position C.III.1, Section C.I.17.5, "Quality Assurance Program Guidance."

The staff reviewed and evaluated the STP QAPD Revision 6 to determine whether it meets NRC regulations by following the guidance in SRP Section 17.5. SRP Section 17.5 provides an outline of a QA Program acceptable to the staff for the DC, early site permit (ESP), COL, construction permit, and operating license applicants. The staff developed SRP Section 17.5 using ASME NQA-1–1994, "Quality Assurance Requirements for Nuclear Facility Applications," as supplemented by additional regulatory and industry guidance for nuclear operating facilities. SRP Section 17.5 also addresses additional QA requirements in 10 CFR Part 50, Appendix A, "General Design Criteria for Nuclear Power Plants," General Design Criterion 1 (GDC 1), "Quality standards and records," and 10 CFR 50.34(f)(3)(ii) and (iii). GDC 1 requires that a QA Program be established and implemented. 10 CFR 50.34(f)(3)(ii) and (iii) specify design and construction QA requirements that must be addressed in a QA Program description.

The STP, Units 3 and 4, QAPD is the top-level document that establishes the QA measures to be applied to the activities related to the design, construction, and operation of an ABWR at the STP, Units 3 and 4, sites.

17.5S.4.1 Organization

The STP, Units 3 and 4, QAPD follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Item A, related to organization. The QAPD describes and defines the responsibility and authority for planning, establishing, and implementing an effective overall QA Program. The QAPD also describes an organizational structure; functional responsibilities; levels of authority; and interfaces for establishing, executing, and verifying QAPD implementation. The QAPD establishes an independence between the organization responsible for verifying a function and the organization that performs the function. In addition, the QAPD allows the STP management to size the QA organization commensurate with the assigned duties and responsibilities.

In addition, in the STP, Units 3 and 4, QAPD, the applicant commits to comply with the quality standards for QA organizations described in NQA-1–1994, Basic Requirement 1 and Supplement 1S-1.

The staff issued RAI 17.5-1, requesting the applicant to provide a flow chart to delineate the organizational interfaces and interrelationships between the STP corporate and onsite QA organizations, as required by Section A, "Organization," of SRP Section 17.5. In RAI 17.5-1, the staff also asked the applicant to provide a more detailed organizational description to fully address the organizational structure, functional responsibilities, levels of authority, and interfaces of the STP QA Program.

In its response to RAI 17.5-1, dated May 22, 2008 (ML081480499), the applicant added two flow charts to the QAPD, "STPNOC Organization" and "STPNOC Units 3 & 4 Organization," which the staff reviewed. The staff found that the two flow charts satisfy the guidance of SRP Section 17.5 A and are therefore acceptable. This item is incorporated into Revision 2 of the QAPD and is therefore closed.

In the letter dated January 19, 2011 (ML11020369), STPNOC notified the staff that, effective January 24, 2011, Nuclear Innovation North America LLC (NINA) became the lead applicant for STP, Units 3 and 4. The letter stated that NINA adopted the quality assurance program, policies, procedures, and processes developed by STPNOC for the project and has retained the STPNOC staff. In addition, NINA assumed full responsibility under the COL application and the licenses for responsibilities associated with all previously performed activities. The staff verified that Revision 6 of the QAPD appropriately incorporates the transition from STPNOC to NINA for the design and construction of STP, Units 3 and 4.

17.5S.4.2 Quality Assurance Program

The applicant's QAPD follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Item B, for the QA Program. The QAPD establishes measures that 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 planned and systematic actions that are necessary to provide confidence that the SSCs will perform their intended safety functions, including certain nonsafety-related SSCs and activities that are significant contributors to plant safety, as described in the STP, Units 3 and 4, FSAR. The QA Program requires the maintenance of a list or system identifying SSCs and activities to which the QAPD applies.

The QAPD provides measures that assess the adequacy of the QAPD and 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 two years. In addition, consistent with SRP Section 17.5 SRP Acceptance Criteria Item 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 forward, so that the interval prescribed for the performance of the activity is not exceeded.

The QAPD also follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Items S and T, for training. The QAPD describes measures that 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 a suitable level of proficiency. The plant's TS 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 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 those individuals responsible for planning, implementing, and maintaining the QAPD.

The QAPD also follows SRP Section 17.5, SRP Acceptance Criteria Item W, for independent program reviews. The QAPD provides measures for establishing an independent review program for activities occurring during the operational phase. In the QAPD, the applicant commits to comply with the quality standards for independent reviews 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-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 ASME Boiler and Pressure Vessel Code. The regulation in 10 CFR 50.55a, "Codes and standards," also requires the use of the latest edition and addenda of Sections III and XI. The staff evaluated this proposed alternative and determined that it is consistent with the regulation in 10 CFR Par 50, Appendix B, Criterion II, "Quality Assurance Program." Therefore, the 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 three years. As an alternative to this requirement, the QAPD proposes to follow the guidance in SRP Section 17.5, SRP Acceptance Criteria Item S.4.c, which states that the prospective lead auditor shall demonstrate an 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 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 staff concluded that this alternative is acceptable.

The staff issued RAI 17.5-2, requesting the applicant to clarify references to the applicability of the *Code of Federal Regulations*. Namely, the applicant referenced 10 CFR 52.59 where 10 CFR 52.79 actually applies; 10 CFR 52.79 identifies the technical information the applicant is

required to include in the FSAR. The staff also noted in RAI 17.5-2, that the STP, Units 3 and 4, QAPD references 10 CFR 50.34(b)(6)(ii), which is no longer required.

In its response to RAI 17.5-2, dated May 22, 2008 (ML081480499), the applicant correctly cites 10 CFR 52.79(a)(27) and removes references to 10 CFR 52.59(a)(25) and 10 CFR 50.34(b)(6)(ii). The applicant's action to remove the improper citations and refer only to 10 CFR 52.79 for the FSAR content satisfied the RAI, and the staff found this response acceptable. The applicant then issued a supplemental response to RAI 17.5-2, dated February 3, 2010 (ML100360834), indicating that the reference was deleted in Revision 2 of the QAPD and replaced with "Regulations," in accordance with Nuclear Energy Institute (NEI) 06-14, Revision 7, "Quality Assurance Program Description." The staff found this response and change acceptable. Thus, RAI 17.5-2 is resolved and closed.

The staff issued RAI 17.5-3, requesting the applicant to verify the intent not to implement the exception to Supplement 2S-1 of ASME NQA-1–1994 for the qualification of personnel performing independent quality verification activities and inspection planning and for the evaluation of the capabilities of inspectors or the training program for inspectors, because the exception is omitted from the application.

In its response to RAI 17.5-3, dated May 22, 2008 (ML081480499), the applicant verified that there will be no exception to NQA-1–1994 Supplement 2S-1, as permitted by the NEI 06-14 template. In Revision 2 of the QAPD, the applicant clarified that Supplement 2S-1 will include the use of the guidance in Appendix 2A-1 as if it were part of the supplement. The staff found this response and change acceptable. Thus, RAI 17.5-3 is resolved and closed.

The staff issued RAI 17.5-6, requesting the applicant to provide more detailed descriptions of functional responsibilities within the STP QA Program and to use specific organizational titles throughout the QAPD. In its response dated May 22, 2008, the applicant replaced Part II, Section I of the QAPD with functional responsibilities of the organizational positions shown on the organizational charts submitted in a response to RAI 17.5-1. The staff reviewed the modified QAPD content and issued RAI 17.5-8, which asked the applicant to clarify the response to RAI 17.5-6 by providing a description of the plan for implementing the QAPD during construction and operations. In RAI 17.5-8, the staff also asked the applicant for additional descriptions of STP's organizational structure and positions and requested an explanation of how STP will incorporate future revisions into the NEI template. In its response to RAI 17.5-8, dated October 21, 2008 (ML082970563), the applicant further revised Part II, Section I of the QAPD. This revision included a clear delineation of functional responsibilities from the construction/preoperation phase through the transition to the operations phase. The applicant also provided refined organizational charts to identify the construction/preoperation organization and the organization for "Four Unit Operations." Subsequently, Revision 6 of the QAPD provided an update to the functional responsibilities and organizational charts to reflect the relationship and responsibilities of NINA and STPNOC. The applicant also committed to comprehensively evaluate NRC-approved revisions to the NEI 06-14 and to revise the STP, Units 3 and 4, QAPD to incorporate the applicable changes. The staff reviewed this response and found that the applicant's revised organizational charts and functional descriptions meet the guidance of SRP Section 17.5. These items were incorporated into Revision 2 of the QAPD. Although the commitment to maintain the QAPD so it is current with NEI 06-14 revisions is acceptable to the staff, Revision 2 of the QAPD (submitted September 30, 2009) did not fully address all of the items discussed in the staff's SER (ML092650695) accepting the use of the QAPD template in NEI 06–14, Revision 7. Thus, the staff closed RAI 17.5-6 and RAI 17.5-8,

and issued a follow-up RAI 17.5-9, on February 16, 2010. The resolution of this RAI is discussed in more detail in Subsections 17.5S.4.17 and 17.5S.4.20 of this SER. As indicated in these SER subsections, the staff accepted the applicant's response to this RAI and verified that the applicant has appropriately revised Revision 4 of the FSAR. As a result, RAI 17.5-9 is resolved and closed.

17.5S.4.3 Design Control

The applicant's QAPD follows the guidance of SRP Section 17.5, SRP Acceptance Criteria Item C for design control. The QAPD establishes the necessary measures that 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 QAPD provisions. The QAPD design process includes provisions for controlling design inputs, outputs, changes, interfaces, records, and organizational interfaces with the applicant and the 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 about QA principles to review design documents to ensure that they contain the necessary QA requirements.

In the QAPD, the applicant commits to comply with the quality standards described in NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facility Applications," Basic Requirement 3 and Supplement 3S-1, to establish the program for design control and verification. The applicant also commits to comply with the requirements of Subpart 2.20 for the subsurface investigation requirements and Subpart 2.7 for the standards for computer software QA controls. The staff found these commitments acceptable.

17.5S.4.4 Procurement Document Control

The applicant's QAPD follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Item D for procurement document control. 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 SRP Section 17.5, SRP Acceptance Criteria Item D.1, the 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 the procurement of items and services.

In the QAPD, the applicant 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 the requirements of Appendix B to 10 CFR Part 50, as applicable to the circumstances of the procurement. The staff evaluated this proposed alternative and determined that it is consistent with

Appendix B, Criterion IV, ”Procurement Document Control.” Therefore, the staff concluded that this alternative is acceptable.

– As an alternative to this requirement, the QAPD proposes that procurement documents allow suppliers to work under the applicant’s QAPD, including under the implementation procedures, if suppliers do not have their own QA Program. The staff evaluated this proposed alternative and determined that the applicant’s QAPD follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Item G, “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 procuring products and services, and suppliers are periodically audited and evaluated to ensure that qualified suppliers continue to provide acceptable products and services. Therefore, the staff concluded that this alternative is acceptable.

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

- In the QAPD, the applicant commits to ensuring that procurement documents prepared for commercial-grade items and procured for use as safety-related items shall contain technical and quality requirements, so that the procured item can be appropriately dedicated. The staff evaluated this proposed commitment and determined that it is consistent with staff guidance in Generic Letter 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products,” dated March 21, 1989; and Generic Letter 91-05, “Licensee Commercial-Grade Procurement and Dedication Programs,” dated April 9, 1991; as delineated in SRP Section 17.5, SRP Acceptance Criteria Items U.1.d and U.1.e. Therefore, the staff concluded that this commitment is acceptable.

17.5S.4.5 Instructions, Procedures, and Drawings

The applicant’s QAPD follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Item E, for instructions, procedures, and drawings. 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, the applicant commits to comply with the quality standards for instructions, procedures, and drawings described in NQA-1–1994, Basic Requirement 5 to establish procedural controls.

17.5S.4.6 Document Control

The applicant's QAPD follows the guidance of SRP Section 17.5, SRP Acceptance Criteria Item F, for document control. The QAPD establishes the necessary measures and governing procedures to control the preparation, review, approval, issuance, and revision 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 should 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 the staff guidance in SRP Section 17.5, SRP Acceptance Criteria Item F.8.

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

The staff conducted an inspection of STP's implementation of its QA Program from January 13, 2009, through January 15, 2009. The limited scope of the inspection focused on STP's quality activities during the due diligence assessment to determine whether Toshiba Corporation is qualified to supply the design of the ABWR for STP, Units 3 and 4, in accordance with 10 CFR Part 52, Appendix A. The results of the inspection are documented in NRC Inspection Report Nos. 0520012/2009201 and 0520013/2009201 and Notice of Violation, dated March 2, 2009 (ML090560120). During the inspection, the staff issued Violations 05200012/2009201-01 and 05200013/2009201-01, because the company did not control and identify the procedures that had been implemented and/or developed for STP, Units 3 and 4, COL activities. As of January 16, 2009, the applicant's QA Program did not include a list of procedures for STP, Units 1 and 2, that were found to be applicable for STP, Units 3 and 4, COL activities. The company did not to maintain a complete list of new procedures that had been issued for STP, Units 3 and 4, to supersede those for STP, Units 1 and 2. In a letter dated April 1, 2009 (ML090990607), the staff described the following corrective actions the company had taken to resolve the violations noted above:

(1) Policy U7-AD01-0004, "Units 3 & 4 Procedure Use and Adherence Policy," is written to establish the list of approved procedures for STP, Units 1 and 2, authorized for use in performing STP, Units 3 and 4, activities.

(2) Procedure U7-P-RM02-0001, "Units 3 & 4 Records Management and Document Control," is revised to identify the location of the list of applicable procedures for STP, Units 3 and 4.

The staff also issued Violations 05200012/2009201-02 and 05200013/2009201-02, after identifying that the applicant had failed to maintain the guidance document for procedure numbering as a controlled document. In response to this issue, the applicant revised Procedure U7-P-AD02-0002, "Units 3 & 4 Procedure Development, Review and Approval," to include the STP, Units 3 and 4, procedure numbering scheme. The applicant also added a requirement to

the procedure stipulating that if a "controlled" procedure makes a transition statement to another procedure, the second procedure must also be a "controlled" procedure.

As stated in the staff's letter to the applicant dated April 15, 2009 (ML090990607), the staff reviewed these corrective actions and found them acceptable.

17.5S.4.7 Control of Purchased Material, Equipment, and Services

The applicant's QAPD follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Item G, for the control of purchased material, equipment, and services. The QAPD establishes the necessary measures and governing procedures to control the procurement of items and services that ensure conformance to specified requirements. The program provides measures to evaluate prospective suppliers so that only qualified suppliers are selected. In addition, the program requires the suppliers to be periodically audited and evaluated to ensure that qualified suppliers continue to provide acceptable products and services.

The program provides acceptance actions such as source verification, receipt inspection, pre- and post-installation tests, and the 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 properly reviewed and approved revisions—to ensure that the items are suitable for the intended service and are of an acceptable quality, consistent with their effects on safety.

In the QAPD, the applicant commits to comply with the quality standards for the control of purchased material, equipment, and services described in NQA-1–1994, Basic Requirement 7 and Supplement 7S-1, to establish procurement verification controls with the following exceptions and alternatives:

- NQA-1–1994, Basic Requirement 7 and Supplement 7S-1, states that procurement sources and the performance of suppliers are to be evaluated. As an exception to these requirements, the QAPD proposes that other 10 CFR Part 50 licensees (other than for STP Units 3 and 4), 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 STP, Units 3 and 4, are not required to be evaluated or audited.

  The staff acknowledged that 10 CFR Part 50 licensees, authorized nuclear inspection agencies, the NIST, and other State and Federal agencies perform work under quality programs acceptable to the NRC, and no additional audits or evaluations are required. However, the STP remains responsible for ensuring that procured items or services conform to the Appendix B program, the applicable ASME Boiler and Pressure Vessel Code requirements, and other regulatory requirements and commitments. The applicant also remains responsible for ensuring that the items or services are suitable for the intended application and for documenting the evaluations that support this conclusion. The applicant's proposed exception provides an appropriate level of quality and safety. The staff determined that this exception is acceptable, as documented in a previous safety evaluation (SE) (ML003693241).

- SRP Section 17.5, SRP Acceptance Criteria Item 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 not requiring procurement source evaluation and selection measures, provided that all of the following conditions are met:

  – Purchase documents will impose additional technical and administrative requirements to satisfy QAPD and technical requirements.

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

  – The supplier's accreditation will require a documented review that verifies the following:

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

      a. National Voluntary Laboratory Accreditation Program (NVLAP), administered by NIST.
      b. American Association for Laboratory Accreditation (A2LA).
      c. ACLASS Accreditation Services (ACLASS).
      d. International Accreditation Service (IAS).
      e. Laboratory Accreditation Bureau (L-A-B).

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

    (3) The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, ranges, and uncertainties.

The staff evaluated the NVLAP and A2LA accreditation programs and found them both acceptable (ML052710224). The staff subsequently determined that the accreditation programs of ACLASS, L-A-B, and IAS are also recognized by the ILAC MRA and are therefore acceptable (ML073440472; ML081140564; and ML081330253).

- 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 before 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 STP or its supplier, at a location other than the nuclear facility site, as long as the documents can be accessed at the nuclear facility site during construction. After the construction is completed, sufficient documentary evidence will be made available to the licensee to support operations.

The 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 after use. Therefore, the 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, the applicant commits in the QAPD to follow NRC guidance discussed in Generic Letters 89-02 and 91-05. In SRP Section 17.5, SRP Acceptance Criteria Items U.1.d and U.1.e provide guidance 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 evaluations, receipt requirements, and quality evaluations of the items to ensure that the items are suitable for their intended use.

The staff determined that this alternative will improve the likelihood of detecting counterfeit and fraudulently marked products and will improve the commercial-grade dedication programs. Therefore, the staff concluded that this alternative is acceptable.

17.5S.4.8 Identification and Control of Materials, Parts, and Components

The applicant's QAPD follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Item H, for identification and control of materials, parts, and components (material traceability). The QAPD establishes the necessary measures for identifying and controlling items such as materials, including consumables and other items with a limited shelf life; parts; components; and partially fabricated subassemblies. The identification of items is maintained throughout fabrication, erection, installation, and use so that each item can be traced to its documentation consistent with the item's effect on safety.

In the QAPD, the applicant commits to comply with the quality standards for material traceability described in NQA-1–1994, Basic Requirement 8 and Supplement 8S-1, to establish provisions for identifying and controlling items.

17.5S.4.9 Control of Special Processes

The applicant's QAPD follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Item I, for the control of special processes. 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 the applicable codes, specifications, and standards.

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

17.5S.4.10 Inspection

The applicant's QAPD follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Item J, for inspections. The QAPD establishes the necessary measures to implement inspections to ensure that 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 inspections, and identifying special tools needed to perform the inspection. Properly qualified personnel

independent of those who perform or directly supervise the work are required to perform the inspections.

In the QAPD, the applicant commits to comply with the quality standards for inspection described in 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 Electronics Engineers (IEEE) Standard (Std) 336–1985, "IEEE Standard Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities." IEEE Std 336–1985 refers to IEEE Std 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 Std 603–1980, "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations." IEEE Std 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.

In the QAPD, the applicant must commit to the definition of safety systems equipment from IEEE Std 603–1980 to appropriately implement NQA-1–1994, Subpart 2.4. In the QAPD, the applicant commits to the definition of safety systems equipment from IEEE Std 603-1980 but does not commit to the balance of IEEE Std 603–1980. This definition applies only to equipment in the context of NQA-1–1994, Subpart 2.4. The 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.

17.5S.4.11 Test Control

The applicant's QAPD follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Item K, for test control. 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, the applicant commits to comply with the quality standards for test control described in NQA-1–1994, Basic Requirement 11, and Supplement 11S-1 to establish provisions for testing.

Furthermore, in the QAPD, the applicant commits to comply with the quality standards for software test control described in NQA-1-1994, Supplement 11S-2 and Subpart 2.7, to establish provisions to ensure that computer software used in applications that affect safety will be prepared, documented, verified, tested, and used in a manner that obtains the expected outputs and maintains the configuration control.

17.5S.4.12 Control of Measuring and Test Equipment

The applicant's QAPD follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Item L, for the control of measuring and test equipment (M&TE). The QAPD establishes the necessary measures to control the calibration, maintenance, and use of the M&TE that provides information important to a safe plant operation.

In the QAPD, the applicant commits to comply with the quality standards for M&TE described in NQA-1–1994, Basic Requirement 12 and Supplement 12S-1, to establish provisions for controlling the M&TE with the following clarifications and exceptions:

- 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 M&TE is found to be out of the required accuracy limits (i.e., out of tolerance) during calibration. The staff determined that this clarification for out-of-calibration conditions is consistent with Supplement 12S-1. Therefore, the staff concluded that this clarification is acceptable.

- As an alternative to 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 the required calibration information because of equipment size or configuration, the required calibration information will be documented and traceable to the equipment. The staff determined that this alternative is consistent with the guidance in SRP 17.5, SRP Acceptance Criteria Item L.3. Therefore, the staff concluded that this alternative is acceptable.

17.5S.4.13 Handling, Storage, and Shipping

The applicant's QAPD follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Item M, for handling, storage, and shipping. 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, the applicant commits to comply with the quality standards for handling, storage, and shipping in NQA-1–1994, Basic Requirement 13 and Supplement 13S-1, to establish provisions for handling, storage, and shipping. In the QAPD, the applicant also commits to comply with NQA-1–1994 Subparts 2.1, 2.2, and 3.2; and Appendix 2.1, with the following clarifications and exceptions:

- In 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 the personnel authorized to access storage areas and to record personnel access. However, the QAPD proposes not to consider these documents as quality records. As an alternative, the applicant will retain these documents in accordance with plant administrative controls. The staff determined that these records did not meet the classification of a quality record as defined in NQA-1–1994 Supplement 17S-1, Section 2.7. Therefore, the staff concluded that this alternative is acceptable.

- In NQA-1–1994 Subpart 2.2, Section 7.1 refers to Subpart 2.15 for requirements related to the handling of items. The QAPD clarifies that the scope of Subpart 2.15 includes hoisting, rigging, and transporting items for nuclear power plants during construction.

The staff determined that this clarification is acceptable because it distinguishes between the requirements for construction and operations.

- In NQA-1–1994 Subpart 3.2, Appendix 2.1 provides guidance on cleaning fluid systems and associated components for nuclear power plants. The QAPD commits to conform to the precautions identified in Section 3 of Appendix 2.1 in accordance with RG 1.37, Revision 1, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants," and to add a suitable chloride stress-cracking inhibitor to fresh water used to flush systems containing austenitic stainless steels. The staff concluded that these commitments are consistent with NRC guidance and are thus acceptable.

- The QAPD adds the clarification that the water quality for final flushes of fluid systems and associated components shall be at least equivalent to the quality of the operating system water. The staff determined that this clarification is acceptable in meeting the guidance of RG 1.37 Regulatory Position C.2, which is not covered by the commitment to NQA-1-1994 Subpart 2.1.

The staff issued RAI 17.5-7, requesting the applicant, as an administrative improvement, to properly categorize commitments and exceptions to NQA-1-1994 under the appropriate subparts. In its response to RAI 17.5-7, dated May 22, 2008 (ML081480499), the applicant revised the STP, Units 3 and 4, QAPD to add a bullet labeled “NQA-1–1994, Subpart 3.2” to properly classify commitments and exceptions to NQA-1–1994. The staff reviewed this response and found the proposed change acceptable. The staff verified that the applicant has appropriately revised Revision 4 of the FSAR. As a result, RAI 17.5-7 is resolved and closed.

17.5S.4.14 Inspection, Test, and Operating Status

The applicant’s QAPD follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Item N, on the inspection, testing, and operating status of items subject to QA oversight. The QAPD establishes the necessary measures to identify the inspection, testing, and operating status of items and components subject to the provisions of the QAPD to maintain personnel and reactor safety and to avoid the inadvertent operation of equipment.

In the QAPD, the applicant commits to comply with the quality standards in this area, as described in NQA-1–1994, Basic Requirement 14, to establish control over/of activities related to their inspection, testing, and operating status.

17.5S.4.15 Nonconforming Materials, Parts, or Components

The applicant’s QAPD follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Item O, for nonconforming materials, parts, or components. 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 the operability of quality SSCs to ensure that the final condition does not adversely affect the safety, operation, or maintenance of the item or service. The results from evaluations of conditions that adversely affect quality are analyzed to identify quality trends documented and reported to upper management, in accordance with the applicable procedures.

In addition, the QAPD establishes the necessary measures to implement the requirements of 10 CFR Part 52, 10 CFR 50.55(e), and 10 CFR Part 21, as applicable.

In the QAPD, the applicant commits to comply with the standards of quality for nonconforming materials, parts, or components described in NQA-1–1994, Basic Requirement 15 and Supplement 15S-1, to establish measures for nonconforming materials.

17.5S.4.16 Corrective Action

The applicant's QAPD follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Item P, for corrective action programs. The QAPD establishes the necessary measures to promptly identify, control, document, classify, and correct conditions that adversely affect quality. The QAPD requires personnel to identify known conditions that adversely affect quality. Reports of conditions that adversely affect quality are analyzed to identify trends. Significant conditions that adversely affect quality are documented and reported to the responsible management. In the case of suppliers working on safety-related activities or in similar situations, the applicant may delegate specific responsibilities for the Corrective Action Program, but the applicant is responsible for the program's effectiveness.

In addition, the QAPD establishes the necessary measures to implement the requirements of 10 CFR Part 52, 10 CFR 50.55, and 10 CFR Part 21, as applicable.

In the QAPD, the applicant commits to comply with the standards of quality for corrective actions described in NQA-1–1994 Basic Requirement 16 to establish a Corrective Action Program.

The staff conducted an inspection of the applicant's implementation of its QA Program from January 13, 2009, through January 15, 2009. The limited-scope inspection focused on the applicant's quality activities during the due diligence assessment to determine whether Toshiba Corporation is qualified to supply the design of the ABWR for STP, Units 3 and 4, in accordance with 10 CFR Part 52, Appendix A. The results of the inspection are documented in NRC Inspection Report Nos. 0520012/2009201 and 0520013/2009201 and Notice of Violation, dated March 2, 2009 (ML090560120).

During the inspection, the staff issued Violations 05200012/2009201-03 and 05200013/2009201-03, because STP Procedure Number U7-P-AD02-0003, "STP Units 3 & 4 Corrective Action and Tracking Program," Revision 0, dated November 20, 2008, did not include any instructions for the notification of appropriate levels of management in the event that a significant condition that adversely affects quality is identified. The staff also noted that Procedure U7-P-AD02-0003 requires the implementation of at least one corrective action to address the root cause of significant conditions that adversely affect quality. But the procedure does not specify that the corrective action should be implemented to preclude a recurrence. In its response to Violations 05200012/2009201-03 and 05200013/2009201-03, dated April 1, 2009, the applicant states that it has revised STP Procedure Number U7-P-AD02-0003, to add the requirement for notification of the appropriate division manager in the event of a significant adverse condition and to revise procedural wording to specify that corrective actions shall be developed to correct or eliminate the root cause(s) and to preclude a recurrence. As discussed in the staff inspection closeout letter to the applicant dated April 15, 2009 (ML090990607), the staff reviewed these corrective actions and found them acceptable.

17.5S.4.17 Quality Assurance Records

The applicant's QAPD follows the guidance in SRP Section 17.5, SRP Acceptance Criteria Item Q, for QA records. The QAPD establishes the necessary measures to ensure that

sufficient records of items and activities affecting quality are generated, identified, retained, maintained, and able to be retrieved.

In establishing measures to ensure that sufficient records of completed items and activities affecting quality are appropriately stored, the QAPD stated that the records and retention times are based on Regulatory Position C.2 and Table 1 of RG 1.28, Revision 3, "Quality Assurance Program Criteria (Design and Construction)." However, the QAPD did not provide a list of records and retention times or commit to those sections of RG 1.28. The staff issued follow-up RAI 17.5-9, on February 16, 2010, requesting the applicant to provide a list of records and retention times or commit to Regulatory Position C.2 and Table 1 of RG 1.28, Revision 3. In its response to RAI 17.5-9, dated March 17, 2010 (ML100770388), the applicant included a commitment to revise Part II Section 17.1 of the QAPD to commit to Regulatory Position C.2 and Table 1 of RG 1.28. The staff found that the response to this part of RAI 17.5-9 and the proposed changes adequately satisfy the guidance of SRP Section 17.5 and are therefore acceptable. The staff verified that the applicant has appropriately revised the QAPD. As a result, RAI 17.5-9 is resolved and closed.

Concerning the use of electronic records storage and retrieval systems, the QAPD conforms to NRC guidance in Generic Letter 88-18, “Proposed Final NRC Generic Letter 88-18, Supplement 1, Guidance on Managing Quality Assurance Records in Electronic Media,” dated September 13, 1999; Regulatory Issue Summary 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, “Authentication of Records and Media”; TG 15-1998, “Management of Electronic Record”; TG 16-1998, “Software Configuration Management and Quality Assurance”; and TG 21-1998, “Electronic Records Protection and Restoration.”

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

- In 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 staff determined that this alternative is acceptable as documented in a previous SE (ML052360625).

17.5S.4.18 Quality Assurance Audits

The applicant’s QAPD follows the guidance of SRP Section 17.5, SRP Acceptance Criteria Item R, for QA audits. The QAPD establishes the necessary measures to implement audits verifying 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.

As stated in the QAPD, the COL applicant or licensee conducts periodic internal and external audits. The purpose of internal audits is to determine that the program and procedures being

audited comply with the QAPD. Internal audits are performed with a frequency commensurate with the safety significance of the program or procedure and in a manner that ensures a complete audit of all applicable QA Program elements in each functional area, within a period of two years after the determination that the program is well-established. External audits determine the adequacy of a supplier's or contractor's QA Program.

The applicant ensures that audits are documented and audit results are reviewed. In accordance with the QAPD, the COL applicant will respond to all audit findings and initiate appropriate corrective actions. In addition, where corrective actions are indicated, the applicant documents the follow-up of applicable areas through inspections, reviews, re-audits, or other appropriate means for verifying the implementation of assigned corrective actions.

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

The staff conducted an inspection of the applicant's implementation of its QA Program from January 13, 2009, through January 15, 2009. The limited-scope inspection focused on quality activities during the due diligence assessment to determine whether Toshiba Corporation is qualified to supply the design of the ABWR for STP, Units 3 and 4, in accordance with 10 CFR Part 52, Appendix A. The results of the inspection are documented in NRC Inspection Report Nos. 05200012/2009201 and 05200013/2009201 and Notice of Violation, dated March 2, 2009 (ML090560120).

During the inspection, the staff issued Violations 05200012/2009201-04 and 05200013/2009201-04, because of the applicant's failure to enter recommendations from a November 2008 audit into the STP Action Tracking System as required by Procedure U7-P-QP02-0003, "Units 3 & 4 Internal Audits," Revision 1, dated October 6, 2008. In response to the violation, the applicant entered the recommendations into the ABWR Corrective Action Program and conducted group training to reiterate the procedural requirements to staff members. As discussed in the staff's inspection closeout letter to the applicant dated April 15, 2009 (ML090990607), the staff reviewed these corrective actions and found them acceptable.

17.5S.4.19 NonSafety-Related SSC Quality Assurance Controls

17.5S.4.19.1 NonSafety-Related SSCs – Significant Contributors to Plant Safety

The applicant's QAPD follows the guidance of SRP Section 17.5, SRP Acceptance Criteria Item V.1, on controls related to nonsafety-related SSCs. The QAPD establishes program controls applied to nonsafety-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 that targets the characteristics or critical attributes rendering the SSC a significant contributor to plant safety, in a context that is consistent with the applicable sections of the QAPD.

The staff issued RAI 17.5-5, requesting the applicant to identify and explain the process for utilizing knowledgeable personnel to perform the verification function within the applicant's organization, as delineated in STP QAPD Part III Section 1.10, "Inspection." In its response to RAI 17.5-5, dated May 22, 2008 (ML081480499), the applicant clarified that knowledgeable personnel will perform inspections to verify conformance of an item or activity to specified

requirements or to verify that activities are satisfactorily accomplished. The staff reviewed the applicant's response and found it acceptable in that it demonstrates conformance with SRP Section 17.5, SRP Acceptance Criteria Item V, "Nonsafety-Related SSC Quality Controls." Therefore, RAI 17.5-5 is resolved and closed.

17.5S.4.19.2 NonSafety-Related SSCs Credited for Regulatory Events

The applicant's QAPD follows the guidance of SRP Section 17.5, SRP Acceptance Criteria Item V.2, to establish the quality requirements for nonsafety-related SSCs credited for regulatory events. In the QAPD, the applicant commits to conform to the following regulatory guidance:

- The applicant shall implement quality provisions for the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in RG 1.189, Revision 2, "Fire Protection for Operating Nuclear Power Plants," dated April 2001.

- The applicant shall implement quality provisions for anticipated transient without scram (ATWS) equipment in accordance with Generic Letter 85–06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related," dated January 1985.

- The applicant 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," dated August 1988.

17.5S.4.20 Regulatory Commitments

The applicant's QAPD follows the guidance of SRP Section 17.5, SRP Acceptance Criteria Item U, for describing regulatory commitments. The QAPD establishes QA Program commitments. In the QAPD, the applicant commits to conform to the following NRC regulatory guides and other QA standards to supplement and support the QAPD, with the noted clarifications and alternatives.

The staff issued RAI 01-14, because FSAR Section 1.9S, "Conformance with Regulatory Criteria," did not address RGs related to QA. The staff requested the applicant to provide a list indicating conformance with, or exceptions to, these RGs. In its response to RAI 01-14, dated October 29, 2009 (ML093430301), the applicant included a list of conformances and exceptions as well as an excerpt from the QAPD, Revision 2, Part IV, "Regulatory Commitments." However, the regulatory guides listed in Section 1.9S and in Part IV of the QAPD were inconsistent. Therefore, the staff issued follow-up RAI 17.5-9, dated February 16, 2010, requesting the applicant to clarify FSAR Section 1.9S and Part IV of the QAPD as appropriate. In its response to RAI 17.5-9, dated March 17, 2010 (ML100770388), the applicant included proposed revisions to FSAR Tables 1.9S-1, "Site-Specific Conformance with Regulatory Guides," and 1.9S-2, "Conformance with Regulatory Guides Noted as "COL Applicant" in DCD," that reference Part IV of the QAPD to address conformance. The staff found the applicant's response to this part of RAI 17.5-9, and the proposed changes acceptable. The staff verified that the applicant has appropriately revised Revision 4 of the STP, Units 3 and 4 FSAR. As a result, RAI 17.5-9 is resolved and closed.

The following lists the NRC RGs and QA standards that support the QAPD:

- RG 1.8, Revision 3, “Qualification and Training of Personnel for Nuclear Power Plants.”

- The QAPD states that Regulatory Positions C.1.1 through C.1.4, C.2.2 through C.2.10, and C.2.13 are in Chapter 13. Additional details are located in Chapter 13 of this SER. The QAPD states that alternatives to and exceptions for education and experience regarding QA personnel addressed by Regulatory Position C.2.1 are discussed in Section 2.6. The QAPD identifies alternatives to Regulatory Positions 2.11 and 2.12 in Section 2.8 as accepted by the staff in a previous SER (ML070510300). The QAPD identifies alternatives to Regulatory Positions 2.14 and 2.15 in Section 2.7 as accepted by the staff in a previous SER (ML070510300). The staff reviewed these clarifications and alternatives and found them consistent with the guidance in SRP Section 17.5, and therefore find them to be acceptable.

- RG 1.26, Revision 3, “Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants.”

- The QAPD states that the applicant conforms to the applicable regulatory positions in FSAR Section 3.2 and the ABWR DCD, Section 3.2. Additional details are in Chapter 3 of this SER. The staff reviewed this clarification and found it consistent with the guidance in SRP Section 17.5 and therefore acceptable.

- RG 1.28, Revision 3, “Quality Assurance Program Requirements (Design and Construction).”

- The QAPD identifies an alternative to Regulatory Position C.1 in Section 2.8 as accepted in a previous SER (ML070510300). The QAPD states that Regulatory Positions C.3.1 and C.3.2 are addressed in Sections 18.2 and 7.1, respectively. The staff reviewed these clarifications and alternatives and found them consistent with the guidance in SRP Section 17.5 and therefore acceptable.

- The QAPD states that Regulatory Position C.2 is discussed in Section 17.1. Section 17.1 stated that the records and retention times are based on Regulatory Position C.2 and Table 1 of RG 1.28, Revision 3, but this section did not provide a list of records and retention times or commit to those sections of the regulatory guide. The staff issued RAI 17.5-9, requesting the applicant to provide a list of records and retention times or commit to Regulatory Position C.2 and Table 1 of RG 1.28, Revision 3. In its response to RAI 17.5-9, dated March 17, 2010 (ML100770388), the applicant included a commitment to revise Part II, Section 17.1 of the QAPD to commit to RG 1.28 Regulatory Position C.2 and Table 1. The staff found that the response to this part of RAI 17.5-9, and the proposed changes adequately satisfy the guidance of SRP 17.5. Therefore, the staff found this change acceptable. The staff verified that the applicant has appropriately revised the QAPD. As a result, RAI 17.5-9 is resolved and closed.

- RG 1.29, Revision 3, “Seismic Design Classification.”

- The QAPD states that STPNOC conforms to the applicable regulatory positions in FSAR Section 3.2 and the ABWR DCD, Section 3.2. Additional details are located in Chapter 3 of this SER. The staff noted that the applicant lists conformance with RG 1.29 Revision 4, issued in March 2007, in FSAR Chapter 1, Table 1.9S-1, “Site-Specific Conformance with Regulatory Guides.” The staff issued RAI 17.5-9, requesting the applicant to clarify

FSAR Section 1.9S and Part IV of the QAPD as appropriate. In its response to RAI 17.5-9, dated March 17, 2010 (ML100770388), the applicant includes a proposed revision in Part IV to the QAPD correcting the reference to RG 1.29, Revision 4. The staff found that the response to this part of RAI 17.5-9, and the proposed changes adequately satisfy the guidance of SRP 17.5. Therefore, the staff found these changes acceptable. The staff verified that the applicant has appropriately revised the QAPD. As a result, Confirmatory Item 17.5-9 is resolved and closed.

- RG 1.33, Revision 2, "Quality Assurance Program Requirements."

- The QAPD states that Regulatory Position C.1 is discussed in Chapter 13 of the FSAR. Additional details are located in Chapter 13 of this SER. The QAPD identifies an alternative to Regulatory Position C.3 by addressing independent review requirements in Section 2.7 of the QAPD. The staff reviewed these clarifications and alternatives and found them consistent with the guidance in SRP Section 17.5, and therefore acceptable.

- The QAPD identifies an alternative to Regulatory Position C.2 by committing to NQA-1-1994 in the QAPD, rather than the ANSI N45.2 series standards listed in the RG. However, the RG also lists ANSI standards other than the N45.2 series. The staff issued RAI 17.5-9, requesting the applicant to describe how the applicant meets each standard listed in the RG. In its response to RAI 17.5-9, dated March 17, 2010 (ML100770388) the applicant stated that the other ANSI standards listed in Regulatory Position C.2 are addressed by other regulatory guides or have been withdrawn. The staff finds the applicant's response acceptable.

- The QAPD identifies an alternative to Regulatory Position C.4 by committing to comply with the quality standard described in NQA-1-1994, Basic Requirement 18 and Supplement 18S-1. The QAPD also identifies an alternative to Regulatory Position C.5 by providing adequate guidance for establishing a QA Program that complies with 10 CFR Part 50, Appendix B, by using NQA-1–1994 supplemented by additional regulatory and industry guidance identified in SRP Section 17.5. The staff issued RAI 17.5-9, requesting the applicant to demonstrate that the QAPD incorporates all of the administrative controls in ANSI N18.7–1976 not included in NQA-1–1994, by developing a line-by-line comparison of ANSI N18.7–1976, the QAPD, and NQA-1-1994 similar to comparisons prepared by operating reactor licensees to support the adoption of NQA-1-1994. In its response to RAI 17.5-9, dated March 17, 2010 (ML100770388), the applicant included a commitment to update the QAPD in accordance with the next revision of NEI 06-14A. The staff issued an SER dated July 13, 2010 (ML101800497), approving NEI 06–14 Revision 9, which was reissued as NEI 06-14A, Revision 7, dated August 10, 2010 (ML102370299). Therefore, the staff found this response acceptable. The staff verified that the applicant has appropriately revised the QAPD. As a result, RAI 17.5-9 is resolved and closed.

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

- The staff issued RAI 17.5-4, requesting the applicant to clarify why RG 1.37 was referenced in Section 13.2 of the QAPD but was not identified as a commitment in Part IV, "Regulatory Commitments," of the STP QAPD. In its response to RAI 17.5-4, dated May 22, 2008 (ML081480499), the applicant revised Part IV of the QAPD to include RG

1.37 as a commitment. The staff reviewed this response and found it acceptable. This item was incorporated into Revision 2 of the QAPD. Therefore, this RAI is closed. The QAPD states that Chapter 1 of the FSAR addresses conformance with, and alternatives and exceptions to, the codes, standards, and other documents identified in Regulatory Position C.1. Additional details are located in SER Chapter 1, "Conformance with Regulatory Criteria." The QAPD states that Regulatory Positions C.2 and C.3 commitments are addressed in Section 13.2. Further details are located in SER Section 13.2. The staff reviewed these clarifications and alternatives and found them consistent with the guidance in SRP Section 17.5 and therefore acceptable.

- ASME NQA-1–1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, as described above in this SER section.

- In Section 13.2 of the QAPD, the staff identified that a commitment is made to NQA-1–1994, Part III. The staff issued RAI 17.5-9, requesting the applicant to add a commitment to Part III to the commitment to NQA-1-1994 in Section IV of the QAPD. In its response to RAI 17.5-9, dated March 17, 2010 (ML100770388), the applicant included a proposed revision to Part IV of the QAPD that adds a commitment to ASME NQA-1–1994 Part III. The staff found that the response to this part of RAI 17.5-9, and the proposed changes adequately satisfy the guidance of SRP 17.5 and are therefore acceptable. The staff verified that the applicant has appropriately revised the QAPD. As a result, RAI 17.5-9 is resolved and closed.

- NIRMA technical guides, as described in Subsection 17.5.4.17 of this SER.

17.5S.5 Post Combined License Activities

There are no post COL activities related to this section.

17.5S.6 Conclusion

The staff reviewed Section 17.5S of the STP, Units 3 and 4, COL FSAR and the STP, Units 3 and 4, QAPD. The staff's review of the STP, Units 3 and 4, QAPD, Revision 2, is based on the review of 10 CFR 52.79(a)(25); 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"; and SRP Section 17.5. The staff's review found the STP, Units 3 and 4, QAPD is acceptable.

The staff reviewed the STP, Units 3 and 4, QAPD and concluded the following:

- The STP, Units 3 and 4, QAPD adequately describes the authority and responsibility of management and supervisory personnel, performance/verification personnel, and audit personnel.

- The STP, Units 3 and 4, QAPD adequately provides that organizations and persons responsible for performing the verification and audit functions have the authority and independence to conduct their activities without undue influence from those directly responsible for costs and schedules.

- The STP, Units 3 and 4, QAPD adequately applies to activities and items that are important to safety.

- The STP, Units 3 and 4, QAPD adequately describes the program for the QA treatment of nonsafety-related SSCs.

- The STP, Units 3 and 4, QAPD adequately describes a philosophy and controls that, when properly implemented, comply with the requirements of 10 CFR 50.34(f)(3)(ii) and (iii) pursuant to 10 CFR 52.79(a)(17); Appendix B to 10 CFR Part 50 pursuant to 10 CFR 52.79(a)(25); and GDC 1 of Appendix A to 10 CFR Part 50.

- FSAR Section 17.5S is identified in Table 13.4S-1, "Operational Programs Required by NRC Regulation and Program Implementation," and the operational phase of the QAP will be implemented 30 days before the scheduled date for initial fuel loading, in compliance with 10 CFR 50.54(a)(1).

Therefore, the staff concluded that the STP, Units 3 and 4, QAPD adequately describes the applicant's QA Program. Accordingly, the staff concluded that the STP, Units 3 and 4, QAPD complies with the applicable NRC regulations and industry standards and can be used for COL activities.

17.6S Maintenance Rule Program

17.6S.1 Introduction

This FSAR section addresses the program for Maintenance Rule implementation based on the requirements of 10 CFR 52.79(a)(15) and 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants"; and on the guidance in RG 1.160, Revision 2 and RG 1.182, Revision 0. RG 1.160, Revision 2 endorses Nuclear Management and Resource Council (NUMARC) 93–01, Revision 2, "Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," which provides one acceptable method for implementing the Maintenance Rule. RG 1.182, Revision 0 is a companion guide to RG 1.160, Revision 2 and provides guidance on implementing the provisions of 10 CFR 50.65(a)(4) by endorsing the February 22, 2000, revision to Section 11 of NUMARC 93-01, as documented in SECY-00-0074, "Regulatory Guide for Assessing and Managing Risk Before Maintenance Activities at Nuclear Power Plants."

17.6S.2 Summary of Application

Section 17.6S of the STP, Units 3 and 4, FSAR Revision 12 incorporates by reference NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52." In addition, in FSAR Section 17.6S, the applicant provides the following:

Supplemental Information

- Subsection 17.6S.1.1b

The correct reference to the D-RAP in NEI 07–02A, paragraph 17.X.1.1.b will be "(DRAP - see FSAR Section 17.3 and 17.4S)."

- Subsection 17.6S.1.2

The correct reference to preventative maintenance per 10 CFR 50.65(a)(2) in NEI 07–02A, paragraph 17.X.1.2 will be "(ref. Section 17.6S.1.3)."

- Subsection 17.6S.1.3

The correct reference to risk assessment and risk management per 10 CFR 50.65(a)(4) in NEI 07–02A, paragraph 17.X.1.3 will be "(ref. Section 17.6S.1.5)."

- Section 17.6S.3

The COL license information item in Section 17.X.3 of NEI 07–02A is addressed in Section 17.6S.3 of the FSAR by describing the operational programs that assure reliability during the operations phase.

17.6S.3 Regulatory Basis

The regulatory basis of the information incorporated by reference is in the staff's SER dated January 24, 2008 (ML073650081), for Topical Report NEI 07–02A. NEI 07–02A provides a complete generic program description for use in developing the section of the COL FSAR associated with Section 17.6 of NUREG–0800.

The regulatory basis for accepting the Maintenance Rule Program is in 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants," and 10 CFR 52.79(a)(15), which requires a COL FSAR to contain a description of the program and its implementation for monitoring the effectiveness of maintenance necessary to meet the requirements of 10 CFR 50.65.

17.6S.4 Technical Evaluation

The staff reviewed FSAR Section 17.6S and checked the referenced Topical Report NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," template guidance to ensure that the combination of the information in the NEI 07-02A template guidance and the information in the COL application represents the complete scope of information relating to this review topic. The staff's review confirmed that the information in the application and the information incorporated by reference address the required information relating to this section.

The staff's findings from the review of the supplemental information related to this subject area are as follows:

1. FSAR Revision 2, Section 17.6S incorporates by reference the NEI template guidance with supplemental information. However, the text in the NEI template guidance is generically numbered as "17.X." The staff issued RAI 17.06-1, requesting the applicant to provide supplemental information in the FSAR to address the formatting change of the section numbers (e.g., Section "17.X" will be changed to Section "17.6S"), as a result of incorporating by reference the NEI template guidance.

   In its response to RAI 17.06-1, dated September 8, 2009 (ML092530407), the applicant stated that FSAR Section 17.6S would be revised as follows to address the numbering convention utilized:

The numbering convention utilized by the NEI Template is maintained in this Section, with "6S" substituted for "X," where it appears in the template numbering.

The staff found that the applicant's response to RAI 17.06-1, sufficiently addresses the concerns associated with this RAI. The staff confirmed that the proposed revision was incorporated into Revision 4 of the FSAR, Section 17.6S. Based on the above discussion, RAI 17.06-1 is resolved and closed.

2. FSAR Revision 2, Section 17.6S, incorporates by reference the NEI 07-02 template guidance. However, according to NEI 07–02A, which incorporates the NRC's revised SER endorsing NEI 07–02, IOE should be applied to various elements of the Maintenance Rule Program and procedure. Therefore, the Maintenance Rule Program should utilize IOE (where appropriate) for scoping, developing performance/condition criteria, monitoring, goal-setting, performing corrective actions, training, and assessing the program, in addition to maintenance and procurement activities. The staff issued RAI 17.06-2, requesting the applicant to justify the exclusion of IOE in FSAR Revision 2 Section 17.6S or revise this section to reflect conformance with NEI 07–02A guidance and its revised SER.

   In its response to RAI 17.06-2, dated September 8, 2009 (ML092530407), the applicant stated that FSAR Section 17.6S would be revised to adopt NEI 07–02A guidance and its revised SER. The staff found that the applicant's response to RAI 17.06-2 sufficiently addresses the concerns associated with this RAI. The staff confirmed that the proposed revisions were incorporated into Revision 4 of the FSAR, Section 17.6S. Based on the above discussion, RAI 17.06-2 is resolved and closed.

The staff reviewed the following information in the COL FSAR:

Supplemental Information

- Subsection 17.6S.1.1b

The applicant's action to change the phrase in paragraph 17.X.1.1.b of NEI 07–02A from "(DRAP - see FSAR Section 17.Y)" to "(DRAP - see FSAR Section[s] 17.3 and 17.4S)," is editorial in nature and is acceptable.

- Subsection 17.6S.1.2

The applicant's action to change the phrase in paragraph 17.X.1.2 of NEI 07–02A from "(ref. Section 17.X.1.3)" to "(ref. Section 17.6S.1.3)," is editorial in nature and is acceptable.

- Subsection 17.6S.1.3

The applicant's action to change the phrase in paragraph 17.X.1.3 of NEI 07–02A from "(ref. Section 17.X.1.5)" to "(ref. Section 17.6S.1.5)," is editorial in nature and is acceptable.

- Section 17.6S.3

The applicant describes the Maintenance Rule Program relationship with the RAP activities in FSAR Section 17.6S.3. The applicant states that the reliability of the SSCs during the

operations phase is assured through the implementation of operational programs, including the maintenance rule program, QA Program, Inservice Inspection and Testing Programs, TS Surveillance Test Program, and the Preventative Maintenance Program. The staff finds that the applicant has satisfactorily addressed the COL license information item in Section 17.X.3 of NEI 07–02A.

The staff reviewed the application and checked the referenced NEI 07–02A template guidance. The staff's review confirmed that the applicant has addressed the required information relating to the maintenance rule program. The License Condition for the Maintenance Rule Program is in Section 17.6S.5, "Post Combined License Activities," of this SER. No outstanding information is expected to be addressed in the COL FSAR related to this section. Based on the above discussion on the Maintenance Rule Program, the staff concluded that the relevant information in the COL FSAR is acceptable and meets the applicable requirements described in Section 17.6S.3 of this SER.

17.6S.5 Post Combined License Activities

License Condition (17-1)

> No later than 12 months after issuance of the COL, the licensee shall submit to the Director of NRO a schedule that supports planning for and conduct of NRC inspections of the Maintenance Rule Program. The schedule shall be updated every 6 months until 12 months before scheduled initial fuel loading, at which point the schedule shall be updated every month thereafter until the maintenance rule program has been fully implemented.

17.6S.6 Conclusion

The staff reviewed Section 17.6S of the STP, Units 3 and 4, COL FSAR and checked the referenced NEI 07–02A template guidance. The staff's review confirmed that the applicant has addressed the required information relating to the Maintenance Rule Program. Based on the discussion in Section 17.6S.4 of this SER on the Maintenance Rule Program, the staff concluded that the relevant information in the COL FSAR is acceptable and meets the requirements of 10 CFR 52.79(a)(15) and 10 CFR 50.65.