17 QUALITY ASSURANCE AND RELIABILITY ASSURANCE

This chapter describes the Nuclear Regulatory Commission (NRC) staff's review of the United States – Advanced Pressurized Water Reactor (US-APWR) Design Control Document (DCD), Tier 2, Chapter 17, "Quality Assurance and Reliability Assurance" Revision 3. DCD Tier 2, Chapter 17 discusses the quality assurance (QA) during the design phase, QA during the construction and operation phases, the QA program (QAP), the reliability assurance program (RAP) and the QAP description (QAPD) for the design certification (DC). It also discusses Mitsubishi Heavy Industries, Ltd. (MHI's), the DC applicant's, position regarding a combined license (COL) applicant's responsibility for developing a QAP for the construction and operations phase and a program for implementation of 10 CFR 50.65, the Maintenance Rule in Section 17.6. The QAP described in Sections 17.1, 17.2, 17.3 and 17.5 of Chapter 17 of DCD Tier 2 is applicable for QA during the DC phase for US-APWR standard plant design activities. The RAP described in Section 17.4 of DCD Tier 2 applies to those structures, systems, and components (SSCs) that are identified as being risk-significant or significant contributors to plant safety.

17.0 Quality Assurance and Reliability Assurance

The MHI QAPD used for the US-APWR is based on MHI Topical Report PQD-HD-19005, Revision 4, "Quality Assurance Program (QAP) Description for Design Certification of the US-APWR (PQD-HD-19005, Rev. 4)," dated April 1, 2011, which was approved by the staff on November 9, 2011 (ML1128401931). The April 4, 2011 revision to the QAPD supercedes all prior versions. The MHI QAP topical report covers the activities associated with the DC of the US-APWR. The QAP is based on the applicable portions of both Appendix B to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 50) and American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) standard NQA-1-1994, "Quality Assurance Requirements for Nuclear Applications," relevant to the US-APWR DCD,Tier 2.

17.1 Quality Assurance during the Design Phase

Section 17.1 of DCD Tier 2 addresses the QAP during design. The information regarding QA during the design of the US-APWR is provided in DCD Tier 2, Section 17.5. DCD Tier 2, Section 17.1, states that the combined license (COL) applicant is responsible for the development of a QAP applicable to site-specific design activities. The staff's evaluation of the design-phase QAP information is provided in Section 17.5 of this safety evaluation report (SER). However, in summary, the staff agrees that the QAP associated with site-specific design activities is the COL applicant's responsibility. This is identified in COL Information Item 17.5(1) in Table 1.8-2 of Chapter 1 of DCD Tier 2.

17.2 Quality Assurance during the Construction and Operations Phase

In Section 17.2 of DCD Tier 2, the applicant indicates that the construction and operations phases are not applicable to the US-APWR DC. DCD Tier 2, Section 17.2,

states that the COL applicant is responsible for development of the construction and operations phase QAP. The staff's evaluation of this information is provided in Section 17.5 of this SER. However, in summary, the staff agrees that the QAP associated with the construction and operation phases is the COL applicant's responsibility. This is identified in COL Information Item 17.5(1) in Chapter 1, Table 1.8-2, of DCD, Tier 2.

17.3 Quality Assurance Program

In Section 17.3 of DCD Tier 2, the applicant indicates that the QAPD of the DC phase QAP for the US-APWR standard plant design is provided in DCD Tier 2, Section 17.5. The applicant indicates that the General Manager of Nuclear Energy Systems Headquarters is responsible for the DC activities of the US-APWR. The design activities performed by the Nuclear Energy Systems Engineering Center for the US-APWR standard plant design are subjected to the QAP controls specified in "Quality Assurance Program (QAP) Description for Design Certification of the US-APWR (PQD-HD-19005 Rev. 4)." Subcontractors of the Nuclear Energy Systems Engineering Center performing design activities in support of the US-APWR are also required to follow the QAP described in PQD-HD-19005, Rev. 4. The staff's evaluation of this information is provided in Section 17.5 of this SER.

17.4 Reliability Assurance Program

17.4.1 Introduction

The US-APWR DCD Tier 2, Revision 3, Section 17.4, "Reliability Assurance Program," addresses the Commission's direction for the RAP provided in its staff requirements memorandum (SRM), dated June 28, 1995, in response to the staff's Secretary-of-the-Commission (SECY) Paper 95-132 (SECY-95-132). The RAP applies to the SSCs that are identified as risk-significant or significant contributors to plant safety. The risk-significant SSCs are determined by using probabilistic, deterministic, and other methods of analysis used to identify and quantify risk, including information obtained from probabilistic risk assessments (PRA), industry operating experience, relevant component failure databases, and expert panels. The guidance for the RAP is presented in:

- 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.

- NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants, LWR [light-water reactor] Edition," Section 17.4, "Reliability Assurance Program," dated March 2007.

- Interim Staff Guidance (ISG) DC/COL-ISG-018, "Interim Staff Guidance on Standard Review Plan, Section 17.4, 'Reliability Assurance Program'" (ADAMS Accession Number ML103010113).

The purpose of the RAP is to provide reasonable assurance that:

- A plant is designed, constructed, and operated in a manner that is consistent with the key assumptions and risk insights for the SSCs within the scope of the RAP.

- The RAP 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.

- The SSCs function reliably when challenged.

The purpose of the RAP can be achieved by implementing the program in two stages.

The first stage of RAP applies to reliability assurance activities that occur before the initial fuel load and is referred to as the design reliability assurance program (D-RAP). The D-RAP during the DC phase is the DC applicant's responsibility and is described in DCD Tier 2, Section 17.4. The D-RAP may need to be modified during site-specific design activities and during construction. D-RAP activities after DC are the COL applicant's responsibility. The staff verifies the D-RAP during the DC and COL application phases through the agency's safety evaluation (SE) review process. After issuance of the COL, the staff verifies implementation of the D-RAP by the COL licensee through the inspections, tests, analyses, and acceptance criteria (ITAAC) process, as

well as through inspections under the construction inspection program during detailed design activities and construction before initial fuel load.

The second stage of the RAP applies to reliability assurance activities conducted during the operations phase of the plant's life cycle, and is the responsibility of the COL licensee. These activities are implemented under operational programs as specified in DCD Tier 2, Section 13.4, "Operational Program Implementation." Upon issuance of a COL by the NRC, operational programs may become license conditions that are implemented by the licensee throughout the life of the plant. The staff verifies implementation of these operational programs using inspections for the duration of the license.

17.4.2 Summary of Application

DCD Tier 1: The Tier 1 information associated with this section is found in DCD Tier 1, Section 2.13, "Design Reliability Assurance Program." This section of the DCD provides the ITAAC for the D-RAP.

DCD Tier 2: The applicant has provided a DCD Tier 2 description of the RAP in Section 17.4, Revision 3, summarized here in part, as follows:

> US-APWR DCD, Tier 2, Section 17.4, "Reliability Assurance Program," addresses the scope, purpose, objectives, essential elements, organizations implementing the D-RAP, including SSC identification and prioritization, use of expert panel and operating experience. This DCD section also addresses integration of the RAP into operational programs, and the COL information needed to implement the portions of the D-RAP for which the COL applicant is responsible and to implement the RAP in the operations phase.

The applicant provided the following documents that form the basis of the US-APWR RAP and the D-RAP ITAAC.

(a) US-APWR DCD Tier 2, Section 17.4, Revision 3, that describes the following:

- the RAP, including the scope, purpose, and objectives of the RAP;
- the essential elements of the D-RAP (i.e., organization, design control, procedures and instructions, records, corrective actions, and audit plans);
- the methodology used for identifying the RAP SSCs, including the use of an expert panel;
- the list of RAP SSCs;
- the identification of dominant failure modes;
- the integration of RAP into operational programs;
- the COL information items;

- the ITAAC for the D-RAP;

(b) US-APWR DCD Tier 1, Section 2.13, Revision 3, “Design Reliability Assurance Program.” This section of the DCD provides the ITAAC for the D-RAP.

Other sections of the DCD interface with DCD Tier 2, Section 17.4 as follows:

- DCD Tier 2, Chapter 19, "Probabilistic Risk Assessment [PRA] and Severe Accident Evaluation," provides the risk evaluations that are used to facilitate the identification of RAP SSCs in DCD Tier 2, Section 17.4. These risk evaluations cover the full spectrum of potential events and the range of plant operating modes considered in DCD Tier 2, Chapter 19 (e.g., full power and low-power/shutdown PRAs for internal events, fire events, seismic events, flooding events, and other external events). The quality control, technical adequacy, and maintenance of the PRA are also covered under DCD Tier 2, Chapter 19. The review of DCD Tier 2, Chapter 19 is performed in accordance with Section 19.0 of the SRP, "Probabilistic Risk Assessment and Severe Accident Evaluation for New Reactors," and is documented in Chapter 19 of this SER.

- All RAP SSCs are subjected to the QA controls that are described in the applicant’s QAPD provided in DCD Tier 2, Section 17.5, "Quality Assurance Program Description." The review of DCD Tier 2, Section 17.5 is performed in accordance with Section 17.5 of the SRP, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants."

- Section 17.6 of DCD Tier 2 addresses the COL applicant’s responsibilities regarding description of its program for meeting the requirements of 10 CFR 50.65, the Maintenance Rule. This is related in that the Maintenance Rule program is one of the operational programs cited in SECY-95-132, Item E, for implementation of the RAP in the operations phase.

ITAAC: The ITAAC associated with DCD Tier 2, Section 17.4 is given in DCD Tier 1, Section 2.13. A single ITAAC for the RAP is provided in Table 2.13-1 of Section 2.13. The acceptance criterion for the ITAAC requires that a report exists and concludes that, for all SSCs that are within the scope of RAP when the COL is issued, the initial design has been subject to the applicable reliability assurance activities of the D-RAP.

Technical Specifications (TS): There are no TS for this area of review.

COL Information or Action Items: DCD Tier 2, Revision 3, Section 17.4.9, “Combined License Information,” provides COL Information Items 17.4(1) and 17.4(2). COL Information Item 17.4(1) identifies the COL activities that must be performed during Phases II and III of the D-RAP. COL Information Item 17.4(2) identifies the COL activities that must be performed to integrate the RAP into operational programs. See Section 17.4.5 below.

Technical Reports: MHI Technical Report MUAP-07030, Revision 3, "US-APWR Probabilistic Risk Assessment" (this report is reviewed as part of the staff's review under DCD Tier 2, Chapter 19).

Topical Reports: There are no topical reports associated with this area of review.

17.4.3 Regulatory Basis

The relevant requirements of the Commission's regulations for this area of review, and the associated acceptance criteria, are given in Section 17.4 of NUREG-0800 (as clarified or changed by DC/COL-ISG-018) and are summarized below. Review interfaces with other SRP sections can be found in Section 17.4 of NUREG-0800.

1. The RAP is implemented in accordance with the Commission policy in the SRM on SECY-95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs," Item E, "Reliability Assurance Program." The requirement to provide a RAP is codified by incorporation within the design-specific rulemaking for an applicant for DC. Meeting this requirement provides evidence that (1) the plant will be designed, constructed, and operated in a manner that is consistent with the key assumptions and risk insights for the RAP SSCs, (2) the RAP SSCs will not degrade to an unacceptable level of performance or condition during plant operations, (3) the frequency of transients that challenge these SSCs will be minimized, and (4) these SSCs will function reliably when challenged. In addition, this becomes part of an application for a COL that references the certified design. In accordance with Commission policy documented in the SRM for SECY-95-132, the ITAAC process, as well as inspections during detailed design and construction before initial fuel load, will verify the implementation of the D-RAP by the COL licensee.

2. In part, 10 CFR 52.47(b)(1) states that an application for a DC must include proposed tests, inspections, analyses, and acceptance criteria, which are necessary and sufficient to provide reasonable assurance that, if the tests, inspections, and analyses are performed and the acceptance criteria are met, a plant that references the design is built and will operate in accordance with the DC.

Acceptance criteria adequate to meet the above requirements include the following:

NUREG-0800, Section 17.4 (as clarified or changed by DC/COL-ISG-018), which lists the information to be submitted for quality elements associated with organization, design control, procedures and instructions, records, corrective action, audit plans, information related to expert panels, and methods used to identify the SSCs to be included in the RAP.

17.4.4 Technical Evaluation

The staff reviewed the documents that form the basis of the US-APWR RAP in accordance with the guidance in Item E of SECY-95-132, SRP Section 17.4 (dated

March 2007, and as clarified or changed by DC/COL-ISG-018), and SRP Section 14.3 ("Inspections, Tests, Analyses, and Acceptance Criteria") (dated March 2007) to determine whether the US-APWR RAP provides reasonable assurance that (1) the plant is designed, constructed, and operated in a manner that is consistent with the key assumptions and risk insights for risk-significant SSCs; (2) the risk significant SSCs do not degrade to an unacceptable level of reliability, availability, or condition during plant operations; (3) the frequency of transients that challenge these SSCs are minimized; and (4) risk-significant SSCs function reliably when challenged. The staff also reviewed SSCs within the scope of the RAP to ensure that all risk-significant contributors are identified and addressed in the program. The objective of the RAP is to ensure that the plant meets the purposes above, through the design, procurement, fabrication, construction, preoperational testing, and operational activities and programs. The DC applicant is responsible for developing and implementing Phase I of the D-RAP. COL applicants referencing the US-APWR design are responsible for developing and implementing Phases II and III of the D-RAP and for integrating the RAP into operational programs.

The staff's review of the US-APWR RAP included the issuance of requests for additional information (RAIs) to the applicant, followed by the evaluation of the applicant's responses to the RAIs. These RAIs covered all aspects of the RAP. The staff's technical evaluation of the information contained in DCD Tier 2, Section 17.4 and DCD Tier 1, Section 2.13 follows in Sections 17.4.4.1 through 17.4.4.8 of this SER.

17.4.4.1 Description of the RAP

The staff reviewed the description of the RAP provided in DCD Tier 2, Sections 17.4.2 ("Introduction") and 17.4.3 ("Scope"). This review was performed in accordance with Item E of SECY-95-132 and SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018) to determine whether this subject review area is consistent with the guidance contained in these documents. Based on Item E of SECY-95-132 and SRP Section 17.4, the application should adequately describe the details of the RAP that will be implemented during the DC and COL design and construction activities preceding initial fuel load. This description should include a discussion of the scope, purpose, and objectives of the RAP.

On the basis of its review of DCD Tier 2, Sections 17.4.2 and 17.4.3, the staff determined that the scope of the RAP includes safety-related and non-safety-related SSCs that are determined to be risk-significant using probabilistic and deterministic analyses, including use of industry operating experience and an expert panel. The purpose of the RAP is to provide reasonable assurance that: 1) the US-APWR is designed, constructed, and operated in a manner that is consistent with the key assumptions and risk insights for the RAP SSCs, 2) the RAP SSCs do not degrade to an unacceptable level of performance or condition during plant operations, 3) the frequency of transients that challenge the RAP SSCs is minimized, and 4) the RAP SSCs function reliably when challenged. The objective of the RAP is to ensure that the plant meets the purposes above, through the design, procurement, fabrication, construction, preoperational testing, and operational activities and programs. The applicant is responsible for developing and implementing Phase I of the D-RAP. COL applicants referencing the US-APWR design are responsible for developing and implementing Phases II and III of the D-RAP and for integrating RAP into operational programs.

The staff finds that the description of the US-APWR RAP (including the scope, purpose and objectives of the RAP) described in DCD Tier 2, Sections 17.4.2 and 17.4.3, Revision 3, is adequate and conforms to the guidance in Item E of SECY-95-132 and SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018). This subject review area is acceptable.

17.4.4.2 Essential Elements of the D-RAP

The staff reviewed the essential elements of the D-RAP (also known as quality controls of the D-RAP) provided in DCD Tier 2, Section 17.4.4 ("Quality Controls"). This review was performed in accordance with Item E of SECY-95-132 and SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018) to determine whether this subject review area conforms to the guidance contained in these reference 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 D-RAP to support DC design activities. These essential elements ensure that the key assumptions and risk insights are consistent with the design and that the list of RAP SSCs is appropriately developed, maintained, and communicated to the appropriate organizations. The application should adequately address the following essential elements of D-RAP that are described in SRP Section 17.4:

- Organization.
- Design Control.
- Controls for procedures.
- Controls for records of activities.
- Corrective action process.
- Audit plans.

The staff's findings based on its review of the information related to this subject area of the DCD are as follows.

(a) DCD Tier 2, Section 17.4.4 identifies the organizations responsible for establishing the scope of the D-RAP, as well as those that develop, coordinate, or implement D-RAP activities. This section also describes how these organizations interface to ensure that the plant will be designed consistently with the key assumptions and risk insights. The General Manager of the US-APWR project has overall responsibility for assuring all affected organizations are aware of the D-RAP and its purpose and requirements. The General Manager of Reactor and Plant Safety is responsible for the conduct and coordination of the Expert Panel, including the use of the PRA results and risk insights. The Reactor and Plant Safety organization includes the risk and reliability organization that is responsible for maintaining and providing the D-RAP related inputs in the design process by participating in the design change process. The risk and reliability organization provides the D-RAP related inputs to the design engineering and QA organizations. The General Manager of QA is responsible for assuring proper implementation of QA program elements. This includes design control, procedures and instructions, records, corrective actions and audits pertaining to the D-RAP. The General Managers of Design Engineering are responsible for implementing the D-RAP and to assure the US-APWR design is consistent with the key assumptions and risk insights of the PRA, and providing feedback to the

risk and reliability organization to ensure key assumptions and risk insights are realistic and achievable. The design control process provides a feedback mechanism for notifying the risk and reliability organization of changes in the design that could affect the PRA.

(b) DCD Tier 2, Section 17.4.4 provides details regarding the D-RAP design control. This section discusses the measures that are established for the identification and control of design interfaces and for coordination among participating design organizations. Since the US-APWR full-scope PRA is not complete and is subject to change, the applicant describes the process used to control the changes in the PRA, which could affect the list of RAP SSCs. In addition, the applicant describes how the design control process provides a feedback mechanism for notifying the risk and reliability organization of changes in the design that could affect the PRA. The D-RAP-related inputs are maintained and updated by the risk and reliability organization and changes thereof are approved by the expert panel. DCD Tier 2, Chapter 19 discusses the quality controls for the risk evaluations that are used in DCD Tier 2, Section 17.4 for the RAP.

(c) DCD Tier 2, Section 17.4.4, describes the controls for procedures used for developing, coordinating, and implementing D-RAP activities. The General Manager of the US-APWR project is responsible for preparing the procedures used in developing, coordinating, and implementing D-RAP activities. In order to examine the adequacy of these procedures, the staff issued RAI 891-6268, Question 17.04-62 (originally identified as RAI 6268, Question 23148) requesting that the applicant submit for the staff's review these D-RAP procedures or provide an overview of these procedures. In its response to RAI 891-6268, Question 17.04-62, dated April 24, 2012, the applicant provided an overview of these procedures. The requirements for implementing the activities associated with the essential elements of D-RAP are defined in four D-RAP specific procedures in addition to the procedures commonly used for US-APWR design activities (e.g., the QAPD and procedures used for design change control). The following procedures are specific to the applicant's D-RAP:

- UES-UAP-20120001, "US-APWR, Procedure for Reliability Assurance Program (RAP)." This procedure outlines: the methods and criteria for the evaluation and identification of risk-significant SSCs, the use of the expert panel, issuance of the list of risk-significant SSCs for D-RAP, organization responsibilities for implementing D-RAP activities, confirmation of the key assumptions in the risk analyses, and QA records for D-RAP activities.

- 5AB61-190, "Procedures for Expert Panel Meeting for US-APWR Design Reliability Assurance Program (D-RAP)." This procedure provides general provisions of the expert panel such as: expert panel meeting instructions, scope of expert panel meetings, expert panel composition, expert panel certification and revocation, expert panel member prerequisites, and recording and maintaining of expert panel meeting minutes.

- 5AB61-191, "Roles of the Reactor Safety Engineering Department in the US-APWR Design Reliability Assurance Program (D-RAP)." This

procedure provides detailed information regarding the roles and responsibilities of the Reactor Safety Engineering Department regarding D-RAP activities for the US-APWR described in UES-UAP-20120001.

- 5AB61-192, "Procedures for Evaluating SSCs for the Purpose of Selecting Risk-Significant SSCs Regarding the US-APWR Design Reliability Assurance Program (D-RAP)." This procedure provides information regarding evaluating and selecting risk-significant SSCs using the PRA results and insights and other methods as described in Section 17.4 of the DCD Tier 2.

In its RAI response dated April 24, 2012, the applicant sufficiently describes each D-RAP procedure, which addresses the essential elements outlined in DC/COL-ISG-018. The staff concludes that the applicant has developed detailed procedures to direct the performance of D-RAP activities. Based on the above discussion, RAI 891-6268, Question 17.04-62 is resolved and closed.

(d) DCD Tier 2, Section 17.4.4 describes the controls for records of D-RAP activities. Records related to the D-RAP include the list of RAP SSCs, expert panel meeting summaries, records and documentation associated with the risk evaluations that are used to facilitate the identification of RAP SSCs, and other QAP records in accordance with the US-APWR QAPD. Records and documentation associated with the risk evaluations are discussed in Chapter 19, "Probabilistic Risk Assessment and Severe Accident Evaluation," of DCD Tier 2. The staff's review of DCD Tier 2, Chapter 19 is documented in Chapter 19 of this SER.

(e) DCD Tier 2, Section 17.4.4 describes the corrective action process applied to D-RAP for Phase I (DC phase) of the D-RAP. COL Information Item 17.4(1) in DCD Tier 2, Section 17.4.9 ("Combined License Information") addresses the corrective action process for Phases II (site-specific design phase) and III (procurement, fabrication, construction, and pre-operational testing phase) of the D-RAP. COL Information Item 17.4(2) addresses the corrective action process for the operational phase of RAP. The staff determined that the corrective action process applied to Phase I of the D-RAP is not clearly described. More specifically, Part e ("Corrective Action") in DCD Tier 2, Section 17.4.4, Revision 2, states: "The CAP [corrective action program] utilized to support the QAPD can be used to implement the corrective actions related to the RAP." The use of the word "can" in the above statement suggests that there may be a possible alternative method for implementing the corrective actions related to the RAP. Therefore, the staff issued RAI 606-4827, Question 17.04-50 (originally identified as RAI 4827, Question 18247) requesting that the applicant clarify the above statement. In its response to RAI 606-4827, Question 17.04-50, dated September 3, 2010, the applicant states that DCD Tier 2, Section 17.4.4 would be revised as follows: "The CAP [corrective action program] utilized to support the QAPD is used to implement the corrective actions related to the RAP." The staff found that the applicant's response to RAI 606-4827, Question 17.04-50 sufficiently addresses this RAI since it is appropriate to use the CAP that supports the QAP to address the RAP corrective action process. The staff confirmed that the proposed revision is incorporated into Revision 3 of the DCD

Tier 2. Based on the above discussion, RAI 606-4827, Question 17.04-50 is resolved and closed.

In accordance with ISG DC/COL-ISG-018, the non-safety-related RAP SSCs should be subjected to QA controls in accordance with the provisions of Subsection V ("Nonsafety-Related SSC Quality Controls") in Section 17.5 of the SRP for all phases of the D-RAP. Therefore, during Phase I of the D-RAP for the DC, the non-safety-related RAP SSCs should be subjected to the appropriate QA controls described in DCD Tier 2, Section 17.5 ("Quality Assurance Program Description"). During Phases II and III of the D-RAP for the COL applicant and holder, the non-safety-related RAP SSCs should be subjected to the appropriate QA controls described in the COL applicant's QAPD. However, it is not clear in DCD Tier 2, Section 17.4, Revision 2, that the non-safety-related RAP SSCs would be subjected to these QA controls. Therefore, the staff issued RAI 606-4827, Question 17.04-51 (originally identified as RAI 4827, Question 18248) requesting that the applicant clarify in the DCD Tier 2 that the non-safety-related RAP SSCs would be subjected to the appropriate QA controls that are described in the QAPD for the DC and COL for all phases of the D-RAP. In its response to RAI 606-4827, Question 17.04-51, dated September 3, 2010, the applicant states that DCD Tier 2, Section 17.4.2 would be revised as follows: "The non-safety-related RAP SSCs would be subjected to the appropriate QA controls that are described in the Section 17.5 of the US-APWR DCD for the Phase I of the D-RAP, and in Section 17.5 of the site specific COL for the Phase II and III of the D-RAP." The staff found that the applicant's response to RAI 606-4827, Question 17.04-51 sufficiently addresses the concerns associated with this question, because the non-safety-related RAP SSCs would be subjected to QA controls in accordance with the provisions of Subsection V in Section 17.5 of the SRP. The staff confirmed that the proposed revision is incorporated into Revision 3 of the DCD Tier 2. Based on the above discussion and the discussion in SER Section 17.4.4.4(b), RAI 606-4827, Question 17.04-51 is resolved and closed.

In accordance with ISG DC/COL-ISG-018, the corrective action process applied to D-RAP activities should ensure that any D-RAP activity determined to be in error, deficient, defective, or nonconforming are promptly identified, reported, and corrected. For example, information used to identify the RAP SSCs may be determined to be incorrect, or there may be a failure to communicate a key assumption to the design engineering organization. Therefore, the corrective action process for D-RAP that is described in DCD Tier 2, Section 17.4.4, Revision 3, is limiting or restrictive, because it applies to only design documents that address SSC reliability assumptions. The staff issued RAI 891-6268, Question 17.04-63 (originally identified as RAI 6268, Question 23149) requesting that the applicant clarify the corrective action process for D-RAP. In its response to RAI 891-6268, Question 17.04-63, dated April 24, 2012, the applicant proposes to clarify in the next revision of DCD Tier 2, Section 17.4.4 that the CAP is applicable to all D-RAP activities. The staff found that the applicant's response sufficiently addresses the concerns associated with this question, because all D-RAP activities would be subjected to the CAP. Based on the above discussion, RAI 891-6268, Question 17.04-63 is resolved. Verification that the proposed change is in the next revision of the DCD Tier 2 is being tracked as **Confirmatory Item 17.04-63**.

(f) DCD Tier 2, Section 17.4.4 describes the details of audit plans for the D-RAP. Audits would include sampling the effectiveness of implementation of the RAP procedures, and consideration of key aspects of the RAP.

On the basis of the discussion in this section and with the exception of staff review and approval of the associated confirmatory item, the staff finds that the essential elements of D-RAP (i.e., organization, design control, procedures, records, corrective action process, and audit plans) are adequately addressed in the application and conform to the guidance in Item E of SECY-95-132 and SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018). This subject review area is acceptable with the exception of staff review and approval of the confirmatory item.

17.4.4.3 Methodology for Identifying the RAP SSCs

The staff reviewed the detailed methodology used to identify the RAP SSCs provided in DCD Tier 2, Section 17.4.7.1 ("SSCs Identification"). This review was performed in accordance with Item E of SECY-95-132 and SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018) to determine whether this subject review area of the DCD Tier 2 conforms to the guidance contained in these documents. Based on Item E of SECY-95-132 and SRP Section 17.4, the application should describe an acceptable methodology for identifying the RAP SSCs as determined by using a combination of probabilistic, deterministic, and other methods of analysis. The methodology should include the use of information obtained from the following sources:

- risk evaluations that cover the full spectrum of potential events and the range of plant operating modes considered in DCD Tier 2, Chapter 19, which include use of non-PRA-type evaluations (e.g., seismic margins analysis) when PRAs have not been performed,
- industry operating experience, and
- expert panel.

The roles and responsibilities of the expert panel should be described since they play an important role in reviewing the information associated with risk significance determinations and could compensate for the limitations of the PRA.

The staff's findings based on its review of the information related to this subject area of the DCD Tier 2 are as follows.

(a) DCD Tier 2, Section 17.4.7.1, Revision 1, describes the methodology for identifying the RAP SSCs and references DCD Tier 2, Section 19.1.7.4 ("PRA Input to the Reliability Assurance Program"), Revision 1, which states: "Risk-significant SSCs are identified for the RAP (Chapter 17, Section 17.4). Key risk-significant SSCs are organized by a Fussell-Vesely (FV) importance greater than 0.005 and risk achievement worth (RAW) greater than 2 in accordance with Reference 19.1-42. These thresholds are consistent with Reference 19.1-43." The stated Reference 19.1-43 refers to Nuclear Energy Institute (NEI) document 00-04, which uses, in addition to the criteria stated above, a common-cause failure (CCF) basic-event RAW criterion of greater than 20 for identifying risk-

significant SSCs. However, it is not clear from DCD Tier 2, Sections 17.4.7.1 and 19.1.7.4, Revision 1, as to what RAW criterion (e.g., 2, 20, or some other value) was used for CCF basic events during RAP SSC identification. Therefore, the staff issued RAI 101-1474, Question 17.04-1 (originally identified as RAI 1474, Question 5342) requesting that the applicant clarify in the DCD the RAW criterion used for CCF basic events.

In its response to RAI 101-1474, Question 17.04-1, dated December 12, 2008, the applicant states that the RAP SSCs are identified by a FV importance greater than 0.005 and a RAW importance greater than 2 as established in NUMARC 93-01 for the maintenance rule program. In the US-APWR RAP, these criteria are applied to both single-failure basic events and CCF basic events. RAP SSCs identified by using a RAW greater than 2 include those SSCs having a RAW greater than 20, which is the RAW criterion for CCF basic events used in NEI-00-04. The applicant also states that the RAW criteria used for CCF basic events in developing the list of RAP SSCs will be clarified in the next revision of the DCD.

The staff finds that the applicant's response to RAI 101-1474, Question 17.04-1 sufficiently addresses the concerns associated with this RAI. Applying the RAW criterion of 2 for CCF basic events is consistent with industry practice and would identify a larger set of RAP SSCs relative to a RAW criterion of 20 for CCF basic events. Therefore, this criterion is acceptable. The staff confirmed that the proposed revision is incorporated into Revision 2 of the DCD. Based on the above discussion, RAI 101-1474, Question 17.04-1 is resolved and closed.

(b) DCD Tier 2, Section 17.4.7.1, Revision 1, describes the methodology for identifying the RAP SSCs and references DCD Tier 2, Section 19.1.7.4, Revision 1. The applicant computed RAWs and FVs for various risk hazards (e.g., internal events, internal fire, and internal flooding at power and shutdown). However, it is not clear from DCD Tier 2, Sections 17.4.7.1 and 19.1.7.4, Revision 1, as to how the risk importance criteria (i.e., FV importance greater than 0.005 and RAW greater than 2) are applied to the various risk hazard models that computed RAWs and FVs. For example, it is not clear whether the RAW and FV criteria applied only to the internal events model, applied to each risk hazard model separately, or applied to the combined or integrated results of the risk hazard models. Therefore, the staff issued RAI 101-1474, Question 17.04-2 (originally identified as RAI 1474, Question 5343) requesting that the applicant clarify in the DCD Tier 2 how the risk importance criteria are applied to the various risk hazard models that computed RAWs and FVs.

In its response to RAI 101-1474, Question 17.04-2, dated December 12, 2008, the applicant stated that the RAW and FV criteria are applied to each risk hazard model separately. For each risk hazard, RAP SSCs are identified based on the risk importance criteria (i.e., FV importance greater than 0.005 and RAW greater than 2). The list of RAP SSCs for each risk hazard is then combined into a single list. Thus, the final list of RAP SSCs provided by the PRA captures the results of all risk hazards. The applicant stated that the next revision of the DCD Tier 2 will clarify how the risk importance criteria were applied to the various risk hazard models.

The staff finds that the applicant's response to RAI 101-1474, Question 17.04-02 sufficiently addresses the concerns associated with this RAI. Applying the RAW and FV criteria to each risk hazard model separately is consistent with industry practice and is conservative, relative to the integrated results approach, since high RAW or FV values from individual risk hazard models cannot be masked by the risk hazard models having low risk importance. Therefore, applying the RAW and FV criteria to each risk hazard model separately is acceptable. The staff confirmed that the proposed revision is incorporated into Revision 2 of the DCD. Based on the above discussion, RAI 101-1474, Question 17.04-02 is resolved and closed.

(c) In DCD Tier 2, Chapter 19, Revision 1, the evaluation of seismic external events is based on a seismic margins analysis (SMA). DCD Tier 2, Sections 17.4.7.1 and 19.1.7.4, Revision 1, does not describe how the SMA is used to identify RAP SSCs. Furthermore, it seems that the applicant does not consider the SMA in identifying RAP SSCs. However, the applicant should consider the SMA in identifying RAP SSCs since these SSCs are credited as part of the safe shutdown paths evaluated under the SMA. In addition to being capable of withstanding seismic events, these SSCs need to have high reliability and availability in order to perform its safe shutdown functions. As such, these SSCs should be in the scope of D-RAP. The SMA is another tool used to identify RAP SSCs in accordance with SECY-95-132. Therefore, the staff issued RAI 101-1474, Question 17.04-4 (originally identified as RAI 1474, Question 5345) requesting that the applicant consider the SMA in identifying RAP SSCs. For example, NEI 00-04, “10 CFR 50.69 SSC Categorization Guideline,” Revision 0, provides an acceptable approach to identifying risk-significant SSCs for the RAP using SMA.

In its response to RAI 101-1474, Question 17.04-4, dated December 12, 2008, the applicant states that the SMA was not previously used to identify RAP SSCs. The applicant states that it will use the SMA to identify additional RAP SSCs according to the approach provided by NEI 00-04. The identified SSCs will be discussed by the expert panel for D-RAP. The applicant also states that the next revision of the DCD will describe the use of the SMA to identify RAP SSCs

The staff finds that the applicant’s use of the SMA to identify additional RAP SSCs is in accordance with NEI 00-04, which is endorsed by NRC Regulatory Guide (RG) 1.201, ”Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to their Safety Significance.” Additionally, the staff confirmed that the proposed revision of DCD Tier 2, Section 17.4.7.1 is incorporated into Revision 2 of the DCD. The staff also confirmed that the SMA is appropriately applied to develop the list of RAP SSCs. Therefore, the staff finds that the applicant's response sufficiently addresses RAI 101-1474, Question 17.04-4, which is thus, resolved and closed.

(d) DCD Tier 2, Section 17.4.7.1, Revision 1, describes the methodology for identifying RAP SSCs and references DCD Tier 2, Section 19.1.7.4, Revision 1, which states: “Risk-significant SSCs are identified for the RAP (Chapter 17, Section 17.4). Key risk-significant SSCs are organized by a FV importance

greater than 0.005 and RAW greater than 2 in accordance with Reference 19.1-42. These thresholds are consistent with Reference 19.1-43." The FV importance can be computed at a basic-event level (i.e., FV of the component for individual failure modes) and at a component level (i.e., FV of the component for all failure modes combined, including common-cause events). Based on References 19.1-42 (NUMARC 93-01) and 19.1-43 (NEI 00-04) the component-level FV importance should be applied to the FV criteria of 0.005. However, DCD Tier 2, Sections 17.4.7.1 and 19.1.7.4, Revision 1, suggests that the FV importance at the basic-event level is applied to the FV criteria, which may not be appropriate. Therefore, the staff issued RAI 101-1474, Question 17.04-5 (originally identified as RAI 1474, Question 5346) requesting that the applicant clarify its use of FV importance for identifying RAP SSCs, in the DCD.

In its response to RAI 101-1474, Question 17.04-5, dated December 12, 2008, the applicant states that the FV importance was previously computed and applied at a basic-event level. The applicant states that it will compute the FV importance at a component level and revise the list of RAP SSCs based on the component-level FVs. The applicant also states that these changes will be incorporated into the next revision of the DCD.

The staff finds that the applicant's response to RAI 101-1474, Question 17.04-5 sufficiently addresses this RAI question. The applicant's use of FV importance at the component level is appropriate and consistent with NEI 00-04 and NUMARC 93-01, which are endorsed by RG 1.201 and RG 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," respectively. The staff confirmed that the proposed revision is incorporated into Revision 2 of the DCD in Tier 2, Section 17.4.7.1. The staff also confirmed the use of FV importance at the component level in developing the list of RAP SSCs in DCD Tier 2, Section 17.4, Table 17.4-1, "Risk-Significant SSCs." Based on the above discussion, RAI 101-1474, Question 17.04-5 is resolved and closed.

(e) Based on DCD Tier 2, Sections 17.4.7.1 and 19.1.7.4, Revision 1, it is not clear whether the expert panel reviewed the categorization of SSCs determined to be not risk-significant (NRS) from quantified PRA results. The expert panel plays an important role in reviewing the information that lead to these NRS determinations (e.g., assures the basis used in the categorization is technically adequate, reviews defense-in-depth implications and reviews safety margin implications). Therefore, the staff issued RAI 101-1474, Question 17.04-6 (originally identified as RAI 1474, Question 5347) requesting that the applicant incorporate into its risk significance methodology, the use of an expert panel to review the categorization of SSCs that were determined to be NRS from quantified PRA results.

In its response to RAI 101-1474, Question 17.04-6, dated December 12, 2008, the applicant stated that the categorization of SSCs determined to be NRS from quantified PRA results is not reviewed explicitly by the expert panel. The applicant states that it will incorporate the use of the expert panel to review the categorization of SSCs determined to be NRS into the methodology, and that the following sentence will be added in the next revision of DCD Tier 2, Section 17.4.7.1: "The EP [expert panel] also reviews the categorization of SSCs determined to be not risk-significant from quantified PRA results (e.g., technical

adequacy of the basis used in the categorization, review of defense-in depth implications, review of safety margin implications)."

The staff finds that the applicant's response to RAI 101-1474, Question 17.04-6 sufficiently addresses the concerns associated with this RAI. The applicant's use of an expert panel to review the categorization of SSCs determined to be NRS meets staff's expectations on the use of an expert panel. The staff confirmed that the proposed revision is incorporated into Revision 2 of the DCD. Based on the above discussion, RAI 101-1474, Question 17.04-6 is resolved and closed.

(f) DCD Tier 2, Section 17.4.7.2 ("Expert Panel"), Revision 1, states: "Each voting member of the RAP EP should have the level of education and experience defined by the RAP implementing procedure." The RAP implementing procedure is not provided in the DCD; therefore, it is not clear what is meant by "…level of education and experience defined by the RAP implementing procedure." Therefore, the staff issued RAI 101-1474, Question 17.04-14 (originally identified as RAI 1474, Question 5355) requesting that the applicant describe the level of education and experience defined by the RAP implementing procedure, in the DCD.

In its response to RAI 101-1474 Question 17.04-14, dated December 12, 2008, the applicant stated that DCD Tier 2, Section 17.4.7.2 will be modified to provide a description of the level of education and experience defined by the expert panel implementing procedure. The applicant stated that the level of education and experience of voting members of the expert panel would be defined in the expert panel implementing procedure for the US-APWR RAP as follows: "A person with a science or technical degree and 10 years of nuclear power plant experience in the specific area, such as design, or similar experience, or, a person with a non-technical degree and 15 years of nuclear power plant experience in the specific area, such as design, or similar experience."

The staff finds that the applicant's response to RAI 101-1474, Question 17.04-14 sufficiently addresses this RAI, and that based on guidance in SRP Section 17.4, the level of education and experience of voting members of the expert panel as described by the applicant is adequate. However, the staff found during its review of DCD Tier 2, Section 17.4.7.2, Revision 2, that the applicant does not incorporate its response to RAI 101-1474, Question 17.04-14 into the DCD. Instead, the applicant provides an alternative description that is not clear. Therefore, the staff issued RAI 606-4827, Question 17.04-53 (originally RAI 4827, Question 18250) as a followup, requesting that the applicant more clearly describe the qualification requirements for members of the expert panel or incorporate the applicant's response to RAI 101-1474, Question 17.04-14, in the DCD. In its response to RAI Question 17.04-53, dated September 3, 2010, the applicant clarified the qualification requirements for the members of the expert panel. This clarification is consistent with the qualification requirements proposed in response to RAI 101-1474, Question 17.04-14, and, therefore, is acceptable. The staff confirmed that the proposed revision is incorporated into Revision 3 of the DCD. Based on the above discussion, RAI 101-1474, Question 17.04-14 and RAI 606-4827, Question 17.04-53 are resolved and closed.

In conclusion, the staff finds that the applicant's methodology for identifying the RAP SSCs uses an appropriate combination of probabilistic and deterministic analyses, including the use of information obtained from:

- risk evaluations that cover the full spectrum of potential events and the range of plant operating modes considered in DCD Tier 2, Chapter 19, which include use of the SMA,
- industry operating experience, and
- expert panel.

The roles and responsibilities of the expert panel are described since they play an important role in reviewing the information associated with risk significance determinations. Also, the applicant's methodology is consistent with common industry practices. Based on the discussion in this section, the staff finds that the detailed methodology used to identify the RAP SSCs described in DCD Tier 2, Section 17.4.7.1 is adequate and conforms to the guidance in Item E of SECY-95-132 and SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018). This subject review area is acceptable.

17.4.4.4 List of RAP SSCs

The staff reviewed the list of RAP SSCs provided in DCD Tier 2, Table 17.4-1 ("Risk-Significant SSCs"). This review was performed in accordance with Item E of SECY-95-132 and SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018) to determine whether this subject review area of the DCD conforms to the guidance contained in these reference documents. Based on Item E of SECY-95-132 and SRP Section 17.4, the application should contain a comprehensive list of RAP SSCs (within the scope of the DC) based on an acceptable methodology that uses a combination of probabilistic, deterministic, and other methods of analysis. The bases for including each RAP SSC should be described. To communicate the RAP SSCs effectively and accurately to the organizations that implement the D-RAP, the RAP SSCs should be clearly identified using text descriptions and specific SSC identification numbers, when applicable. In addition, the boundaries of the RAP SSCs should be clearly defined to provide a common basis for understanding the RAP SSCs.

The staff's findings based on its review of the information related to this subject area of the DCD are as follows.

(a) DCD Tier 2, Table 17.4-1 provides the list of RAP SSCs. However, the staff identified additional SSCs, which do not appear in DCD Tier 2, Table 17.4-1, Revisions 1 through 3, that could potentially be risk-significant based on specific US-APWR PRA results, risk insights, and PRA assumptions. Therefore, the staff issued the following RAIs requesting that the applicant evaluate these SSCs for inclusion in DCD Tier 2, Table 17.4-1:

- RAI 398-1961, Question 17.04-48 (remote shutdown panel)

- RAI 175-1676, Question 17.04-38 and RAI 398-1961, Question 17.04-49 (SSCs associated with instrumentation and control systems)
- RAI 101-1474, Question 17.04-18 (structures that house risk-significant SSCs)
- RAI 150-1635, Question 17.04-21 (Emergency Feedwater System pit water level indicators)
- RAI 150-1635, Question 17.04-22 (High-Head Safety Injection System, HPI, motor-operated valves 014A, B, C, D)
- RAI 150-1635, Question 17.04-23 and Supplement RAI 385-2293, Question 17.04-43 (Component Cooling Water System, CCW, valves necessary to provide cooling water to the HPI pumps)
- RAI 150-1635, Question 17.04-24 (CCW valves necessary to provide cooling water to the Containment Spray System and Residual Heat Removal System pumps and heat exchangers)
- RAI 150-1635, Question 17.04-25 (valves and auxiliary tank associated with the Refueling Water Storage System)
- RAI 150-1635, Question 17.04-26 and Supplement RAI 385-2293, Question 17.04-41 (redundant strainers in the Essential Service Water System, ESWS)
- RAI 150-1635, Question 17.04-29 (SSCs associated with alternate containment cooling by the Containment Fan Cooler System)
- RAI 150-1635, Question 17.04-30 and Supplement RAI 385-2293, Question 17.04-44 (CCW valves necessary to provide cooling water to the Charging Injection System, CHI, pumps)
- RAI 150-1635, Questions 17.04-31, 32, and Supplement RAI 385-2293, Question 17.04-40 (CHI motor-operated valves, seal water injection filters, and seal water injection isolation valves)
- RAI 606-4827, Question 17.04-56 (Emergency Feedwater System, EFWS, motor-operated valves 101A, B, C, and D)
- RAI 606-4827, Question 17.04-56 (EFWS pump actuation cabinets)
- RAI 606-4827, Question 17.04-56 (Fire Suppression System, FSS, motor-operated valve 004, check valve 006, and orifice FS02)
- RAI 101-1474, Question 17.04-15 and RAI 606-4827, Question 17.04-56 (fire water suppression pumps)

- RAI 606-4827, Question 17.04-56 (Main Steam System safety valves 511A-D, 512A-D, 513A-D, and 514A-D)
- RAI 606-4827, Question 17.04-56 (Chilled Water System check valves 005B and C)
- RAI 606-4827, Question 17.04-56 (SSCs related to the Boric Acid Transfer System)
- RAI 891-6268, Question 17.04-67 (CCW pump room floor drain pit water level sensors)
- RAI 891-6268, Question 17.04-67 (additional piping segments for CHI and FSS systems)
- RAI 891-6268, Question 17.04-67 (CCW surge tank A)
- RAI 891-6268, Question 17.04-67 (containment isolation valves VCS-AOV-356 and VCS-AOV-357)

The applicant addresses the above RAIs in responses dated December 12, 2008, February 6, 2009, March 10, 2009, April 3, 2009, July 10, 2009, July 18, 2009, September 3, 2010, and June 12, 2012. In its responses, the applicant describes its re-evaluation of the risk significance of these additional SSCs, which take into consideration the re-quantified PRA results from Revision 3 of MUAP-07030, "US-APWR Probabilistic Risk Assessment," the operating experience, and the expert panel discussions. As a result, the applicant determined that these additional SSCs are risk-significant. The staff verified the applicant's evaluations by examining the US-APWR PRA results (MUAP-07030) and applying the methodology used to identify the RAP SSCs provided in DCD Tier 2, Section 17.4.7.1. With the exception of the additional risk-significant SSCs associated with RAI 17.04-67 discussed above, the staff confirmed that the applicant includes in DCD Tier 2, Table 17.4-1, the additional SSCs determined to be risk-significant. Based on the above discussion, with the exception of RAI 17.04-67, the RAIs listed above are resolved and closed. RAI 17.04-67 is considered resolved; however, the incorporation of the additional risk-significant SSCs associated with RAI 17.04-67 into the next revision of Table 17.4-1 of the US-APWR DCD Tier 2 is being tracked as **Confirmatory Item 17.04-67**.

(b) The boundaries (e.g., electrical and mechanical boundaries) of the RAP SSCs should be clearly defined so that the scope of RAP SSCs can be effectively communicated to the organizations that implement the D-RAP and to provide a common basis for understanding the RAP SSCs (e.g., it is important to know the boundaries of the RAP SSCs for which the QA controls are applicable). Therefore, as discussed in SE Section 17.4.4.2 above, the staff issued RAI 606-4827, Question 17.04-51 (originally RAI 4827, Question 18248) requesting that the applicant define or identify, in DCD Tier 2, the boundaries of the RAP SSCs.

In its response to RAI 606-4827, Question 17.04-51, dated September 3, 2010, the applicant stated that DCD Tier 2, Section 17.4 will be modified to state that

the non-safety-related RAP SSCs would be subjected to the appropriate QA controls that are described in Section 17.5 of DCD Tier 2 for Phase I of the D-RAP and in Section 17.5 of the COL FSAR for Phases II and III of the D-RAP. The component boundaries are defined through reference to the US-APWR PRA (MUAP-07030). The staff finds that the applicant's response to RAI 606-4827, Question 17.04-51 sufficiently addresses the concerns associated with this question. The staff reviewed the component boundary definitions in the US-APWR PRA and found that it adequately defines the component boundaries to ensure that the scope of RAP SSCs can be effectively communicated to the organizations that implement the D-RAP. The staff confirmed that the proposed revision is incorporated into Revision 3 of the DCD. Based on the above discussion and the discussion in SE Section 17.4.4.2, RAI 606-4827, Question 17.04-51 is resolved and closed.

In conclusion, based on the discussion in this section and with the exception of the staff's review and approval of the associated confirmatory item, the staff finds that the list of RAP SSCs described in DCD Tier 2, Table 17.4-1, is adequate and conforms to the guidance in Item E of SECY-95-132 and SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018). Pending staff's review and approval of the associated confirmatory item, this subject review area of the DCD is acceptable.

17.4.4.5 Identification of Dominant Failure Modes

The staff reviewed the applicant's process for determining dominant failure modes of RAP SSCs described in DCD Tier 2, Section 17.4.7.1. In addition, the staff reviewed the list of dominant failure modes provided in DCD Tier 2, Table 17.4-1. This review was performed in accordance with Item E of SECY-95-132 and SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018) to determine whether this subject review area of the DCD conforms to the guidance contained in these reference documents. Based on Item E of SECY-95-132 and SRP Section 17.4, the application should describe the process for determining dominant failure modes of RAP SSCs that considers industry experience, analytical models, and applicable requirements.

The staff's findings based on its review of the information related to this subject area of the DCD are as follows.

(a) DCD Tier 2, Section 17.4.7.1, Revision 2, describes the process for determining the dominant failure modes of RAP SSCs. However, it is not clear that industry operating experience is considered by the expert panel in the identification of dominant failure modes. Therefore, the staff issued RAI 606-4827, Question 17.04-52 (originally RAI 4827, Question 18249) requesting that the applicant include the consideration or review of industry operating experience in its process for determining dominant failure modes. In its response to RAI 606-4827, Question 17.04-52, dated September 3, 2010, the applicant stated that DCD Tier 2, Section 17.4.7.1, Part b, would be modified to state: "In the expert panel's discussion, review of dominant failure modes are also considered in order to reflect industry operating experience." The staff found that the applicant's response to RAI 606-4827, Question 17.04-52 sufficiently addresses the consideration of industry operating experience in its process for determining dominant failure modes. Based on the above discussion, RAI 606-4827,

Question 17.04-52 is resolved. Verification that the proposed change is in Revision 4 of the DCD Tier 2 is being tracked as **Confirmatory Item 17.04-52**.

(b) DCD Tier 2, Table 17.4-1, Revisions 2 and 3, lists the dominant failure modes for each RAP SSC. However, the staff identified additional failure modes for some RAP SSCs that could be potentially dominant failure modes based on specific US-APWR PRA results, risk insights, and PRA assumptions. Therefore, the staff issued RAI 606-4827, Question 17.04-58 (originally RAI 4827, Question 18255) and RAI 891-6268, Question 17.04-66 (originally RAI 6268, Question 23152) requesting that the applicant evaluate these potentially dominant failure modes for inclusion in DCD Tier 2, Table 17.4-1.

In its response to RAI 606-4827, Question 17.04-58, dated September 3, 2010, and RAI 891-6268, Question 17.04-66, dated June 12, 2012, the applicant describes its evaluation of the potentially dominant failure modes for inclusion in DCD Tier 2, Table 17.4-1. The applicant identifies the following additions or changes to the list of dominant failure modes in DCD Tier 2, Table 17.4-1:

Component	Addition or Change to the List of Dominant Failure Modes
NCS-MOV-020C, D	Added failure mode “OD” (fail to open)
NCS-MOV-007C, D	Added failure mode “OD”
Piping for Component Cooling Water System	Deleted failure mode “SF” (software failure)
SIS-VLV-010A, B, C, D	Added failure mode “FS” (functional failure by seismic hazard)
MSS-MOV-507A, B, C, D	Failure mode “CF” in Table 17.4-1 is an editorial error, changed to “CD” (fail to close)
RHS-MOV-021A, B, C, D	Added failure modes “OD” and “CM” (spurious closure)
RWS-AOV-022	Added failure modes “CD” and “OM” (spurious opening)
Control Rod	Failure mode “CF” in Table 17.4-1 is an editorial error, changed to “FR” (functional failure of control rods)
Control Rod Drive Mechanism	Failure mode “CF” in Table 17.4-1 is an editorial error, deleted “CF”
VWS-MOV-401 and 409	Added failure modes “CD”, “IL” (internal leak), and “OM”

MSS-TCV-550A to Q	Added failure modes “OD” and “CM”
NCS-MTK-001B	Deleted failure modes “IL” and “OM” as they are specific to valves
CCWS Piping	Deleted failure mode “IL” as it is specific to valves
P1, P2 Non-Class 1E Station Service Transformers	Deleted failure mode “SO” (spurious open) as it is specific to circuit breakers
Numerous SSCs listed in DCD Tier 2, Table 17.4-1	Added seismic failure modes from the seismic margins analysis

The staff confirmed the applicant’s evaluation of the potentially dominant failure modes by examining the US-APWR PRA results (MUAP-07030) and applying the methodology used for determining dominant failure modes described in DCD Tier 2, Section 17.4.7.1. Therefore, the staff found that the applicant's responses to RAI 606-4827, Question 17.04-58 and RAI 891-6268, Question 17.04-66 are acceptable. The staff confirmed that the changes proposed in the response to RAI 606-4827, Question 17.04-58 are incorporated into Revision 3 of the DCD Tier 2, and, therefore, this RAI is resolved and closed. Also, based on the above discussion, RAI 891-6268, Question 17.04-66 is resolved. Verification that the proposed changes are in the next revision of the DCD Tier 2 is being tracked as **Confirmatory Item 17.04-66**.

In conclusion, based on the discussion in this section, with the exception of staff’s review and approval of the associated confirmatory items, the staff finds that the identification of dominant failure modes for RAP SSCs described in DCD Tier 2, Section 17.4.7.1 and Table 17.4-1 is adequate and conforms to the guidance in Item E of SECY-95-132 and SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018). This subject review area of the DCD is acceptable with the exception of staff review and approval of the confirmatory items.

17.4.4.6 Integration of RAP into Operational Programs

The staff reviewed the integration of RAP into operational programs, which is described in DCD Tier 2, Sections 17.4.2 and 17.4.5 ("Integration into Existing Operational Programs”). This review was performed in accordance with Item E of SECY-95-132 and SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018) to determine whether this subject review area of the DCD conforms to the guidance contained in these reference documents. Based on Item E of SECY-95-132 and SRP Section 17.4, the DCD should specify a COL information item for the COL applicant to propose a process for integrating the RAP into operational programs to meet the objectives of the RAP during plant operations.

DCD Tier 2, Section 17.4.2 states that the COL applicant is responsible for integrating the RAP into operational programs (e.g., maintenance rule, surveillance testing, in-service inspection, in-service testing, maintenance, and QA), including providing a process for corrective actions related to design and operational errors that degrade non-safety-related SSCs within the scope of the RAP. The COL applicant will provide a description of the proposed method for developing/integrating the operational RAP into

operating plant programs to meet the objectives of the RAP during plant operations, in the COL application. This COL activity is specified by COL Information Item 17.4(2). Based on the discussion provided above, DCD Tier 2 adequately specifies a COL information item (i.e., COL Information Item 17.4(2)) for the COL applicant to propose a process for integrating the RAP into operational programs. Therefore, this subject review area of the DCD is consistent with the guidance in Item E of SECY-95-132 and SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018), and is therefore, acceptable.

17.4.4.7 COL Information Items

The staff reviewed the COL information items provided in DCD Tier 2, Section 17.4.9 ("Combined License Information"). This review was performed in accordance with Item E of SECY-95-132 and SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018) to determine whether this subject review area of the DCD conforms to the guidance contained in these reference documents. Based on Item E of SECY-95-132 and SRP Section 17.4, the DCD should specify the appropriate COL information items to support D-RAP during the detailed design and construction phase.

The staff's findings based on its review of the information related to this subject area of the DCD are as follows:

DCD Tier 2, Section 17.4.9, Revision 1, specifies COL Information Items 17.4(1) and 17.4(2). COL Information Item 17.4(1) describes the COL applicant's responsibilities for Phases II and III of the D-RAP. COL Information Item 17.4(2) describes the COL applicant's responsibilities for integrating the RAP into operational programs. However, both COL information items are unclear and not sufficiently complete to meet the recommendations in Item E of SECY-95-132 and DC/COL-ISG-018. For example, in COL Information Item 17.4(1), it is not clear as to what activities would be completed during the COL application phase as opposed to those that would be completed during the detailed design and construction phases. Also, it is not clear in COL Information Item 17.4(1) that the QA controls implemented during the detailed design and construction phases would address non-safety-related RAP SSCs. In COL Information Item 17.4(2), it is not clear as to what activities would be completed during the COL application phase as opposed to those that would be completed during the operations phase. Also, COL Information Item 17.4(2) should address the following in accordance with SECY-95-132:

- Establishing reliability performance goals for the RAP SSCs during the operational phase (for example, implementation of the maintenance rule program following the guidance contained in RG 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," is one acceptable method for establishing performance goals provided that the RAP SSCs are categorized as high-safety-significant within the scope of the maintenance rule program).

- Establishing performance and condition monitoring requirements during the operational phase to provide reasonable assurance that the RAP SSCs do not degrade to an unacceptable level of reliability, availability, or condition during plant operations.

The staff issued RAI 101-1474, Question 17.04-10, RAI 175-1676, Question 17.04-36, and RAI 398-1961, Question 17.04-47 requesting that the applicant address the above issues. The applicant addresses these RAI questions in its responses dated December 12, 2008, March 3, 2009, and July 18, 2009. In its responses, the applicant proposes changes to COL Information Items 17.4(1) and 17.4(2) as shown in Table 17.4-1 of this SE.

The staff finds that the applicant's proposed changes to COL Information Items 17.4(1) and 17.4(2) in response to these RAIs conform to the guidance in Item E of SECY-95-132 and SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018). The applicant's proposed changes clarifies the COL information items and specifies those activities that should be completed during the COL application phase and those that should be completed during the detailed design and construction phases. The proposed revised COL Information Item 17.4(1) indicates that the QA requirements are applicable to all RAP SSCs, including the non-safety-related RAP SSCs. The proposed revised COL Information Item 17.4(2) addresses the establishment of reliability performance goals and performance and condition monitoring requirements during the operational phase for the RAP SSCs. Therefore, the staff finds that the applicant's responses to RAI 101-1474, Question 17.04-10; RAI 175-1676, Question 17.04-36; and RAI 398-1961, Question 17.04-47 sufficiently addresses these RAIs. The staff subsequently confirmed that the proposed revised COL information items are incorporated into Revision 2 of the DCD. Based on the above discussion, RAI 101-1474, Question 17.04-10; RAI 175-1676, Question 17.04-36; and RAI 398-1961, Question 17.04-47 are resolved and closed.

The staff finds that the COL information items described in DCD Tier 2, Section 17.4.9, Revision 3, are adequate and conform to the guidance in Item E of SECY-95-132 and SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018). This subject review area of the DCD is acceptable.

17.4.4.8 D-RAP ITAAC

The staff reviewed the ITAAC for the D-RAP provided in DCD Tier 1, Section 2.13 ("Design Reliability Assurance Program") and discussed in DCD Tier 2, Section 17.4.8 ("ITAAC for the D-RAP"). This review was performed in accordance with Item E of SECY-95-132, SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018), and SRP Section 14.3 to determine whether this subject review area of the DCD conforms to the guidance contained in these reference documents.

The staff's findings from the review of the information related to this subject area of the DCD are as follows. DCD Tier 1, Section 2.13, Revision 1, specifies a design commitment that the D-RAP provides reasonable assurance that the design of the RAP SSCs is consistent with the assumptions used in the risk analyses. The associated D-RAP ITAAC acceptance criteria ensures that the estimated reliability of each as-built RAP SSC be equal to or exceed the assumed reliability, and that these estimated reliabilities take into account industry experience. The staff noted that the D-RAP ITAAC should not solely be based on numerical values because some numerical estimates (e.g., estimated reliability, assumed reliability) may not be available, and additional aspects of D-RAP are needed in the D-RAP ITAAC in order to address other key assumptions and risk insights. Therefore, the applicant's D-RAP ITAAC under DCD Tier

1, Section 2.13, Revision 1, may not be practical or effective in providing reasonable assurance that the plant is designed and constructed in a manner that is consistent with the key assumptions and risk insights for the RAP SSCs. It is important to have a process that would control reliability and availability of these RAP SSCs. Therefore, the staff issued RAI 175-1676, Question 17.04-37 (originally RAI 1676, Question 6211) requesting that the applicant consider revising the D-RAP ITAAC in DCD Tier 1, Section 2.13 to take into consideration the staff's comments provided above.

In its response to RAI 175-1676, Question 17.04-37, dated April 3, 2009, the applicant proposes a revised D-RAP ITAAC that would ensure each RAP SSC is subjected to the appropriate D-RAP reliability assurance activities described in DCD Tier 2, Section 17.4 (e.g., applying the essential elements of D-RAP and subjecting each RAP SSC to the appropriate QA controls). In accordance with Item E of SECY-95-132 and SRP Section 17.4, these D-RAP reliability assurance activities ensure that the plant is designed and constructed in a manner that is consistent with the key assumptions (including reliability and availability assumptions in PRA, when applicable) and risk insights for the RAP SSCs. Therefore, the staff finds that the applicant's response to RAI 175-1676, Question 17.04-37 sufficiently addresses this RAI. The staff confirmed that the proposed revision is incorporated into Revision 2 of the DCD Tier 1. Based on the above discussion, RAI 175-1676, Question 17.04-37 is resolved and closed. In a public meeting with the applicant held on February 16, 2011 (ADAMS Accession Number ML110340312), the staff discussed the revised guidance for D-RAP ITAAC to be published in DC/COL-ISG-018 and recommended that the applicant revise the D-RAP ITAAC based on this guidance. DC/COL-ISG-018 was published in March 2011, and subsequently, the applicant revised the D-RAP ITAAC in DCD Tier 1, Section 2.13, Revision 3, to be consistent with the guidance in DC/COL-ISG-018. The staff finds that the D-RAP ITAAC provided in DCD Tier 1, Section 2.13, Revision 3, is adequate and meets the guidance in DC/COL-ISG-018.

The staff noted that, the discussion of the D-RAP ITAAC provided in DCD Tier 2, Section 17.4.8, Revision 3, does not seem to be consistent with the revised D-RAP ITAAC in DCD Tier 1, Section 2.13, Revision 3. The staff issued RAI 891-6268, Question 17.04-68 (originally RAI 6268, Question 23155) requesting that the applicant clarify the discussion of the D-RAP ITAAC in DCD Tier 2, Section 17.4.8. In its response to RAI 891-6268, Question 17.04-68, dated April 24, 2012, the applicant clarified the discussion of the D-RAP ITAAC in DCD Tier 2, Section 17.4.8 and proposed to incorporate it into the next revision of the DCD Tier 2. The staff finds the applicant’s clarification to be consistent with the D-RAP ITAAC in DCD Tier 1, Section 2.13, Revision 3, and therefore, to be acceptable. Based on the above discussion, RAI 891-6268, Question 17.04-68 is resolved. Verification that the proposed change is in the next revision of the DCD Tier 2 is being tracked as **Confirmatory Item 17.04-68**.

In conclusion, based on the discussion in this section, with the exception of the staff’s review and approval of the associated confirmatory item, the staff finds that the D-RAP ITAAC described in DCD Tier 1, Section 2.13 and DCD Tier 2, Section 17.4.8 is adequate and conforms to the guidance in Item E of SECY-95-132 and SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018). This subject review area of the DCD is acceptable, with the exception of staff review and approval of the confirmatory item.

17.4.5 Combined License Information Items

The following is a list of COL information item numbers and descriptions from Section 17.4.9, "Combined License Information," and Table 1.8-2, "Compilation of All Combined License Applicant Items for Chapters 1-19," of the US-APWR DCD Tier 2, Revision 3. The staff's evaluation of these COL information items is discussed above in Section 17.4.4.7, "COL Information Items," of this SE.

Table 17.4-1
US-APWR Combined License Information Items

Item No.	Description	Section
17.4(1)	The COL Applicant shall be responsible for the development and implementation of the Phases II and III of the D-RAP, including QA requirements. In the Phase II, the plant's site-specific information should be introduced to the D-RAP process and the site-specific risk-significant SSCs should be combined with the US-APWR design risk-significant SSCs into a list for the specific plant. Phase II is performed during the COL application phase and updated/maintained during the COL license holder phase. In the Phase III, procurement, fabrication, construction, and test specifications for the SSCs within the scope of the RAP should ensure that significant assumptions, such as equipment reliability, are realistic and achievable. The QA requirements should be implemented during the procurement, fabrication, construction, and pre-operation testing of the SSCs within the scope of the RAP. Phase III is performed during the COL license holder phase and prior to initial fuel loading. The COL Applicant will propose a method by which it will incorporate the objectives of the reliability assurance program into other programs for design or operational errors that degrade nonsafety-related, risk-significant SSCs.	17.4.9
17.4(2)	The COL Applicant shall be responsible for the development and implementation of the RAP during the operations phase, in which the RAP activities should be integrated into the existing operational program (e.g., Maintenance Rule, surveillance testing, in-service inspection, in-service testing, and QA). The RAP during the operations phase should also include the process for providing corrective actions for design and operational errors that degrade non-safety-related SSCs within the scope of the RAP. A description of the proposed method for developing/integrating the operational RAP into operating plant programs (e.g., maintenance rule, QA) is performed during the COL application phase. The development/integration of the operational RAP is performed during the COL license holder phase and prior to initial fuel loading. All SSCs identified as risk-significant within the scope of the D-RAP should be categorized	17.4.9

Item No.	Description	Section
	as high-safety-significant (HSS) within the scope of initial Maintenance Rule. The integration of reliability assurance activities into existing operational programs will also address establishment of: 1) Reliability performance goals for risk-significant SSCs consistent with the existing maintenance and QA processes on the basis of information from the D-RAP (for example, implementation of the maintenance rule following the guidance contained in RG 1.160 is one acceptable method for establishing performance goals provided that SSCs are categorized as HSS within the scope of the Maintenance Rule program), and 2) Performance and condition monitoring requirements to provide reasonable assurance that risk-significant SSCs do not degrade to an unacceptable level during plant operations.	

17.4.6 Conclusions

The US-APWR DCD Tier 2, Section 17.4, Revision 3, together with DCD Tier 1, Section 2.13, Revision 3, form the basis of the RAP for the US-APWR. The NRC staff reviewed the documents that form the basis of the US-APWR RAP in accordance with Item E of SECY-95-132, SRP Section 17.4 (as clarified or changed by DC/COL-ISG-018), and SRP Section 14.3 and confirmed that with the exception of the associated confirmatory items, the applicant has adequately addressed the required information relating to the RAP. With the exception of the staff's review and approval of the associated confirmatory items, the staff concludes that the US-APWR RAP is acceptable and conforms to the guidance in Item E of SECY-95-132 and SRP Section 17.4.

17.5 Quality Assurance Program Description

17.5.1 Introduction

DCD Tier 2, Section 17.5, "Quality Assurance Program Description," describes a QAP applicable to activities performed during the DC phase of the nuclear power plant. The US-APWR QAPD is described by reference to the "Quality Assurance Program (QAP) Description for Design Certification of the US-APWR," PQD-HD-19005, Revision 4 dated April 1, 2011. The QAPD is based on the requirements of ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II.

17.5.2 Summary of Application

DCD Tier 1: There are no DCD Tier 1 entries for this area of review.

DCD Tier 2: The applicant has provided a DCD Tier 2 description of the QAP in Section 17.5, summarized here in part, as follows:

> The US-APWR DCD, Tier 2, Section 17.5, "Quality Assurance Program Description," states that the QAP is the top-level policy that establishes the QA policy and assigns major functional responsibilities for the design of the US-APWR. The applicant states that the QAP provides for the methods and establishes the QAP and administrative control requirements described in PQD-HD-19005, Revision 4. The QAPD for the DC phase has been prepared on the basis of the staff-approved QAP template, NEI 06-14 (Revision 4 and earlier revisions), "Quality Assurance Program Description," which was initially approved by the staff in a SER dated April 25, 2007. The COL applicant is to be responsible for the development of a QAPD for site-specific design activities and for plant construction and operation.

ITAAC: There are no ITAAC for this area of review.

Technical Specifications (TS): There are no TS for this area of review.

COL Information or Action Items: See Section 17.5.5 below.

Technical Reports: There are no technical reports associated with this area of review.

Topical Reports: The Topical Report associated with DCD Tier 2, Chapter 17, Section 17.5, is "Quality Assurance Program (QAP) Description for Design Certification of the US-APWR," PQD-HD-19005, Revision 4, dated April 1, 2011.

17.5.3 Regulatory Basis

The relevant requirements of the Commission's regulations for these areas of review, and the associated acceptance criteria, are given in Section 17.5 of NUREG-0800, the SRP, and are summarized below. Review interfaces with other SRP sections can be found in Section 17.5 of NUREG-0800.

The regulatory basis of the information described in MHI Topical Report PQD-HD-19005, "Quality Assurance Program (QAP) Description for Design Certification of the US-APWR," Revision 4, is addressed within the staff's SER related to Topical Report PQD-HD-19005, Revision 1, dated January 24, 2008 (ML073610579), as supplemented by letter from the NRC to MHI dated November 9, 2011 (ML1128401931).

1. Appendix A to 10 CFR Part 50, GDC 1, "Quality Standards and Records," requires that a QAP be established and implemented.

2. Appendix B to 10 CFR Part 50 specifies 18 QA criteria which must be addressed in the QAPD. Appendix B establishes QA requirements for the design, fabrication, construction, and testing of SSCs of the facility. The pertinent requirements of 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 SSCs.

3. 10 CFR 50.34(b)(6)(ii) requires that the information regarding the controls to be used for a nuclear power plant include a discussion for how the applicable requirements of Appendix B will be satisfied.

4. 10 CFR 50.34(f)(3)(ii) and (iii) specify design and construction QA requirements, which must be addressed in a QAPD.

5. 10 CFR 50.54(a)(3)(ii), as it relates to changes to a QAPD that are not considered to be reductions in commitment, allows a licensee to use a QA alternative or exception approved by an NRC staff SE provided that the bases of the staff's approval is applicable to the licensee's facility.

6. 10 CFR 50.55a requires the SSCs be designated, fabricated, erected, constructed, tested, and inspected to quality standards commensurate with the importance of the safety function to be performed.

7. 10 CFR 52.47(a)(19) requires, in part, that a DC application contain the technically relevant information in a final safety analysis report (FSAR) that describes the facility, presents the design bases and the limits for its operation, and presents a safety analysis of the SSCs and of the facility as a whole, and must include a description of the QAP to be applied to the design of the SSCs of the facility. 10 CFR 52.47(a)(19) further requires that the description of the QAP for a nuclear power plant include a discussion of how the applicable requirements of Appendix B will be satisfied.

8. 10 CFR 52.47(a)(21) requires a standard DC applicant to include a QAPD, which satisfies applicable portions of Appendix B to 10 CFR Part 50.

Acceptance criteria adequate to meet the above requirements are listed in Section 17.5, Subsection II "Acceptance Criteria," paragraph entitled "SRP Acceptance Criteria" of NUREG-0800, the SRP, and are summarized below:

1. American National Standards Institute/American Nuclear Society Standard N-18.7.

2. ASME Standard NQA-1-1994.

In addition, acceptable alternatives and exceptions are listed in this NUREG-0800 section.

17.5.4 Technical Evaluation

By letter dated January 24, 2008, the staff issued a SER that approved the QAPD in the applicant's MHI Topical Report PQD-HD-19005, Revision 1, for the US-APWR DC activities. Subsequently, by letter dated April 8, 2011, the applicant submitted a revised QAPD (PQD-HD-19005, Revision 4) for review and approval. By letter dated November 9, 2011, the staff issued a Supplemental SER that approved the revised QAPD (PQD-HD-19005, Revision 4) for the US-APWR DC activities on the basis that the changes to the QAPD did not constitute any reduction in commitment from the staff's previously approved version. Specifically, the staff evaluated the MHI US-APWR QAP to verify that it meets the commission's regulations by following the guidance in NUREG-0800, SRP Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants."

The staff confirmed that Section 17.5 of the US-APWR DCD Tier 2 incorporates PQD-HD-19005, Revision 4, without exception, for control of activities affecting quality during the DC of the US-APWR, and is, therefore, acceptable.

The staff's inspection of the applicant's implementation of the QAP as it relates to the US-APWR project was being tracked as **Open Item 17.05-01**. In December 2010, a NRC inspection team conducted a limited scope inspection at the MHI facility in Kobe, Japan, as documented in inspection report number 05200021/2010-201, dated February 2, 2011 (ML110210624). The purpose of the NRC inspection was to verify that the applicant's QA processes and procedures were effectively implemented with regards to the applicant's US-APWR DC application activities. In this inspection, the NRC inspectors identified three violations of NRC requirements related to aspects of the QAP including: (1) lack of objective evidence supporting external audit findings, (2) failure to document nonconformances in a timely manner, and (3) failure to implement measures to assure that the cause of significant conditions adverse to quality was determined and corrective action taken to preclude repetition. In its response to these violations dated March 2, 2011 (ML1106703531), the applicant addressed the issues. The applicant's response included a description of proposed changes to the QAP, including MHI implementing procedures, and additional training of MHI personnel to correct these deficiencies. On the basis of the inspection results, and subsequent responses to the violations by the applicant, which the staff found acceptable, **Open Item 17.05-01 is resolved.**

17.5.5 Combined License Information Items

The following is a list of item numbers and descriptions from Table 1.8-2 of the DCD Tier 2:

Table 17.5-1
US-APWR Combined License Information Items

Item No.	Description	Section
17.5(1)	The COL applicant shall develop and implement a QAPD for site-specific design activities and for plant construction and operation.	17.5.1

The NRC staff has reviewed the proposed COL information item and has determined it is consistent with the requirements set forth in 10CFR52.79(a)(25)regarding a description of the QAP for COLs, and is, therefore, acceptable.

17.5.6 Conclusions

The staff used the requirements of Appendix B to 10 CFR Part 50, 10 CFR 52.47(a)(19) and the guidance of SRP Section 17.5 as the bases for evaluating the acceptability of the MHI US-APWR QAP as described in Sections 17.1, 17.2, 17.3, and 17.5 of the MHI US-APWR DCD Tier 2. On the basis of its review, the staff concludes that the MHI US-APWR QAP, as described in DCD Tier 2, Sections 17.1, 17.2, 17.3, and 17.5, provides adequate guidance for establishing a QAP that complies with applicable NRC regulations and industry standards and may be used for DC activities.

17.6 Description of the Applicant's Program for Implementation of 10 CFR 50.65, the Maintenance Rule

17.6.1 Introduction

The description of the implementation of the Maintenance Rule program in DCD Tier 2, Section 17.6 addresses the COL applicant's program for Maintenance Rule implementation based on the requirements of 10 CFR 50.65.

17.6.2 Summary of Application

The US-APWR DCD, Tier 2, Section 17.6, "Description of the Applicant's Program for Implementation of 10 CFR 50.65, the Maintenance Rule," addresses the maintenance rule program for a COL. DCD Tier 2, Section 17.6, Revision 3, states that the COL applicant must provide a description of the maintenance rule program, and its implementation, for monitoring the effectiveness of maintenance necessary to meet the requirements of 10 CFR 50.65, in its FSAR. The applicant identified this as COL Information Item 17.6(1) as shown in Section 17.6.5 of this SE.

DCD Tier 1: There are no DCD Tier 1 entries for this area of review.

DCD Tier 2: The applicant has provided a DCD Tier 2 description of the applicant's program for implementation of the Maintenance Rule in Section 17.6, summarized here in part, as follows:

> The COL applicant must provide in its FSAR a description of the maintenance rule program, and its implementation, for monitoring the effectiveness of maintenance necessary to meet the requirements of 10 CFR 50.65.

ITAAC: There are no ITAAC for this area of review.

TS: There are no TS for this area of review.

COL Information or Action Items: See Section 17.6.5 below.

Technical Reports: There are no technical reports associated with this area of review.

Topical Reports: There are no topical reports associated with this area of review.

17.6.3 Regulatory Basis

The relevant requirements of the Commission's regulations for these areas of review, and the associated acceptance criteria, are given in Section 17.6 of NUREG-0800, the SRP, and are summarized below. Review interfaces with other SRP sections can be found in Section 17.6 of NUREG-0800.

1. 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants."

2. This regulatory basis is provided for information only since it is applicable to a COL applicant's FSAR Section 17.6: Paragraph (a)(15) of 10 CFR 52.79, which requires that a COL FSAR include a description of the program, and its implementation, for monitoring the effectiveness of maintenance necessary to meet the requirements of 10 CFR 50.65.

Acceptance criteria adequate to meet the above requirements are contained in the following:

1. NUMARC 93-01, as endorsed by RG 1.160, represents an acceptable approach for implementing a Maintenance Rule program in accordance with 10 CFR 50.65. The applicant's program should be consistent with the industry guidance as endorsed and qualified by the RG. Deviations should be explained and justified.

2. For COL reviews, the description of the operational program and proposed implementation milestones for the Maintenance Rule program are reviewed in accordance with 10 CFR 50.65. The implementation milestones are plant-specific except that 10 CFR 50.65 requires that the program be fully implemented by the time fuel load is authorized.

17.6.4 Technical Evaluation

The staff reviewed Section 17.6 of the US-APWR DCD, Tier 2, in accordance with SRP Section 17.6 to ensure that the proposed maintenance rule program meets the requirements in this document.

The following provides the staff's findings from the review of this subject area. DCD Tier 2, Section 17.6.1 ("Combined License Information"), Revision 1, provided COL Information Item 17.6(1), which states: "The COL applicant develops and implements the program for implementation of 10 CFR 50.65, the Maintenance Rule." It is not clear to the staff what is meant by "…develops and implements…." in COL Information Item 17.6(1). For example, COL Information Item 17.6(1) could incorrectly be interpreted as the COL applicant, during the COL application phase, will create and maintain maintenance rule program documents and implement the maintenance rule program in accordance with 10 CFR 50.65. These activities, however, are typically performed during the license holder phase. Under 10 CFR 52.79(a)(15), the COL applicant must provide a description of the program, and its implementation, for monitoring the effectiveness of maintenance necessary to meet the requirements of 10 CFR 50.65, in its FSAR. The staff requested through RAI 137-1688, Question 17.06-1 (originally identified as RAI 1688, Question 6214) that the applicant clarify COL Information Item 17.6(1) in DCD Tier 2, Section 17.6.1 taking into consideration the comments provided above (i.e., the COL applicant must provide in its FSAR a description of the maintenance rule program, and its implementation, for monitoring the effectiveness of maintenance necessary to meet the requirements of 10 CFR 50.65).

In its response to RAI 137-1688, Question 17.06-1 dated January 21, 2009, the applicant states that COL Information Item 17.6(1) in the DCD will be changed to state: "The COL applicant must provide in its FSAR a description of the maintenance rule

program, and its implementation, for monitoring the effectiveness of maintenance necessary to meet the requirements of 10 CFR 50.65."

The staff finds that the applicant's response to RAI 137-1688, Question 17.06-1 sufficiently addresses this RAI. Subsequently, the staff confirmed that the proposed revision is incorporated into Revision 2 of DCD Tier 2. Therefore, RAI 137-1688, Question 17.06-1 is resolved and closed.

17.6.5 Combined License Information Items

The following is a list of combined license information item numbers and descriptions from Section 17.6.1 and Table 1.8-2 of the US-APWR DCD, Tier 2, Revision 2.

Table 17.6-1
US-APWR Combined License Information Items

Item No.	Description	Section
17.6(1)	The COL applicant must provide in its FSAR a description of the maintenance rule program, and its implementation, for monitoring the effectiveness of maintenance necessary to meet the requirements of 10 CFR 50.65.	17.6.1

17.6.6 Conclusions

The US-APWR DCD, Tier 2, Section 17.6, Revision 3, addresses the maintenance rule program. The staff reviewed DCD Tier 2, Section 17.6 in accordance with SRP Section 17.6. The review confirmed that the applicant has adequately addressed the required information relating to the maintenance rule. In addition, the staff concludes that it is appropriate for the applicant to state that the maintenance rule program referred to in DCD Tier 2, Section 17.6 is the responsibility of the COL applicant. Thus, it adequately addresses the guidance in SRP Section 17.6, and therefore, is acceptable.