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 STP Nuclear Operating Company (STPNOC) Units 3 and 4 Advanced Boiling-Water Reactors (ABWRs).

17.0 Introduction

This section of the FSAR addresses COL license 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.

Section 17.0 of the South Texas Project (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, Appendix A, with no departures.

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 ABWR and the QA Program for procurement, fabrication, installation, construction, and testing of the structures, systems, and components (SSCs) in the facilities. In addition, this section addresses the QA Program implemented during the COL development.

17.1.2 Summary of Application

Section 17.1 of the STP Units 3 and 4 COL FSAR incorporates by reference Section 17.1 of the certified ABWR DCD, Revision 4, referenced in 10 CFR Part 52, Appendix A, with no departures.

In addition, in FSAR Section 17.1, the applicant provides the following:

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 and NQA-1a–1983 and the quality-related Regulatory Guides (RGs) listed in Table 17.0-1 of the DCD. The applicant states that the STP Units 3 and 4 QA Program Description (QAPD) is in Section 17.5S.

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).

In addition, the relevant requirements of the Commission regulations for QA, and the associated acceptance criteria, are in Section 17.5 of NUREG–0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants, (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 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, NRC staff reviewed and approved Section 17.1 of the certified ABWR DCD. The staff reviewed Section 17.1 of the STP Units 3 and 4 COL FSAR and compared it to 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 design and construction phases.

The staff reviewed the information in the COL FSAR:

COL License Information Item

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

NRC 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 Safety Evaluation Report [SER]).

The staff conducted an inspection of the applicant's implementation of the QA Program from January 13 through January 15 of 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. 0500012/2009201 and 0500013/2009201 and Notice of Violation, dated March 2, 2009 (ML090560120).

[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

As a follow-up to the January 2009 inspection of the applicant, the staff issued RAI 01-9 because STP is applying the operational QAPD (OQAPD) to activities performed during the COL application phase. But the applicant does not provide a reference to the OQAP in the COL application. Section 17.1 of the STP COL application states 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. RAI 01-9 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 6 months before docketing the STP COL application, for the activities being implemented under the OQAP.

The applicant's response to RAI 01-9 includes a commitment to revise Section 17.1 of the STP COL application to incorporate by reference the OQAP. The response also clarifies that in place of an earlier indication that a transition to full implementation of the STP Units 3 and 4 QAPD will be completed within 60 days of NRC approval of the QAPD, the applicant will complete the transition to full implementation of the QAPD by September 30, 2009. The response also summarizes the gap analysis the applicant performed to identify and justify the differences between the OQAP and the acceptance criteria in SRP 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 requirements of SRP 17.5 and are therefore acceptable. This item is being tracked as **Confirmatory Item 01-9** pending NRC review and approval of the revised FSAR.

17.1.5 Post Combined License Activities

There are no post COL activities related to this section.

17.1.6 Conclusion

The NRC staff's finding related to information incorporated by reference is in NUREG–1503. NRC staff reviewed the application and checked the referenced DCD. The staff's review confirmed that the applicant has addressed the relevant information. With the exception of **Confirmatory Item 01-9**, 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 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 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 (see Section 17.5S of this SER).

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 ABWRs.

17.2.2 Summary of Application

Section 17.2 of the STP Units 3 and 4 COL FSAR 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 COL 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 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.

The relevant requirements and the associated acceptance criteria for reviewing COL License Information Item 17.1 are in Section 17.5 of NUREG–0800.

17.2.4 Technical Evaluation

As documented in NUREG–1503, NRC 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.

[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

17.2.6 Conclusion

The NRC staff's finding related to information incorporated by reference is in NUREG–1503. NRC 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 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 COL license information item 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.
- 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. The objective during this stage is to ensure that the reliability of the risk-significant SSCs is maintained during plant operations. NRC 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 inspections during detailed design and construction before initial fuel loading.

17.3.2 Summary of Application

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

In addition, in COL 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 essential elements of the D-RAP during the design and construction phases.

- COL License Information Item 17.4 Provision for O-RAP

The applicant describes the operational RAP (O-RAP) activities 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, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs," May 22, 1995.

- Section 17.4, "Reliability Assurance Program," of NUREG–0800.

17.3.4 Technical Evaluation

As documented in NUREG–1503, NRC 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 information in the COL FSAR:

[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 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 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 NRC staff's finding related to information incorporated by reference is in NUREG–1503. NRC 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 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 confirmed that the applicant has addressed the relevant information relating to the RAP, and no outstanding information is expected to be addressed in the COL FSAR related to this section.

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, "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 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.
- 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. NRC 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 incorporates by reference Section 17.3 of the certified ABWR DCD, Revision 4, referenced in 10 CFR Part 52, Appendix A. Section 17.4S, "Reliability Assurance Program," of the FSAR addresses COL License Information Items 17.2, 17.3, and 17.4, which are associated with Section 17.3.

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 essential elements of the D-RAP during the design and construction phases.

- COL License Information Item 17.4 Provisions 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, "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," May 22, 1995.

- Section 17.4, "Reliability Assurance Program," of NUREG–0800.

17.4S.4 Technical Evaluation

NRC 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 Provisions 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 this information meets the guidance in these documents. The staff's review of the supplemental information included the requests for additional information (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 *Essential Elements of D-RAP*

NRC staff reviewed the essential elements of the D-RAP (also known as quality 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 essential elements of the D-RAP to support the COL design and construction activities. These essential elements 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 essential elements 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 reactor 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. An example is the first bullet under FSAR Subsection 17.4S.1.1.2, Revision 2, which states:

> The Plant Designer panel member maintains the design interface to ensure that any proposed design changes that involve risk-significant SSCs modeled in the PRA are identified and periodically reviewed.

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 the response to RAI 17.04-5 dated September 28, 2009 (ML092730239), the applicant stated that FSAR Section 17.4S will be revised to address interface responsibilities of the expert panel related to risk-significant SSCs not modeled in the STP Units 3 and 4 PRA. The applicant will add the following statement to FSAR Subsection 17.4S.1.1.2:

> The Plant Designer panel member maintains the design interface to ensure 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.

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.

(b) FSAR Subsections 17.4S.1.1 and 17.4S.1.2 provide adequate details on the applicant's D-RAP design control. These subsections 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. The controls for procedures and instructions used to implement the D-RAP 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 single procedure describes the process for an activity that applies to both safety-related and nonsafety-related SSCs, a single procedure (or procedures) that meets the full quality program requirements of Part II will be utilized. 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 to develop procedures and instructions for implementing the D-RAP activities that are described in the FSAR.

In a letter dated September 28, 2009 (ML092730239), the applicant's response to RAI 17.04-8 states that the applicant will 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 development and approval of this procedure is targeted for early November of 2009. The applicant will accomplish the development and approval of this procedure under the cognizance of the D-RAP expert panel or, at a minimum, an expert panel working group under the direction of one or more expert panel members. The full expert panel will be established in October of 2009. Following the approval of the D-RAP coordinating procedure, the goal is to have the D-RAP Program procedures finalized by the end of 2009 and implemented under the cognizance of the full expert panel during the first quarter of 2010. 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 will perform an audit to verify that the applicant appropriately implemented the D-RAP activities described above. This audit is expected to occur during the first quarter of 2011. Based on the above discussion, RAI 17.04-8 is resolved pending the staff's audit, which is being tracked as **Confirmatory Item 17.04-8**.

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

(e) FSAR Section 17.4S.8 describes the process for corrective action applied to the RAP. Any SSC, including nonsafety-related SSCs, experiencing a maintenance rule functional failure (MRFF) requires the use of this process to document the failure, determine its cause, and identify the actions taken to preclude a recurrence. Other failures of SSCs that are not MRFFs will be documented and corrected as described by the QAPD (see FSAR Section 17.5S).

(f) FSAR Section 17.4S.9 describes the details of the RAP audit plans. 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; Corrective Action Program; Maintenance Rule; Technical Specifications; 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 essential elements of the D-RAP. With the exception of the confirmatory item described in this section, no outstanding information is expected to be addressed in the COL FSAR related to this section. The staff's review confirmed that pending resolution of the confirmatory items discussed above, the relevant information in the COL FSAR is acceptable, and meets the applicable requirements described in Section 17.4S.3 of this SER.

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

NRC 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 Section 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 Section 17.4S.1.4, which includes the use of the PRA and deterministic techniques. 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. The deterministic categorization process is described in FSAR Subsection 17.4S.1.4.2 and is directly attributable to the importance of the system function supported by the SSCs. 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.

FSAR Section 17.4S.1 describes the use of an expert panel to identify risk-significant SSCs that are not modeled in the PRA to augment PRA techniques in ranking the risk of SSCs using deterministic techniques, operating experience, and expert judgment and to act as a final approver of risk-significant SSCs. FSAR Subsection 17.4S.1.3 describes the qualification requirements for members of the expert panel. The expert panel and designated working group (or groups) consists of designated individuals with expertise in the areas of risk assessment, operations, maintenance, engineering, QA, and licensing. At a minimum, the combined expert panel and working group(s) should include at least three individuals with a minimum of 5 years of experience at the STP or at a similar nuclear plant. There should also be at least one individual who has worked on modeling and updating the PRA for the STP or at a similar plant for a minimum of 3 years. When utilized, expert panel representatives from contracting design organizations are required to have a minimum of 3 years of experience establishing risk rankings for nuclear plant

SSCs using the PRA or deterministic techniques that may include failure modes and effects analyses.

(b) In FSAR Section 17.4S.1.4, Revision 2, the SSCs in the scope of the D-RAP have a risk-significant category of either "High" or "Medium." However, the criteria for these categories are not defined in the FSAR. Therefore, the staff issued RAI 17.04-6 requesting the applicant to define the “High” and “Medium” risk categories.

In a letter dated September 28, 2009 (ML092730239), the applicant’s response to RAI 17.04-6 states that the “Medium” risk category will be removed from FSAR Section 17.4S. This response includes a proposed markup of the related changes to FSAR Section 17.4S.

The staff reviewed the applicant's response to RAI 17.04-6 and concluded from the proposed markup that the applicant will merge the “Medium” risk category into the “High” risk category. For example, in FSAR Subsection 17.4S.1.4.2, Revision 2, the “High” risk category has a score ranging between 71 and 100, while the ”Medium” risk category has a score ranging between 41 and 70. The applicant's proposed markup of FSAR Subsection 17.4S.1.4.2 deletes the “Medium” risk category, and the ”High” risk category now has a score ranging between 41 and 100.

The staff found this change acceptable, but noted that the applicant’s proposed revision to the text in FSAR Subsection 17.4S.1.4.2, which is in the response to RAI 17.04-6, does not seem to be appropriate:

> Specifically, a weighted score of 25 on any one question results in a HIGH categorization.

The merging of the “Medium” risk category into the “High” risk category suggests that the applicant’s proposed revision to FSAR Section 17.4S should imply that a weighted score between 15 and 25 on any one question results in a “High” risk categorization. For example, the loss of an SSC function that is safety significant for a shutdown (i.e., weight value of 3 in Subsection 17.4S.1.4.2) and has a high impact and/or occurs frequently (i.e., numerical answer of 5 in Subsection 17.4S.1.4.2), would have a weighted score of 15 and should be included in the “High” risk category. Another example, the loss of an SSC function that directly fails another risk-significant system (i.e., weight value of 4 in Subsection 17.4S.1.4.2) and has a high impact and/or occurs frequently (i.e., numerical answer of 5 in Subsection 17.4S.1.4.2), would have a weighted score of 20 and should be included in the “High” risk category. Therefore, the staff issued RAI 17.04-11 requesting the applicant to clarify the integration of the “Medium” risk category into the “High” risk category. Because RAI 17.04-11 addresses the unresolved issues in RAI 17.04-6, RAI 17.04-6 is considered resolved. In the response to RAI 17.04-11 dated February 3, 2010 (ML100360834), the applicant states that FSAR Section 17.4S will be revised to state that a weighted score of 15 or more on any one question results in a “High” risk categorization. The staff found that the applicant's response to RAI 17.04-11 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 17.04-11 is resolved and Open Item 17.04-11 is closed.

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. 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 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*

NRC staff reviewed the list of risk-significant SSCs in 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 in 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 (which is in Appendix 19K of FSAR Chapter 19) incorporates by reference Appendix 19K of the certified ABWR DCD, which was updated to account for site-specific design information and design departures. This process meets the regulatory requirements. 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 the PRA techniques used in the referenced ABWR DCD by employing (1) an expert panel, (2) the deterministic technique described in FSAR Subsection 17.4S.1.4, and (3) industry operating experience.

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 Section 17.4S.1.4. Also, the staff 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 (RBCW) 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.

The applicant responded to RAIs 17.04-7 and 17.04-9 in letters dated September 28, 2009; April 14, 2010; and May 19, 2010 (ML092730239, ML101090144, and ML101410206). The applicant states that the SSCs in the HPCF, RHR, RBCW, and RSW systems whose common cause failures are not modeled in the ABWR DCD PRA will be evaluated by the D-RAP expert panel. The panel will use the detailed design

processes described in FSAR Subsection 17.4S.1.4. The applicant also states 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. The development and approval of this procedure is targeted for early November of 2009. The applicant will accomplish the development and approval of this procedure under the cognizance of the D-RAP expert panel or, at a minimum, an expert panel working group under the direction of one or more expert panel members. The full expert panel will be established in October of 2009. Following the approval of the D-RAP coordinating procedure, the goal is to have the D-RAP program proceduralized by the end of 2009 and implemented under the cognizance of the full expert panel during the first quarter of 2010. The applicant expects to complete a majority of the system reviews under the D-RAP program by the end of 2010. The applicant also specifies 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 activities. The FSAR will be updated in accordance with 10 CFR 50.71(e) to provide the expert panel with the failure modes and RAP activities recommended for this set of risk-significant equipment. The milestone date for Commitment 17.4-1 is September 30, 2011.

The staff found that the applicant's response to RAIs 17.04-7 and 17.04-9 sufficiently addresses the staff's concerns associated with these RAIs. The staff will conduct an audit to review the records and procedures associated with STP's D-RAP. This audit will facilitate the staff's determination that the list of risk-significant SSCs within the scope of the D-RAP is being developed appropriately and in accordance with the processes described in FSAR Subsection 17.4S.1.4. This audit is expected to occur during the first quarter of 2011. Based on the above discussion, RAIs 17.04-7 and 17.04-9 are resolved pending a staff review of the revised FSAR section and the staff audit describe above, which is being tracked as **Confirmatory Item 17.04-9**.

(b) In FSAR Revision 2, Appendix 19K, the description of the risk significance of the circulating water system (CWS) pump circuit breakers is inconsistent. For example, the CWS pump circuit breakers are 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 a letter dated September 28, 2009 (ML092730239), the applicant's response to RAI 17.04-3 states that tripping the CWS pumps upon detection of turbine building flooding is not required for flood control. As such, the applicant identifies the changes to be made in FSAR Section 19K.7. The staff agreed with these changes. However, the applicant does not address the necessary changes to FSAR Table 19K-4, Revision 2, which considers the CWS pump circuit breakers as risk significant through incorporation by reference to 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 a letter dated February 3, 2010 (ML100360834), the applicant's response to RAI 17.04-10 states that Table 19K-4 of FSAR Chapter 19 will 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. Based on the above discussion, RAIs 17.04-3 and 17.04-10 are resolved and Open Item 17.04-10 is closed.

Verification that the proposed changes are in the next FSAR revision is being tracked as **Confirmatory Item 17.04-10**.

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

- reactor core isolation cooling (RCIC) pressure sensor PIS-Z605 miscalibrated
- RCIC Flow Sensor FT-007-2 miscalibrated
- RHR Flow Transmitters (CCF miscalibration)
- Level 8 Sensors (CCF miscalibration)

However, this deletion is 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 to Table 19K-4 of the ABWR DCD. Therefore, the staff issued RAI 17.04-2 requesting the applicant to clarify whether these components are in the scope of the D-RAP and, if necessary, to revise FSAR Appendix 19K.

In a letter dated September 28, 2009 (ML092730239), the applicant's response to RAI 17.04-2 states that the instrumentation components deleted in FSAR Revision 2 Tables 19K-1 and 19K-2 are no longer risk-significant, after the incorporation of the CCFs described in the applicant's response to RAI 17.04-1. The applicant will modify FSAR Table 19K-4 to be consistent with the entries in Tables 19K-1 and 19K-2. The staff found that the applicant's response to RAI 17.04-2 sufficiently addresses the concerns associated with this RAI. Based on the above discussion, RAI 17.04-2 is resolved. Verification that the proposed changes are in a future revision of the FSAR is being tracked as **Confirmatory Item 17.04-2**.

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. With the exception of the confirmatory items described in this section, no outstanding information is expected to be addressed in the COL FSAR related to this section. As a result of these confirmatory items, the staff was unable to finalize the conclusions relating to the list of risk-significant SSCs, in accordance with NRC requirements.

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. NRC 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*

NRC 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, quality assurance, surveillance testing, inservice inspection, inservice testing, and maintenance. 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. 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 described in Section 17.4S.3 of this SER.

17.4S.4.6 *D-RAP ITAAC*

In accordance with the staff's review of the D-RAP ITAAC in SRP Section 14.3, the application incorporates by reference the D-RAP ITAAC of the ABWR DCD and is therefore acceptable.

17.4S.5 Post Combined License Activities

The applicant identifies a commitment (COM 17.4-1) in FSAR Section 17.4S, Revision 4, to complete all of the expert panel system reviews, provide an updated list of the set of D-RAP SSCs, and have the program elements in place to control future activities. The FSAR will be updated in accordance with 10 CFR 50.71(e) to provide the expert panel with the failure modes and recommended RAP activities for this set of risk-significant equipment.

17.4S.6 Conclusion

NRC 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. However, as a result of the identified confirmatory items associated with the RAP, the staff is unable to finalize conclusions for the RAP information.

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, the applicant provides a reference to the STP QAPD that is submitted as a separate document. NRC received "Submittal of Quality Assurance Program Description, Revision 2," dated September 30, 2009. 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

- STP 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, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

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

NRC staff reviewed the conformance of Section 17.5S of the STP Units 3 and 4 COL FSAR to the guidance in RG 1.206 Section C.III.1, Chapter 17, Section C.III.17.5, "Quality Assurance Program Guidance."

The staff reviewed STP Units 3 and 4 COL License Information Item 17.1, which is included under Section 17.0 of the STP Units 3 and 4 COL FSAR. COL License Information Item 17.1 resolves the COL information item related to the QA Program discussed in Sections 17.1 and 17.2 of the STP Units 3 and 4 COL FSAR.

The staff reviewed and evaluated the STP QAPD, Revision 2, 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 design certification, 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," supplemented by additional regulatory and industry guidance for nuclear operating facilities. SRP 17.5 also addresses additional QA requirements in 10 CFR Part 50, Appendix A, General Design Criterion 1 (GDC 1), and 10 CFR 50.34(f)(3)(ii) and (iii). GDC 1, "Quality Standards and Records," 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.

NRC 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. RAI 17.5-1 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.

The applicant's response to RAI 17.5-1 dated May 22, 2008 (ML081480499), adds 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 requirements of SRP Section 17.5 A and are therefore acceptable. This item is incorporated into Revision 2 of the QAPD and is therefore closed.

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 2 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 technical specifications delineate the minimum qualifications for plant and support staff. Personnel are required to complete the training for positions identified in 10 CFR 50.120, "Training and qualification of nuclear 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 paragraph II.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. NRC 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 3 years. As an alternative to

this requirement, the QAPD proposes to follow the guidance in SRP Section 17.5 paragraph II.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. NRC staff evaluated this proposed alternative and determined that it is consistent with the regulation in 10 CFR Part 50, Appendix B, Criterion II. Therefore, the staff concluded that this alternative is acceptable.

NRC 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.

The applicant's response to RAI 17.5-2 dated May 22, 2008 (ML081480499), 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. The staff found this response and change acceptable. Thus, RAI 17.5-2 is 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.

The applicant's response to RAI 17.5-3 dated May 22, 2008, verifies that there will be no exception to NQA-1–1994 Supplement 2S-1, as permitted by the NEI template. In Revision 2 of the QAPD, the applicant clarifies 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 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. The applicant's response dated May 22, 2008, replaces 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. RAI 17.5-8 also asked for additional descriptions of the STP's organizational structure and positions and requested an explanation of how the STP will incorporate future revisions into the NEI template. The applicant's response to RAI 17.5-8 dated October 21, 2008 (ML082970563), further revises Part II Section I of the QAPD. This revision includes a clear delineation of functional responsibilities from the construction/preoperation phase through the transition to the operations phase. The applicant also provides refined organizational charts to identify the STPNOC construction/preoperation organization and the organization for "Four Unit

Operations." The applicant also commits to comprehensively evaluate NRC-approved revisions to the NEI template 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 requirements of SRP 17.5. These items are incorporated into Revision 2 of the QAPD. Although the commitment to maintain the QAPD so it is current with NEI template revisions is acceptable to the staff, Revision 2 of the QAPD (submitted September 30, 2009) does not fully address all of the items discussed in the SER (ML092650695) accepting the use of the QAPD template in NEI 06–14, Revision 7. Thus, RAI 17.5-6 and RAI 17.5-8 are closed. The staff issued a follow-up, RAI 17.5-9, on February 16, 2010, which is being tracked as part of **Confirmatory Item 17.5-9**. This item is discussed in more detail in Subsections 17.5S.4.17 and 17.5S.4.20.

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, 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. NRC 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. NRC 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. NRC staff evaluated this proposed alternative and determined that it provides an adequate QA review of procurement documents before awarding the contract and after any 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. NRC 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 NRC 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 STPNOC's implementation of its QA Program from January 13 through January 15 of 2009. The limited scope of the inspection focused on STPNOC'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. 0500012/2009201 and 0500013/2009201 and Notice of Violation, dated March 2, 2009 (ML090560120). During the inspection, NRC 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 Units 3 and 4 COL activities. As of January 16, 2009, STPNOC's QA Program did not include a list of procedures for Units 1 and 2 that were found to be applicable for Units 3 and 4 COL activities. The company did not to maintain a complete list of new procedures that had been issued for Units 3 and 4 to supersede those for Units 1 and 2. In a letter dated April 1, 2009 (ML090990607), staff describes the following corrective actions the company has 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 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 the STP), 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 are not required to be evaluated or audited.

  NRC 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 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.

NRC 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 the 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 Items 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. NRC staff determined that the use of the definition of safety systems equipment is acceptable because it is consistent with the requirements of NQA-1–1994, Subpart 2.4.

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 paragraph II.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. NRC 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. NRC 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. NRC 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. NRC 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 comply with the precautions identified in Section 3 of Appendix 2.1 in accordance with RG 1.37, and to add a suitable chloride stress-cracking inhibitor to fresh water used to flush systems containing austenitic stainless steels. NRC 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. NRC staff determined that this clarification is acceptable in meeting the requirements of RG 1.37 Regulatory Position C.2, which are 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. The applicant's response to RAI 17.5-7 dated May 22, 2008 (ML081480499), revises 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. This item is being tracked as **Confirmatory Item 17.5-7** pending NRC review and approval of the revised FSAR.

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 STPNOC's implementation of its QA Program from January 13 through January 15 of 2009. The limited-scope inspection focused on STPNOC'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. 0500012/2009201 and 0500013/2009201 and Notice of Violation, dated March 2, 2009 (ML090560120).

During the inspection, NRC 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, does 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. The applicant's response in a letter dated April 1, 2009, states that the company 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 states that the records and retention times are based on Regulatory Position C.2 and Table 1 of RG 1.28, Revision 3. However, the QAPD does 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. The applicant's response to RAI 17.5-9 dated March 17, 2010 (ML100770388), includes 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 requirements of SRP Section 17.5 and are therefore acceptable. This item is being tracked as part of **Confirmatory Item 17.5-9** pending NRC review and approval of the revised QAPD.

Concerning the use of electronic records storage and retrieval systems, the QAPD complies with 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, TG 15 1998, TG 16-1998, and TG 21-1998.

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.

NRC 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.

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 2 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 STPNOC's implementation of its QA Program from January 13 through January 15 of 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 with10 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, NRC 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.

NRC 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." The applicant's response to RAI 17.5-5 dated May 22, 2008 (ML081480499), clarifies the reference to "the process that utilizes knowledgeable personnel to perform the verification function" as a means of performing inspections to verify the conformance of an item or activity to specified requirements. The applicant identifies this process as an independent verification, a simultaneous verification, or a similar process. The staff reviewed the applicant's response and found it acceptable in that it demonstrates compliance with SRP Section 17.5, SRP Acceptance Criteria Item V, "Nonsafety-Related SSC Quality Controls." RAI 17.5-5 is therefore 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 comply with 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," issued in 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.

17.5.4.20 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 comply with the following NRC regulatory guides and other QA standards to supplement and support the QAPD, with the noted clarifications and alternatives.

NRC 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 compliance with, or exceptions to, these RGs. The applicant's response to RAI 01-14 dated October 29, 2009, includes a list of conformances and exceptions as well as an except 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 are inconsistent. Therefore, the staff issued follow-up RAI 17.5-9 on February 16, 2010, requesting the applicant to clarify FSAR Section 1.9S and Part IV of the QAPD as appropriate. The applicant's response to RAI 17.5-9 dated March 17, 2010 (ML100770388), includes proposed revisions to FSAR Tables 1.9S-1 and 1.9S-2 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. This issue is being tracked as part of **Confirmatory Item 17.5-9** pending NRC review and approval of the revised FSAR.

- RG 1.8, Revision 3, "Qualification and Training of Personnel for Nuclear Power Plants," dated May 2000.

  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 acceptable.

- RG 1.26, Revision 3, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," dated February 1976.

  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 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)," dated August 1985.

  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 states 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 does 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 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. The applicant's response to RAI 17.5-9 dated March 17, 2010 (ML100770388), includes 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 requirements of SRP 17.5. Therefore, the staff found this change acceptable. This issue is being tracked as part of **Confirmatory Item 17.5-9** pending NRC review and approval of the revised QAPD.

- RG 1.29, Revision 3, "Seismic Design Classification," dated September 1978.

  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 on February 16, 2010, requesting the applicant to clarify FSAR Section 1.9S and Part IV of the QAPD as appropriate. The applicant's response to RAI 17.5-9 dated March 17, 2010 (ML100770388), 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 requirements of SRP 17.5. Therefore, the staff found these changes acceptable. This issue is being tracked as part of **Confirmatory Item 17.5-9** pending NRC review and approval of the revised QAPD.

- RG 1.33, Revision 2, "Quality Assurance Program Requirements," issued in February 1978.

  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 45.2 series standards listed in the regulatory guide. However, the regulatory guide also lists ANSI standards other than the N45.2 series. The staff issued follow-up RAI 17.5-9 on February 16, 2010, requesting the applicant to describe how the applicant meets each standard listed in the regulatory guide.

  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 on

February 16, 2010, 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 the requirements 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. Otherwise, the applicant must commit to RG 1.33. The applicant's response to RAI 17.5-9 dated March 17, 2010 (ML100770388), includes 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. This issue is being tracked as part of **Confirmatory Item 17.5-9** pending NRC review and approval of the revised QAPD.

- RG 1.37, Revision 1, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants," dated March 2007.

  NRC staff issued RAI 17.5-4 requesting the applicant to clarify why RG 1.37 is referenced in Section 13.2 of the QAPD but is not identified as a commitment in Part IV, "Regulatory Commitments," of the STP QAPD. The applicant's response dated May 22, 2008, revises Part IV of the QAPD to include RG 1.37 as a commitment. The staff reviewed this response and found it acceptable. This item is 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 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 in previous sections above.

  In Section 13.2 of the QAPD, the staff identified that another commitment is made to NQA-1–1994, Part III, Subpart 3.2, Appendix 2.1, and Section 3. The staff issued RAI 17.5-9 on February 16, 2010, requesting the applicant to add Part III to this section. The applicant's response to RAI 17.5-9 dated March 17, 2010 (ML100770388), includes a proposed revision to Part IV of the QAPD that adds a commitment to ASME NQA-1-1994 Part III, as described in the QAPD. The staff found that the response to this part of RAI 17.5-9 and the proposed changes adequately satisfy the requirements of SRP 17.5 and are therefore acceptable. This item is being tracked as part of **Confirmatory Item 17.5-9** pending NRC review and approval of the revised QAPD.

- 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

NRC 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 found that with the exception of the identified confirmatory items, the STP Units 3 and 4 QAPD is acceptable.

NRC 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 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 NRC staff concluded that with the exception of the identified confirmatory items, 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 section of the FSAR addresses the program for implementing the maintenance rule based on the requirements of 10 CFR 52.79(a)(15) and 10 CFR 50.65 and the guidance in RGs 1.160 and 1.182. RG 1.160 endorses Nuclear Management and Resources Council (NUMARC) 93-01 Revision 2, which provides one acceptable method for implementing the maintenance rule. RG 1.182 is a companion guide to RG 1.160 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, Revision 2.

17.6S.2 Summary of Application

Section 17.6S of the STP Units 3 and 4 FSAR 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 SER dated January 24, 2008 (ML073650081), for Topical Report NEI 07–02A Revision 0, “Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52.” NEI 07–02A Revision 0 provides a complete generic program description for use in developing the section of the COL FSAR associated with Section 17.6, "Maintenance Rule," 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

NRC staff reviewed FSAR Section 17.6S and checked the referenced Topical Report NEI 07-02A 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 a letter dated September 8, 2009 (ML092530407), the applicant's response to RAI 17.06-1 states that FSAR Section 17.6S will 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 is incorporated into Revision 4 of the FSAR, Section 17.6S. Based on the above discussion, RAI 17.06-1 is resolved.

2. FSAR Section 17.6S, Revision 2 incorporates by reference the NEI 07-02 template guidance. However, according to NEI 07–02A Revision 0, which incorporates the NRC's revised safety evaluation endorsing NEI 07–02, industry operating experience (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 safety evaluation.

   In a letter dated September 8, 2009 (ML092530407), the applicant's response to RAI 17.06 2 states that FSAR Section 17.6S will be revised to adopt NEI 07–02A guidance and its revised safety evaluation. 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 are incorporated into Revision 4 of the FSAR, Section 17.6S. Based on the above discussion, RAI 17.06-2 is resolved.

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, Technical Specifications Surveillance Test Program, and the Preventative Maintenance Program. The applicant satisfactorily addresses 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. 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

There are no post COL activities related to this section.

17.6S.6 Conclusion

NRC 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.