17.0 QUALITY ASSURANCE

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

17.0 Introduction

This section of the FSAR addresses the COL license Information Item 17.1 by referencing the various sections in Chapter 17 where the applicant's QA Program for construction and operation phases are discussed. The staff's review of the applicant's QA Program is in Section 17.5S.

Section 17.0 of the STP Units 3 and 4 COL FSAR incorporates by reference Section 17.0 of the certified ABWR design control document (DCD) Revision 4 referenced in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, 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) 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 17.1 of NUREG–0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants."

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, U.S. Nuclear Regulatory Commission (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 design and construction.

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, operations, and preparation of site-specific design activities (see Section 17.5S of this Safety Evaluation Report [SER]).

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 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 design and construction phases that were incorporated by reference have been resolved.

[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

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 operations activities (see Section 17.5S of this SER).

The staff's review confirmed that the applicant has addressed the relevant information, and with exception to **Confirmatory Item 01-9** (see Section 17.5S.4.1), no outstanding information is expected to be addressed in the COL FSAR related to this section

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 17.2 of NUREG–0800.

The relevant requirements and the associated acceptance criteria for reviewing COL License Information Item 17.1 are in Section 17.2 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 operation phase.

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

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

17.2.5 Post Combined License Activities

There are no post COL activities related to this section.

17.2.6 Conclusion

The 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.

The staff's review confirmed that the applicant has addressed the relevant information, and no outstanding information is expected to be addressed in the COL FSAR related to this section.

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 a 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.

[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

- 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 Holder is verified using the inspections, tests, analyses, and acceptance criteria (ITAAC) process, as well as inspections and audits 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 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 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 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 phase.

- COL License Information Item 17.4 Provision for operational RAP (O-RAP)

The applicant describes the 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 phase.

The staff reviewed the information in the COL FSAR:

COL License Information Items

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

The applicant addresses COL License Information Items 17.2, 17.3, and 17.4 in Section 17.4S of the FSAR. The staff's review of 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.

[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

17.3.7 References

SECY-95-132, “Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs,” U.S. Nuclear Regulatory Commission, May 1995 (ADAMS Accession No. ML003708005).

NUREG–0800, “Reliability Assurance Program (RAP),” Section 17.4, U.S. Nuclear Regulatory Commission, March 2007.

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 for 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 Holder is verified using the ITAAC process as well as inspections and audits during detailed design and construction 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 phase.

- 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 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

NRC staff reviewed this supplemental information in accordance with Item E of SECY-95-132 and Standard Review Plan (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 Section 17.4S.4.1 of this SER. The review and resolution of COL License Information Item 17.4 is addressed in Section 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. The 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 that 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 under the first bullet of 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, which are not modeled in the PRA.

In a letter dated September 28, 2009, the applicant's response to RAI 17.04-5 states 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 will confirm that the proposed revision is incorporated in Revision 4 of the FSAR. The staff identified this RAI as **Confirmatory Item 17.04-5**.

(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 used to identify these SSCs. 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 (non-safety 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 non-safety 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, the applicant's response to RAI 17.04-8 states that current plans call 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 STP 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 current 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 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 these activities. This audit is expected to occur during 2010. The staff identified this RAI 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 an activity affecting 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 corrective action process applied to the RAP. Any SSC, including non-safety related SSCs, experiencing a maintenance rule functional failure (MRFF) requires the use of the corrective action process to document the failure, its cause determination, and actions to preclude a recurrence. Other failures of SSCs that are not MRFFs will be documented and corrected as described by the QAPD (refer to 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 design, procurement, fabrication, construction, and preoperational testing; PRA modeling and risk assessment; deterministic evaluations from the expert panel; the Corrective Action Program; the Maintenance Rule; Technical Specifications; and other operational programs. These programs are subject to audits as described in the QAPD.

As a result of the identified confirmatory items associated with this section the staff was unable to finalize the conclusions for the essential elements of the D-RAP.

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

NRC staff reviewed the applicant's detailed methodology used to evaluate, identify, and prioritize the list of risk-significant SSCs, which is 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. 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 Section 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 Section 17.4S.1.3 describes the qualification requirements for members of the expert panel. The expert panel and designated working group (or groups) consist of designated individuals with expertise in the areas of risk assessment, operations, maintenance, engineering, quality assurance, and licensing. At a minimum, the combined expert panel and working group(s) should include at least three individuals with a minimum of five 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 a similar plant for a minimum of three years. When utilized, expert panel representatives from contracting design organizations are required to have a minimum of three years of experience establishing risk rankings for nuclear plant SSCs using the PRA or deterministic techniques (that may include failure modes and effects analysis).

(b) In FSAR Section 17.4S.1.4, 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 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, the applicant’s response to RAI 17.04-6 states that the “Medium” risk category will be removed from FSAR Section 17.4S. The 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 Section 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 in the text to FSAR Subsection 17.4S.1.4.2, which is also 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;

Because the “Medium” risk category, which was included in the scope of the D-RAP under Revision 2 of FSAR Section 17.4S, is now merged into the “High” risk category suggests that the applicant’s above revision should infer 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 a safety significant for 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 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. The staff identified this RAI as **Open Item 17.04-11**.

(c) The applicant’s response to RAI 17.04-6 also clarifies the methodology used to evaluate, identify, and prioritize the list of risk-significant SSCs. The applicant states that common cause failures (CCFs) included in the Level-1 internal events PRA model use the same screening criteria for Fussell-Vesely (FV) and risk-achievement worth (RAW) as the independent events, as indicated in Table 19K-1 of the FSAR. Also, the qualitative risk analyses (e.g., fire-induced vulnerability evaluation or seismic margins analysis) and PRA models for which risk importance measures are not available are evaluated in ABWR DCD Appendix 19K. As part of the D-RAP, these will be addressed by the applicant's expert panel, as shown in FSAR Figure 17.4S-1.

As a result of the identified open item associated with this section the staff was unable to finalize the conclusions for the detailed methodology used to evaluate, identify, and prioritize the list of risk-significant SSCs and the use of the expert panel.

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 FSAR Section 19K. 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.

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 COL FSAR preparation incorporates by reference, with the appropriate departures and site-specific supplements, the list of risk-significant SSCs in Appendix 19K of the referenced ABWR DCD. As the D-RAP enters the detailed design, procurement, fabrication, and construction phases, it is important to ensure that the list of site-specific, risk-significant SSCs is sufficiently complete, because the D-RAP activities for these SSCs are prepared and implemented under the approved QAPD referenced in FSAR Section 17.5S. Therefore, the staff issued **RAI 17.04-7** requesting the applicant to provide a plan for performing the

following activities that are described in FSAR Section 17.4S.1, Revision 3. This will ensure that the list of risk-significant SSCs is sufficiently complete to support the D-RAP program activities during the detailed design, procurement, fabrication, and construction phases:

- Identify the risk-significant SSCs not modeled in the PRA.
- Implement STP's process for maintaining, revising, and establishing new risk rankings described in FSAR Section 17.4S.1.4.
- Establish and utilize an expert panel with STP representation to (a) augment PRA techniques in ranking the risk of SSCs using deterministic techniques, operating experience, and expert judgment; and (b) validate and finalize the list of risk-significant SSCs.

In a letter dated September 28, 2009, the applicant's response to RAI 17.04-7 states that the expert panel will use the deterministic risk criteria described in FSAR Subsection 17.4S.1.4.2 to identify risk-significant SSCs that are not already modeled in the PRA. In this case, these SSCs will be considered for addition to the PRA model or will provide a documented justification for not modeling the SSC in the PRA. These SSCs will also be included in the scope of the D-RAP. The list of risk-significant SSCs will be maintained and updated throughout the detailed design, procurement, fabrication, and construction phases. The applicant references the time schedule described in the response to RAI 17.04-8, which states that the full expert panel will be established in October of 2009. Following the approval of the D-RAP coordinating procedure, the current goal is to have the D-RAP program proceduralized by the end 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 17.04-7 sufficiently addresses the concerns in this RAI. The staff will perform an audit to verify that the applicant has appropriately implemented these activities. This audit is expected to occur during 2010. This RAI is being tracked as **Confirmatory Item 17.04-7**.

(b) The initial identification of the site-specific, risk-significant SSCs during the COL FSAR preparation incorporates by reference, with the appropriate departures and site-specific supplements, the list of risk-significant SSCs in Appendix 19K of the referenced ABWR DCD. This includes the following CCFs that were added to the plant-specific PRA under Departure STD DEP 19.3-1 ("Evaluation of Common Cause Failures") (refer to Tables 19K-1 and 19K-2 of FSAR Revision 3).

- Reactor Service Water System (RSW) and Reactor Building Cooling Water System (RBCW) Divisions A, B, & C CCF failure
- RSW and RBCW Divisions A & B CCF failure
- RSW and RBCW Divisions B & C CCF failure
- RSW and RBCW Divisions A & C CCF failure
- High-Pressure Core Flooder System (HPCF) CCF failure
- Residual Heat Removal (RHR) core flood system CCF failure
- RHR suppression pool cooling CCF failure

However, it is not clear from FSAR Section 19K, Revision 3, as to which specific SSCs (e.g., check valves RSW-F001A through F and motor-operated valves RSW-F013A through F) are

associated with these risk-significant CCFs. Therefore, the staff issued **RAI 17.04-1** requesting the applicant to identify in FSAR Section 19K the specific SSCs that are in the scope of the D-RAP and are associated with these risk-significant CCFs.

In a letter dated September 28, 2009, the applicant's response to RAI 17.04-1 proposes to include in FSAR Section 19K those SSCs of the HPCF, RHR, RBCW, and RSW systems whose CCFs are significant contributors to system unavailability or to core damage frequency (CDF), which are identified in ABWR Standard Safety Analysis Report (SSAR) Section 19D.8.6.

As explained below, the staff found that the SSCs of the HPCF, RHR, RBCW, and RSW systems that the applicant proposes to add to the scope of the D-RAP, in response to RAI 17.04-1, may not be complete. Based on Section 19D.8.6 of the ABWR SSAR, the following SSCs are considered in the CCF sensitivity analysis for the HPCF, RHR, RBCW, and RSW systems: pumps, pump auxiliary equipment, manual valves, motor-operated valves, check valves, room air conditioners, spargers, strainers, circuit breakers, flow transmitters, heat exchangers, and temperature elements. Section 19D.8.6 of the ABWR SSAR also identifies the most significant CCF contributors to system unavailability or to CDF for these systems (e.g., pumps, strainers, room air conditioners). It is important to note, however, that those SSCs whose CCFs are not significant contributors to system unavailability or to CDF could still be considered risk important (i.e., the CCFs of these SSCs can have a high RAW or FV) and therefore included in the scope of the D-RAP. For example, based on the discussion in Section 19D.8.6 of the ABWR SSAR, the CCF of the HPCF pumps is a significant contributor to system unavailability or CDF and has a high risk importance according to Table 19K-1 of the FSAR. Although the CCF of the HPCF check valves may not be a significant contributor to system unavailability or to CDF, its CCF risk importance (e.g., RAW) is very similar to that of the HPCF pumps and should therefore be included in the scope of the D-RAP. Therefore, the staff issued supplemental **RAI 17.04-9** requesting the applicant to re-evaluate these SSCs for inclusion in the D-RAP based on their CCF risk importance (e.g., RAW and FV). The staff identified this RAI as **Open Item 17.04-9**.

(c) In FSAR Section 19K Revision 2, the risk significance of the Circulating Water System (CWS) pump circuit breakers is described inconsistently. For example, the CWS pump circuit breakers are identified as risk-significant under FSAR Section 19K.7 and FSAR Table 19K-4, which incorporate by reference the CWS pump breakers, although the CWS pump circuit breakers are not identified as risk-significant under 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 Section 19K accordingly.

In a letter dated September 28, 2009, 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 Table 19K-4 of STP FSAR Revision 2, which considers the CWS pump circuit breakers risk-significant through incorporation by reference into 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. The staff identified this RAI as **Open Item 17.04-10.**

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

- RCIC Pres 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 into 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 Section 19K accordingly.

In a letter dated September 28, 2009, the applicant's response to RAI 17.04-2 states that the instrumentation components deleted in FSAR Tables 19K-1 and 19K-2 (Revision 2) were no longer risk-significant, after the incorporation of the CCFs described in the applicant's response to RAI 17.04-1. FSAR Table 19K-4 will be modified to be consistent with the Table 19K-1 and 19K-2 entries. The staff found that the applicant's response to RAI 17.04-2 sufficiently addresses the concerns associated with this RAI. The staff will confirm that the proposed revision is incorporated into Revision 4 of the FSAR. The staff identified this RAI as **Confirmatory Item 17.04-2**.

As a result of the identified confirmatory and open items associated with this section the staff was unable to finalize the conclusions for the list of risk-significant SSCs in the scope of the site-specific D-RAP.

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

For the non-safety related, risk-significant SSCs, the applicant provides QA controls in the applicant's QAPD related to COL design and construction activities, 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 17.5.4.19 of the STP SER.

17.4S.4.5 *Integration of RAP into Operations 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. 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 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 operation.

The following discussion provides the staff's findings from the review of the supplemental information related to this subject area. The applicant describes the O-RAP activities during the operations phase through integration of the RAP into the Maintenance Rule, QA, surveillance testing, inservice inspection, inservice testing, and maintenance programs to meet the

objectives of the RAP during plant operation. 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 a 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 non-safety related, risk-significant SSCs that include establishing appropriate corrective actions for potential design and operational errors that degrade these SSCs.

Based on the discussion in this subsection, the staff concluded that the proposed process for integrating the RAP into operational programs is adequate and meets the guidance in Item E of SECY-95-132 and SRP Section 17.4. The proposed process is therefore acceptable.

17.4S.4.6 *D-RAP ITAAC*

In accordance with the staff's review of the D-RAP ITAAC under 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

There are no post COL activities related to this section.

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 and open items associated with the RAP, the staff is unable to finalize conclusions for the RAP information.

17.4S.7 References

NRC Inspection Manual, “Construction Inspection Program: Inspections of Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC),” Chapter 2503, U.S. Nuclear Regulatory Commission.

NUREG–0800, “Reliability Assurance Program (RAP),” Section 17.4, U.S. Nuclear Regulatory Commission, March 2007.

SECY-95-132, “Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs,” U.S. Nuclear Regulatory Commission, May 1995 (ADAMS Accession No. ML003708005).

Scott Head, STPNOC, to Document Control Desk, NRC, Subject: "South Texas Project, Units 3 and 4, Docket Nos. 52-012 and 52-013, Response to Request for Additional Information," September 28, 2009 (ADAMS Accession No. ML092730239).

17.5S Quality Assurance Program Guidance

17.5S.1 Introduction

Section 17.5S, "Quality Assurance Program Guidance," of the STP FSAR addresses the establishment and implementation of a QA Program applicable during the design, fabrication, construction, testing, and operation of the 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.. The 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 satisfied based on the Commission's regulatory requirements related to QA Programs, which are set forth in 10 CFR 52.79(a)(25) and Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50.

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 those 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 design certification, early site permit (ESP), COL, construction permit, and operating license applicants. The staff developed SRP Section 17.5 using ASME Standard NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," (Reference 2) supplemented by additional regulatory and industry guidance for nuclear operating facilities.

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, paragraph II.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 flowchart 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) adds two flowcharts to the QAPD, "STPNOC Organization" and "STPNOC Units 3 & 4 Organization," which the staff reviewed. The staff found that the two flowcharts satisfy the requirements of SRP Section 17.5 A and are therefore acceptable. This item was incorporated into Revision 2 of the QAPD. Therefore, the staff has closed this item.

The staff conducted an inspection of STPNOC's implementation of its QA Program from January 13 through 15, 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 STPNOC 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.

As a follow-up to the January 2009 inspection of the STP, the staff issued **RAI 01-9** because STP is applying the operational QAPD (OQAP) to activities performed during the COL application phase. But the STP did 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 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, STPNOC now intends to complete the transition to full implementation of the QAPD by September 30, 2009. The response to the RAI 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 the 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 response to **RAI 01-9** and the proposed changes adequately satisfy the requirements of SRP 17.5. Therefore, the staff found this change acceptable. This item is identified as **Confirmatory Item 01-9**, pending NRC review and approval of the revised FSAR.

17.5S.4.2 Quality Assurance Program

The applicant's QAPD follows the guidance for the QA Program in SRP Section 17.5, paragraph II.B. 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 non-safety 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 paragraph II.B.8, the QAPD applies a grace period of 90 days to activities that must be performed on a periodic basis. The next due date for the performance of an activity that invokes the 90-day grace period remains unchanged. The next due date for an activity performed before the scheduled due date is moved 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, paragraphs II.S and II.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, that 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 identified in RAI 17.5-2 that the STP Units 3 and 4 QAPD provides a reference to 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, 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). Based on the applicant's action to remove the improper citations and refer only to 10 CFR 52.79 for the FSAR content, the staff found this response acceptable. The applicant issued a supplemental response to **RAI 17.5-2**, dated February 3, 2010, 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 STP's QAPD implementation during construction and operations. RAI 17.5-8 also asked for additional descriptions of the STP's organizational structure and position descriptions and requested an explanation of how the STP will incorporate future revisions to the NEI template. The applicant's response to RAI 17.5-8 (dated October 21, 2008) further revises Part II, Section I of the STP Units 3 and 4 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/pre-operation organization and the organization for "Four Unit Operations." The STPNOC 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 STPNOC's revised organizational charts and functional descriptions meet the requirements of SRP 17.5. These items were incorporated into Revision 2 of the QAPD. The STP's commitment to maintain the QAPD so it is current with NEI template revisions was acceptable, however, Revision 2 of the QAPD, submitted September 30, 2009, does not fully address all items discussed in the SER (ML092650695) accepting the use of the QAPD template contained in NEI 06-14, Revision 7. Thus, **RAI 17.5-6 and RAI 17.5-8** are closed and follow-up RAI **17.5-9** was issued on February 16, 2010. This RAI is being tracked as **Open Item 17.5-9**. This item is discussed in more detail in Sections 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, paragraph II.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, paragraph II.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 paragraph II.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 implementing 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 paragraph II.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 procured products and services, and suppliers are periodically audited and evaluated to ensure that qualified suppliers continue to provide acceptable products and services. Therefore, the 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 change. Therefore, the staff concluded that this alternative is acceptable.

- In the QAPD, the applicant commits 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 (Reference 3); and Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991 (Reference 4); as delineated in SRP Section 17.5, paragraphs II.U.1.d and II.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 paragraph II.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, paragraph II.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 paragraph II.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 15, 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 STPNOC 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.

During the inspection, NRC staff issued Violations 05200012/2009201-01 and 05200013/2009201-01 because the company had failed to 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 Units 1 and 2 procedures that were found to be applicable for Units 3 and 4 COL activities. The company neglected to maintain a complete list of new Units 3 and 4 procedures that had been issued to supersede Units 1 and 2 procedures. The applicant's response in a letter dated April 1, 2009, describes the following corrective actions the company has taken to resolve the issue.

(1) Policy U7-AD01-0004, "Units 3 & 4 Procedure Use and Adherence Policy," is written to establish the list of Units 1 and 2 procedures 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 STPNOC 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 company also added a requirement to the procedure that stipulates if a "controlled" procedure makes a transition statement to another procedure, the second procedure must also be a "controlled" procedure.

As stated in the Commission's letter to the STPNOC dated April 15, 2009, 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 paragraph II.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 by properly reviewed and approved revisions—to ensure that the items are suitable for the intended service and are of acceptable quality, consistent with their effect on safety.

In the QAPD, 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 control 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 National Voluntary Laboratory Accreditation Program (NVLAP) administered by NIST, and other State and Federal agencies perform work under quality programs acceptable to the NRC, and that no additional audits or evaluations are required. However, 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 evaluation that supports this conclusion. The proposed exception provides an appropriate level of quality and safety. The staff determined that this exception is acceptable, as documented in a previous SE (Reference 5).

- SRP Section 17.5, paragraph II.L.8 establishes provisions for the procurement of commercial-grade calibration services for safety-related applications. As an exception to these provisions, the QAPD proposes not to require 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.
  - A documented review of the supplier's accreditation will be performed and will include a verification of the following:

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

    a. 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 (Reference 6). 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 (References 7, 8, and 9).

- 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, paragraphs II.U.1.d and II.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, paragraph II.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, paragraph II.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, paragraph II.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 Electronic Engineers (IEEE) Standard 336-1985, "IEEE Standard Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities," (Reference 5). IEEE Standard 336-1985 refers to IEEE Standard 498-1985, "IEEE Standard Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities," (Reference 6). Each of these standards uses the definition of safety systems equipment from IEEE Standard 603-1980, "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations," (Reference 7). IEEE Standard 603-1980 defines "safety system" as

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

  In the QAPD, the applicant must commit to the definition of safety systems equipment from IEEE Standard 603-1980 to appropriately implement NQA-1-1994, Subpart 2.4. In the QAPD, the applicant commits to the definition of safety systems equipment from IEEE Standard 603-1980 but does not commit to the balance of IEEE Standard 603-1980. This definition applies only to equipment in the context of 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, paragraph II.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 affecting safety will be prepared, documented, verified, tested, and used so that the expected outputs are obtained and the configuration control is maintained.

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 M&TE that provide 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 control of M&TE with the following clarification and exception.

- The QAPD clarifies that the out-of-calibration conditions described in paragraph 3.2 of Supplement 12S-1 of NQA-1-1994 refer to cases where the M&TE are found to be out of the required accuracy limits (i.e., out of tolerance) during calibration. NRC staff determined that the clarification for the 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, paragraph II.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 paragraph II.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 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 do 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 has determined that this clarification is acceptable because it distinguishes between the requirements for construction and operation.
- In NQA-1-1994 Subpart 3.2, Appendix 2.1 provides guidance on the cleaning of fluid systems and associated components for nuclear power plants. The QAPD commits to comply with the precautions identified in Section 3 of the 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 RG 1.37 Regulatory Position C.2 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) 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 identified 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 STP's QAPD follows the guidance in SRP Section 17.5, paragraph II.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 avoid the inadvertent operation of equipment.

In the QAPD, the applicant commits to comply with the quality standards described in this area, as described in NQA-1-1994, Basic Requirement 14, to establish control of activities related to 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, paragraph II.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 of 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 paragraph II.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 responsible management. In the case of suppliers working on safety-related activities or similar situations, the applicant may delegate specific responsibilities for the Corrective Action Program, but the applicant maintains responsibility 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 15, 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 STPNOC 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.

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 that at least one corrective action be implemented 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 repetition. 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 Commission's inspection closeout letter to the STPNOC dated April 15, 2009, 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 paragraph II.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, but it does not provide a list of records and retention times or commit to those sections of the RG. 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,. This item is being tracked as **Open Item 17.5-9**.

Concerning the use of electronic records storage and retrieval systems, the QAPD complies with the 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 paragraph II.R for QA audits. The QAPD establishes the necessary measures to implement audits to verify that activities covered by the QAPD are performed in conformance with documented requirements. The audit program is reviewed for effectiveness as part of the overall audit process.

In the QAPD, the COL applicant or Holder conducts periodic internal and external audits. Internal audits are conducted 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 such a manner as to ensure that an audit of all applicable QA Program elements is completed for each functional area, within a period of 2 years 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 to verify 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 15, 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 STPNOC Units 3 and 4 in accordance with 10 CFR Part 52, Appendix A. The results of the inspection are documented in NRC Inspection Report Nos. 05200012/2009201 and 05200013/2009201 and Notice of Violation.

During the inspection, NRC staff issued Violations 05200012/2009201-04 and 05200013/2009201-04 because the STPNOC failed 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 STPNOC 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 Commission's inspection closeout letter to the STPNOC dated April 15, 2009, the staff reviewed these corrective actions and found them acceptable,

17.5S.4.19 Non-Safety Related SSC Quality Assurance Controls

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

The applicant's QAPD follows the guidance of SRP Section 17.5, paragraph II.V.1 on controls related to non-safety related SSCs. The QAPD establishes program controls applied to non-safety related SSCs that are significant contributors to plant safety and to which Appendix B does not apply. The QAPD applies specific controls to these items in a selected manner,

targeting the characteristics or critical attributes that render the SSC a significant contributor to plant safety consistent with applicable sections of the QAPD.

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 STP'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) 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(V), "Non-safety Related SSC Quality Controls." Thus **RAI 17.5-5** is closed.

17.5S.4.19.2 Non-Safety Related SSCs Credited for Regulatory Events

The applicant's QAPD follows the guidance of SRP Section 17.5, paragraph II.V.2 to establish the quality requirements for non-safety 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, "Fire Protection for Operating Nuclear Power Plants," issued 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 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," issued August 1988.

17.5.4.20 Regulatory Commitments

The applicant's QAPD follows the guidance of SRP Section 17.5, paragraph II.U for describing its 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 01-9** because FSAR Chapter 1.9S, "Conformance with Regulatory Criteria," did not address RGs related to quality assurance. The staff requested that STP provide a list of conformances/exceptions to these RGs. The applicant's response to **RAI 01-9**, dated October 29, 2009, includes a list of conformances and exceptions as well as an except from the QAPD, Part IV, "Regulatory Commitments," Revision 2. The RGs listed in Chapter 1.9S and 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 Chapter 1.9S and Part IV of the QAPD as appropriate. This item is being tracked as **Open Item 17.5-9**.

- RG 1.8, Revision 3, "Qualification and Training of Personnel for Nuclear Power Plants," issued 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 addressed in Chapter 13. Additional detail is located in Chapter 13 of this SER. The QAPD states that the alternatives and exceptions for education and experience for quality assurance personnel addressed by Regulatory Position C.2.1 are addressed in Section 2.6. The QAPD identifies alternatives to Regulatory Positions 2.11 and 2.12 in Section 2.8 as accepted in a previous SER (ML070510300). The QAPD identifies alternatives to Regulatory Positions 2.14 and 2.15 in Section 2.7 as accepted in a previous SER (ML070510300). The staff reviewed these clarifications and alternatives and found that they were consistent with the guidance in SRP 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," issued February 1976.

  The QAPD states that STPNOC conforms to the applicable Regulatory Positions through FSAR Section 3.2 and the ABWR DCD Section 3.2. Additional detail is located in Chapter 3 of this SER. The staff reviewed this clarification and found it consistent with the guidance in SRP 17.5 and therefore acceptable.

- RG 1.28, Revision 3, "Quality Assurance Program Requirements (Design and Construction)," issued 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 17.5 and therefore acceptable.

  The QAPD states that Regulatory Position C.2 is addressed 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 RG. 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,. This item is being tracked as part of **Open Item 17.5-9**.

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

  The QAPD states that STPNOC conforms to the applicable Regulatory Positions through FSAR Section 3.2 and the ABWR DCD Section 3.2. Additional detail is located in Chapter 3 of this SER. NRC staff noted that STP lists conformance with RG 1.29, Revision 4, issued March 2007, in FSAR Chapter 1, Table 1.9S-1, Site-Specific Conformance with Regulatory Guides. The staff issued follow-up **RAI 17.5-9** on February 16, 2010, requesting the applicant to clarify FSAR Chapter 1.9S and Part IV of the QAPD as appropriate. This item is being tracked as part of **Open Item 17.5-9**.

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

  The QAPD states that Regulatory Position C.1 is addressed in Chapter 13 of the FSAR. Additional detail is 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 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 RG. However, the RG also lists other ANSI standards other than N45.2 series. The staff issued follow-up **RAI 17.5-9** on February 16, 2010, requesting the applicant to describe how each of how each of the standards listed in the RG are met.

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 quality assurance program that complies with 10 CFR Part 50, Appendix B, by using NQA-1-1994, as supplemented by additional regulatory and industry guidance identified in SRP Section 17.5. The staff issued follow-up **RAI 17.5-9** on February 16, 2010, requesting the applicant to demonstrate that the QAPD has incorporated 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 those prepared by operating reactors to support adoption of NQA-1-1994. Otherwise, the STP must commit to RG 1.33. These items are being tracked as part of **Open Item 17.5-9**.

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

  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 was incorporated into Revision 2 of the QAPD. Therefore, the staff has closed this item. The QAPD states that Chapter 1 of the FSAR addresses conformance, alternatives, and exceptions to the codes, standards and other documents identified in Regulatory Position C.1. Additional detail is 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 detail is located in Section 13.2. The staff reviewed these clarifications and alternatives and found them consistent with the guidance in SRP 17.5 and therefore acceptable.

- ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, as described in foregoing sections.

  In Section 13.2 of the QAPD, the staff identified that another commitment to NQA-1-1994 is made to Part III, Subpart 3.2, Appendix 2.1, Section 3. The staff issued follow-up **RAI 17.5-9** on February 16, 2010, requesting the applicant to add Part III to this section. This item is being tracked as part of **Open Item 17.5-9**.

- 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 in accordance with 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. In FSAR Section 17.5S, the applicant addresses COL License Information Item 17.1. However, as a result of the identified confirmatory and open items associated with the QAPD, the staff was unable to finalize the conclusions for this section in accordance with the NRC requirements.

17.5S.7 References

1. NUREG-0800, "Standard Review Plan," Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," March 2007.

2. American Society of Mechanical Engineers. "Quality Assurance Requirements for Nuclear Facility Applications," ANSI/ASME Standard NQA-1-1994, Washington DC.

3. Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," dated March 21,1989.

4. Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991.

5. U.S. NRC, Office of Nuclear Reactor Regulation, "Edwin I. Hatch Nuclear Power Station, Units 1 and 2, Approval of Relief Request RR-27, Third -Year Interval Inservice Inspection Program (TAC Nos. MA6163 and MA6164)," (ADAMS Accession No. ML003693241), March 20, 2000.

6. U.S. NRC, Office of Nuclear Reactor Regulation, "Palo Verde Nuclear Generating Station, Units 1, 2, and 3 – Approval of Change To Quality Assurance Program (Commercial-Grade Calibration Services) (TAC Nos. MA4402, MC4403, and MA4404)," (ADAMS Accession No. ML052710224), September 28, 2005.

7. U.S. NRC, Office of Nuclear Reactor Regulation, Letter of Recognition of ACLASS Accreditation Services, "Reply to Your Letter Dated September 26, 2007, Seeking Agency Assistance in Accepting ACLASS Accreditation Services," (ADAMS Accession No. ML073440472), December 19, 2007.

8. U.S. NRC, Office of Nuclear Reactor Regulation, Letter of Recognition of Laboratory Accreditation Bureau (L-A-B), "Reply to Your Letter Dated February 29, 2008, Seeking Assistance in Accepting Laboratory Accreditation Bureau," (ADAMS Accession No. ML081140564), April 22, 2008.

9. U.S. NRC, Office of Nuclear Reactor Regulation, Letter of Recognition of International Accreditation Services, "Reply to Your Letter Dated March 3, 2008, Seeking Assistance in Accepting International Accreditation Services, INC," (ADAMS Accession No. ML081330253), May 14, 2008.

10. Institute of Electrical and Electronic Engineers (IEEE) Standard 336-1985, “IEEE Standard Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities.”

11. Institute of Electrical and Electronic Engineers (IEEE) Standard 498-1985, “IEEE Standard Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities.”

12. Institute of Electrical and Electronic Engineers (IEEE) Standard 603-1980, "EEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations.”

13. U.S. NRC, Office of Nuclear Reactor Regulation, Safety Evaluation of the Proposed Change to the Quality Assurance Program, "Approval of Nuclear Management Company Quality Assurance Topical Report,” (ADAMS Accession No. ML052360625), August 26, 2005.

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 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 07-02, “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 07-02, 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 07-02, 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 07-02, 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 07-02 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 NRC FSER (dated January 24, 2008) for Topical Report NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," Revision 0. NEI 07-02A 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 07-02 template guidance to ensure that the combination of the information in the NEI 07-02 template guidance and the information in the COL application 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 this section.

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

1. FSAR Section 17.6S (Revision 2) incorporates by reference the NEI 07-02 template guidance with supplemental information. The text in the NEI 07-02 template is, however, 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 07-02 template.

   In a letter dated September 8, 2009, 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.

[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

The staff found that the applicant's response to RAI 17.06-1 sufficiently addresses the concerns associated with this RAI. The staff will confirm that the proposed revision is incorporated into Revision 4 of the FSAR. The staff identified this RAI as **Confirmatory Item 17.06-1**.

2. According to NEI 07-02A Revision 0, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," dated March 2008, 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, performance/condition criteria development, monitoring, goal-setting, corrective action, training, program assessment, and maintenance and procurement activities. The staff issued **RAI 17.06-2** requesting the applicant to justify the exclusion of IOE in FSAR Section 17.6S (Revision 2) or revise this section to reflect conformance with NEI 07-02A guidance and its revised safety evaluation.

   In a letter dated September 8, 2009, 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 will confirm that the proposed revision is incorporated into Revision 4 of the FSAR. The staff identified this RAI as **Confirmatory Item 17.06-2**.

The staff reviewed the following information in the COL FSAR:

Supplemental Information

- 17.6S.1.1b

The applicant's action to change the phrase in paragraph 17.X.1.1.b of NEI 07-02 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.

- 17.6S.1.2

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

- 17.6S.1.3

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

- 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 07-02.

As a result of the identified confirmatory items associated with this section the staff was unable to finalize the conclusions for the Maintenance Rule Program.

17.6S.5 Post Combined License Activities

There are no post COL activities related to this section.

17.6S.6 Conclusion

NRC staff reviewed the STP application and checked the referenced NEI 07-02 template guidance. The staff's review confirmed that the applicant has addressed the required information relating to Maintenance Rule Program. With the exception of the **Confirmatory Items 17.06-1 and 17.06-2,** no outstanding information is expected to be addressed in the COL FSAR related to this section.

As a result of the identified confirmatory items associated with the Maintenance Rule Program, the staff was unable to finalize the conclusions on the Maintenance Rule Program in accordance with the requirements of 10 CFR 52.79(a)(15) and 10 CFR 50.65.

17.6S.7 References

NUMARC 93-01, "Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," Revision 2, Nuclear Energy Institute, April 1996.

NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," Nuclear Energy Institute, March 2008.

Regulatory Guide 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," Revision 2, U.S. Nuclear Regulatory Commission.

Regulatory Guide 1.182, "Assessing and Managing Risk Before Maintenance Activities at Nuclear Power Plants," U.S. Nuclear Regulatory Commission, May 2000.

Scott Head, STPNOC, to Document Control Desk, NRC, Subject: "South Texas Project, Units 3 and 4, Docket Nos. 52-012 and 52-013, Response to Request for Additional Information," September 8, 2009 (ADAMS Accession No. ML092530407).