Safety Evaluation Report With Open Items for the U.S. EPR

Chapter 17, “Quality Assurance”

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17 QUALITY ASSURANCE

17.0 Quality Assurance and Reliability Assurance

The AREVA NP, Inc., (AREVA) Quality Assurance Program Description (QAPD) used for the U.S. EPR is based on ANP-10266, Revision 2, "AREVA NP Inc. Quality Assurance Plan (QAP) for Design Certification of the U.S. EPR Topical Report," dated December 2008. The AREVA QAPD topical report covers the activities associated with the design certification of the U.S. EPR. The QAPD is based on the applicable portions of both Appendix B to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50 and American Society for Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) standard NQA-1-1994, "Quality Assurance Requirements for Nuclear Applications," relevant to the U.S. EPR Final Safety Analysis Report (FSAR).

17.1 Quality Assurance During Design

Section 17.1 of the FSAR addresses the quality assurance (QA) program during design. The information regarding QA during the design of the U.S. EPR was provided in Tier 2, Section 17.5 of the U.S. EPR Design Certification FSAR. The staff's evaluation of this information is provided in Section 17.5 of this report.

17.2 Quality Assurance During the Operations Phases

Section 17.2 of the FSAR addresses the QA program during the construction and operations phases of the plant. The FSAR Tier 2, Section 17.2 states that the QA programs associated with the construction and operations phases are not applicable for the U.S. EPR design certification and that a combined license (COL) applicant that references the U.S. EPR design certification will provide the QA programs associated with the construction and operations phases. The staff agrees that the QA programs associated with the construction and operations phases are the COL applicant's responsibility. This is identified as COL Information Item 17.2-1 in FSAR Tier 2, Table 1.8-2, U.S. EPR Combined License Information Items.

Table 17.2-1 U.S. EPR Combined License Information Items

Item No.	Description	FSAR Tier 2 Section	Action Required by COL Applicant	Action Required by COL Holder
17.2-1	A COL applicant that references the U.S. EPR design certification will provide the Quality Assurance Programs associated with the construction and operations phases.	17.2	Y	

17.3 Quality Assurance Program Description

FSAR, Tier 2, Section 17.3 addresses the QA program applicable to the design, procurement, inspection, and/or testing of items and services, as described in the QAPD. The information regarding the QAPD for the U.S. EPR was provided in FSAR, Tier 2, Section 17.5. The staff's evaluation of this information is provided in Section 17.5 of this report.

17.4 Reliability Assurance Program

17.4.1 Introduction

The Reliability Assurance Program (RAP) applies to the systems, structures, and components (SSCs) that are identified as risk-significant or significant contributors to plant safety. This section addresses the RAP, which the applicant uses to enhance safety by focusing on the risk-significant SSCs. In order to identify the risk-significant SSCs, the RAP employs probabilistic, deterministic, and other methods of analysis and provides for the consideration of information obtained from other sources such as plant-specific and site-specific probabilistic risk analysis (PRA), industry operating experience (IOE), relevant component failure databases, and expert panels.

The RAP is intended to address the Commission policy established in the staff requirements memorandum (SRM), dated June 28, 1995, for Item E, "Reliability Assurance Program," of SECY-95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs (SECY 94-084)," dated May 22, 1995. The purposes of the RAP are to assure that:

- An advanced reactor is designed, constructed, and operated in a manner that is consistent with the assumptions and risk insights for these risk-significant SSCs
- The risk-significant SSCs do not degrade to an unacceptable level during plant operations
- The frequency of transients that challenge advanced reactor SSCs is minimized
- These SSCs function reliably when challenged

The applicant described the RAP for the U.S. EPR as a two-stage process. The first stage applies prior to initial fuel load, and is referred to as the design reliability assurance program (D-RAP). This stage is implemented through the inspections, tests, analyses, and acceptance criteria (ITAAC) before initial fuel load. The second stage applies to reliability assurance activities for the operations phase of the plant life cycle.

17.4.2 Summary of Application

FSAR Tier 1: A description of the RAP is provided in FSAR Tier 1, Section 3.2.

FSAR Tier 2: The applicant has provided an FSAR Tier 2 discussion of the RAP program including an outline of the two phases of implementation. The procedures for identification and prioritization of SSCs are discussed together with the use of an expert panel.

ITAAC: The ITAAC for the RAP is provided in FSAR Tier 1, Table 3.2-1, "Reliability Assurance Program ITAAC," which indicates that an inspection will be performed to verify that the RAP assures that the plant is designed and has been constructed in a manner consistent with the key assumptions and risk insights for risk-significant SSCs.

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

17.4.3 Regulatory Basis

The relevant requirements of NRC regulations for this area of review, and the associated acceptance criteria, are listed in the Standard Review Plan (SRP) Section 17.4 and are summarized below. Review interfaces with other SRP sections can also be found in SRP Section 17.4.

In part, 10 CFR 52.47(b)(1) states that an application for a design certification must contain proposed ITAAC, 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 design certification.

In accordance with Commission policy established in the SRM on SECY 95-132, Item E, "Reliability Assurance Program," the requirement to provide a RAP is codified by incorporation within the design-specific rulemaking for an applicant for a combined license who references the certified design.

17.4.4 Technical Evaluation

The staff has reviewed the proposed RAP for the U.S. EPR design in accordance with the guidance provided in SRP Section 17.4 and SECY-95-132 to determine whether the U.S. EPR RAP assures that (1) the plant is designed, constructed, and operated in a manner that is consistent with the assumptions and risk insights for risk-significant SSCs; (2) the risk-significant SSCs do not degrade to an unacceptable level during plant operations; (3) the frequency of transients that challenge advanced reactor SSCs are minimized; and (4) risk-significant SSCs function reliably when challenged. The staff also reviewed the SSCs within the scope of the RAP to ensure all risk-significant contributors are identified and addressed in the program.

As discussed in FSAR Tier 2, Section 17.4, the U.S. EPR RAP was developed focusing on design resources for risk-significant SSCs and on maintaining the reliability of such SSCs during the design and operation stages of the plant. The U.S. EPR RAP is executed as an integral part of the design process and is implemented during the detailed design phase so that the important U.S. EPR reliability assumptions of the PRA are considered throughout the course of plant life. The U.S. EPR RAP is implemented in two stages. The first stage applies to reliability assurance activities that occur before the initial fuel load, and the second stage applies to reliability assurance activities for an operating plant. The objective of the RAP during the design stage is to provide reasonable assurance that the reactor design meets the four preceding considerations in the areas of design, procurement, fabrication, construction, and preoperational testing activities and programs. The objective of the second stage of the RAP is to verify that the reliability of the SSCs within the scope of the RAP is maintained during plant operation. The activities for the second stage will be integrated into relevant existing programs, such as the Maintenance Rule (MR), surveillance testing, inservice inspection, inservice testing, and QA

programs. Plant programs will provide reasonable assurance that the reliability of SSCs will remain acceptable.

For the reasons set forth below, the staff determined that the RAP scope and purpose described in the FSAR Tier 2, Section 17.4 and summarized above meet the acceptance criteria in SRP Section 17.4 and the guidance in SECY-95-132 and are, therefore, acceptable.

FSAR Tier 2, Section 17.4.3 describes that the design certification applicant is responsible for formulating and implementing Phase 1 of the RAP including RAP scope, objectives, design consideration, identification and prioritization of SSCs, RAP organization, and expert panel. The design certification applicant engineering organization is responsible for the safety analyses, risk and reliability analyses, and the PRA necessary to support the development of the RAP. The design certification applicant risk and reliability personnel are responsible for keeping the design staff cognizant of the risk-significant items of the RAP, program needs, and project status.

The applicant's engineering design procedural controls are being applied to the RAP to provide guidance for the design control process, control of design changes, and storage and retrieval controls. The design control procedure defines the process for performing, documenting, and verifying design activities. The QA records procedure provides for QA record retention. The self-assessment, corrective action, and audit procedures specify the responsibilities associated with respective audits of the applicant engineering organization.

The staff has determined that the organization, design control, procedures and instructions, records, audit plans, and corrective action QA attributes described in FSAR Tier 2, Section 17.4.3 and summarized above conform to the description in SECY-95-132 and SRP Section 17.4 and are, therefore, acceptable.

FSAR Tier 2, Section 17.4.2.2 describes the process used for identifying SSCs that are significant contributors to plant safety. The U.S. EPR design certification process includes a combination of probabilistic and deterministic insights such as PRA analytical results, industry experience, regulations, expert panel process, and engineering judgment. The PRA results from both Level 1 and Level 2 assessments are used for identifying and prioritizing the SSCs. The Level 1 PRA provides an evaluation of the accident sequences from initiating events and failures of safety functions that lead to core damage. Level 2 risk significance is determined qualitatively by identifying dominant contributors to severe accidents and offsite fission product releases. Other hazards including internal fire, internal flooding, high winds, tornadoes, and seismic have also been considered in the process. Risk-significant SSCs were judged based on the risk achievement worth (RAW) or Fussell-Vesely (FV) worth of the respective SSCs. In a June 3, 2008, response to Request for Additional information (RAI) 5, Question 17.04-1, the applicant provided the importance measure criteria used to identify risk-significant SSCs as follows:

- Sum of FV for all basic events modeling the SSC of interest, including common cause events ≥ 0.005
- Maximum of component basic event RAW values ≥ 2
- Maximum of applicable common cause events RAW values ≥ 20

The staff has determined that the above importance measure criteria conform to the NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline," as endorsed by RG 1.201, "Guidelines for Categorizing SSCs in Nuclear Power Plants According to Their Safety Significance," and are, therefore, acceptable.

The staff noted that risk-significant passive SSCs are excluded from the scope of the U.S. EPR RAP and raised this concern in RAI 21, Question 17.04-02. In an August 8, 2008 response, the applicant stated that, due to limited information available at the design stage on the passive SSCs, the full scope of RAP will include passive components such as tanks and check valves that are modeled in the U.S. EPR PRA and identified as risk-significant, and the passive components that will be identified as risk-significant based on deterministic insights. Piping will not be included in the RAP, since it is assumed to be covered under the inservice inspection program. The full scope of RAP, including the final list of risk-significant SSCs and how they are included in the RAP or integrated into the other operational programs, is the responsibility of the COL applicant.

The staff reviewed the response and determined it conforms to the SRP and, therefore, is acceptable. The COL applicant shall be responsible for establishing the full scope of RAP, including the risk-significant passive SSCs and site-specific SSCs, and integrating all identified risk-significant SSCs into other operational programs.

The applicant stated in the COL Information Item 17.4-1 that "[a] COL applicant that references the U.S. EPR design certification will identify the site-specific SSCs within the scope of the RAP."

The staff determined that FSAR Tier 2, Section 17.4 does not explicitly describe whether the deterministic insights are included in the risk-significant SSCs determination process or not. Thus, in RAI 21, Question 17.04-6, the staff requested that the applicant indicate the SSCs identified as risk-significant by the deterministic insights and provide the basis. In an August 8, 2008, response, the applicant stated that the deterministic insights in the risk-significant SSC determination process have been incorporated by using an expert panel. The panel determined if the SSCs that are categorized as not risk-significant, based on the probabilistic ranking, should be categorized as risk-significant based on various deterministic criteria. The applicant further stated that the expert panel has evaluated each system to determine the safety significance of the system using the following criteria:

- Potential contribution to the initiating events
- Implicit contribution to the core damage frequency
- Implicit contribution to the large release frequency
- Potential contribution to seismic margin analysis
- Considerations in Technical Specifications
- Detection of component failures
- Potential effect of component failure on the other systems

In addition, in an August 8, 2008, response to RAI 21, Question 17.04-7, the applicant confirmed that the expert panel has reviewed the categorization of the U.S. EPR systems that were determined to not be risk-significant based on the quantified PRA results. The applicant's expert panel has identified multiple systems that should be considered for the RAP on the component/structure level and added them to the scope of the RAP. Table 17.04-7-1 of the applicant's response indicates the systems that have been added based on the expert panel review and provides the justification for adding them.

The staff reviewed the list of risk-significant SSCs and determined that the fire water distribution system (FWDS), sprinkler system, spray deluge system, and core melt stabilization system (CMSS) had been excluded from the scope of the RAP. In RAI 268, Question 17.04-22, the staff requested that the applicant include these systems in the scope of the RAP or provide further justification if these systems are considered to be insignificant to plant safety. In an October 30, 2009, response to RAI 268, Question 17.04-22, the applicant stated that the RAP expert panel re-screened the systems and determined that all four systems belonged in the scope of the RAP. The applicant also stated that the FSAR will be revised to include these systems in the scope of the RAP. The staff concludes that the applicant's response to RAI 268, Question 17.04-22 fulfills the staff's request by incorporating the FWDS, sprinkler system, spray deluge system, and CMSS into the scope of the RAP and is, therefore, acceptable. **RAI 268, Question 17.04-22 is being tracked as a confirmatory item** to ensure that the FSAR is revised accordingly. The reliability data bases used to identify risk significant failure modes are evaluated in Section 19.1 of this report.

On the basis of the information noted above, the staff concludes, that the process used for identifying risk-significant SSCs included in the U.S. EPR RAP, which includes a combination of probabilistic and deterministic insights, conforms to the methodology described in SRP Section 17.4 and SECY-95-132 and is, therefore, acceptable.

The staff reviewed the qualification standards for members of the expert panel utilized in the applicant's process as described in FSAR Tier 2, Section 17.4.2. The U.S. EPR D-RAP expert panel consisted of individuals who possess extensive knowledge in the areas of PRA, risk and reliability, plant operation, and system engineering and maintenance. In an August 8, 2008, response to RAI 21, Question 17.04-8, the applicant stated that the selection of the expert panel members for the RAP is similar to the process outlined in ASME-RA-Sb-2005, as endorsed by Regulatory Guide (RG) 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities." The members were selected based on level of experience and knowledge of a particular technical area of relevance to the issue.

The applicant's standards and process for selecting the members of the expert panel meet the guidance in RG 1.200 and are, therefore, acceptable.

The staff reviewed the FSAR and determined that the list of risk-significant SSCs has not been included in FSAR Tier 2, Section 17.4. This is not consistent with the guidance in SECY-95-132, which indicates that an application for advanced reactor design certification should contain a list of the SSCs designated as risk significant. Thus, in RAI 21, Questions 17.04-3, 17.04-7, 17.04-12, and RAI 226, Question 17.04-16, the staff requested additional information on the identification and prioritization of risk-significant SSCs within the scope of the U.S. EPR RAP and also requested the applicant to include in the FSAR a comprehensive list of

risk-significant SSCs. In an August 8, 2008, response to RAI 21, Questions 17.04-3 and 17.04-7, the applicant provided the following tables describing the risk-significant SSCs within the scope of the U.S. EPR RAP.

- Table 17.04-3-1: Important SSCs based on the FV Values, from Total, Internal Events, Fire, Flood, and Total Level 2 Evaluations (including dominant failure modes)
- Table 17.04-3-2: Important SSCs based on the RAW Values, from Total, Internal Events, Fire, Flood, Total Level 2, and Common Cause Evaluations
- Table 17.04-3-3: Important Common Cause Groups and Associated Components
- Table 17.04-7-1: Systems Added to the RAP by the Expert Panel

Additionally, in a July 24, 2009, response to RAI 226, Question 17.04-16, the applicant agreed to add the following two tables to the FSAR Tier 2, Section 17.4:

- FSAR Tier 2, Table 17.4-1: Input to RAP List from Importance Measures and Initiating Event Contribution
- FSAR Tier 2, Table 17.4-2: Design Certification Scope Systems and Structures Included within RAP

The staff examined the SSCs identified in the tables mentioned above and in the applicant's October 30, 2009, response to RAI 268, Question 17.04-22, and concluded that the list of risk-significant SSCs is comprehensive and consistent with the level of details during the design stage and is, therefore, acceptable. **RAI 226, Question 17.04-16 is being tracked as a confirmatory item** to ensure that the FSAR is revised accordingly.

The staff reviewed the non-system-based RAP ITAAC provided in FSAR Tier 1, Section 3.2, and determined that FSAR Tier 1, Table 3.2-1 did not clearly specify the ITAAC commitment wording and the associated acceptance criteria for the U.S EPR RAP. Thus, in RAI 21, Question 17.04-15 and follow-up RAI 226, Question 17.04-17, the staff requested that the applicant revise FSAR Tier 1, Table 3.2-1 to detail the ITAAC commitment wording and the acceptance criteria. In a June 23, 2009, response to RAI 226, Question 17.04-17, the applicant proposed to revise the FSAR Tier 1, Section 3.2, Item 2.1, and FSAR Tier 1, Table 3.2-1, to use ITAAC wording "proposed by the NRC in a meeting with the ITAAC Closure Working Group (ML090340056, page 8 of 12)." The staff has since revised the ITAAC wording that it plans to issue in interim staff guidance for RAP ITAAC in DC/COL (ISG-018). The staff requested that the applicant reconsider its wording to be incorporated in the U.S. EPR FSAR Tier 1, Section 3.2, Item 2.1 and Table 3.2-1 to conform to the wording in ISG-018. **RAI 355, Question 17.04-23 which is associated with this request is being tracked as an Open Item**.

17.4.5 Combined License Information Items

Table 17.4-1 provides a list of RAP related COL information item numbers and descriptions from FSAR Tier 2, Table 1.8-2:

Table 17.4-1 U.S. EPR Combined License Information Items

Item No.	Description	FSAR Tier 2 Section	Action Required by COL Applicant	Action Required by COL Holder
17.4-1	A COL applicant that references the U.S. EPR design certification will identify the site-specific SSCs within the scope of the RAP.	17.4.2	Y	
17.4-2	A COL applicant that references the U.S. EPR design certification will provide the information requested in Regulatory Guide 1.206, Section C.I.17.4.4.	17.4.4	Y	

17.4.6 Conclusions

As discussed above, the staff reviewed FSAR Tier 2, Section 17.4 in accordance with Item E of SECY-95-132 and SRP Section 17.4 and determined that:

- FSAR Tier 2, Section 17.4 adequately describes the scope, purpose, and objectives of the RAP, which meets the recommendations in Item E of SECY-95-132 and SRP Section 17.4 and, therefore, is acceptable.

- The essential elements (i.e., organization, design control, records, corrective action, audit plans, and corrective action QA attributes) for the D-RAP, as described in FSAR Tier 2, Section 17.4.3, meet the recommendations in Item E of SECY-95-132 and SRP Section 17.4 and, therefore, are acceptable.

- The implementation of the RAP during the design certification phase and operations phase, described in FSAR Tier 2, Section 17.4.2, conforms to the recommendations in Item E of SECY-95-132 and SRP Section 17.4 and, therefore, is acceptable.

- The process used to identify risk-significant SSCs described in FSAR Tier 2, Section 17.4 conforms to the methodology in Item E of SECY-95-132 and SRP Section 17.4 and, therefore, is acceptable.

- The qualification standards for the expert panel members conform to the SRP Section 17.4 and, therefore, are acceptable.

- As detailed in the evaluation section above, the list of risk-significant SSCs identified in the design stage is comprehensive and consistent with the level of details during the design stage and, therefore, is acceptable.

Therefore, except for the open item and confirmatory items discussed above, the staff concludes that the U.S. EPR RAP presented in the FSAR Tier 2, Section 17.4 and the non-system-based RAP ITAAC provided in FSAR Tier 1, Table 3.2-1 are acceptable.

17.5 Quality Assurance Program Description

17.5.1 Introduction

FSAR Tier 2, Section 17.5 describes a QA program applicable to activities performed during the design certification phase of a nuclear power plant. Section 17.5 notes that design certification does not include fabrication, erection, installation, or operations. The AREVA U.S. EPR QAPD is described in the AREVA Topical Report ANP 10266A, Revision 2.

17.5.2 Summary of Application

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

FSAR Tier 2: The applicant has provided a FSAR Tier 2 discussion in which it is indicated that AREVA NP does not delegate any of the activities associated with planning, establishing, or implementing the overall QA program to others and retains responsibility for the program. This is also where the AREVA topical report is referenced.

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

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

17.5.3 Regulatory Basis

The regulatory basis of the information described in the U.S. EPR Topical Report ANP-10266, Revision 2, "AREVA NP Inc. Quality Assurance Plan (QAP) for Design Certification of the U.S. EPR Topical Report," dated December 2008, is addressed within the staff's Safety Evaluation Report (SER) related to the topical report dated April 26, 2007.

17.5.4 Technical Evaluation

By letter dated April 26, 2007, the staff issued an SER that approved the QAPD in the topical report for the U.S. EPR design certification activities. Specifically, the staff evaluated the U.S. EPR QAPD to verify that it meets the Commission 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."

As documented in the staff's SER for the U.S. EPR topical report, SRP Section 17.5 was a draft document at the time of the review. The final version of SRP Section 17.5 recommends a commitment to RG 1.37, Revision 1, "Quality Assurance Requirements for Cleaning of Fluid

Systems and Associated Components of Water-Cooled Nuclear Power Plants." During the review of FSAR Tier 2, Section 17.5, the staff noted that the U.S. EPR Topical Report ANP-10266A does not commit to the regulatory guidance provided in RG 1.37, Revision 1. The staff noted that U.S. EPR Topical Report ANP-10266A, committed to RG 1.37, Revision 0. Additionally, FSAR Tier 2, Section 1.9, Table 1.9-2, "U.S. EPR Conformance with Regulatory Guides," does discuss conformance with RG 1.37, Revision 1, and the associated FSAR sections. However, the staff noted that this conformance is not applicable to FSAR Tier 2, Section 17.5.

Accordingly, in RAI 38 Question 17.5-1, the staff requested that FSAR Tier 2, Section 1.9, Table 1.9-2 and the U.S. EPR Topical Report ANP-10266A be revised to show conformance and commitment to RG 1.37, Revision 1. In a July 24, 2008, response, the applicant proposed to revise FSAR Tier 2, Table 1.9-2 to add a reference to FSAR Tier 2, Section 17.5. The staff has reviewed the proposed revision to FSAR Tier 2, Table 1.9-2 and finds it to be acceptable. In addition, the applicant proposed to revise Topical Report ANP-10266A to commit to RG 1.37 Revision 1 and to delete the reference to American National Standards Institute (ANSI) N45.2.1-1973, which is no longer referenced in RG 1.37, Revision 1. The staff has reviewed the proposed revisions to ANP-10266A and finds it to be acceptable. The staff reviewed Revision 1 of FSAR, Tier 2 and Revision 2 of ANP-10266 and confirmed that the proposed changes have been incorporated. Therefore, RAI 38, Question 17.5-1 is resolved.

The staff confirmed that FSAR Tier 2, Section 17.5 incorporates ANP-10266A, Revision 2, without exception, for control of activities affecting quality during the design certification of the U.S. EPR.

Staff Inspection of U.S. EPR QAPD Implementation

The staff intends to conduct an inspection of the applicant's implementation of the QAPD as it relates to the U.S. EPR project. This inspection will be documented in an inspection report and will be described in Section 17.5.3 of the staff's final safety-evaluation report input. **RAI 227, Question 17.5-2, which is associated with this inspection, is being tracked as an open item.**

17.5.5 Combined License Information Items

Table 17.5-1 provides a list of QA related COL information item numbers and descriptions from FSAR Tier 2, Table 1.8-2:

Table 17.5-1 U.S. EPR Combined License Information Items

Item No.	Description	FSAR Tier 2 Section	Action Required by COL Applicant	Action Required by COL Holder
	No applicable items were identified in the FSAR.			

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 U.S. EPR QAPD. Except for the open item discussed above, the staff has concluded, for the reasons set forth above, that the U.S. EPR QAPD is acceptable to establish a QA program in accordance with applicable NRC regulations and industry standards for design certification activities.

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

17.6.1 Introduction

This section addresses the MR program based on the requirements of 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants," and the guidance provided to the industry by the Nuclear Management and Resources Council (NUMARC) and its successor, the Nuclear Energy Institute (NEI). NUMARC 93-01, "Industry Guidance for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," is endorsed by the staff in RG 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants." Section 11.0 of NUMARC 93-01 was later revised. The revision is endorsed by the staff in RG 1.182, "Assessing and Managing Risk Before Maintenance Activities at Nuclear Power Plants." NEI 07-02A, "Generic FSAR Template Guidance for MR Program Description for Plants Licensed Under 10 CFR Part 52," provides a template for presenting MR information and is also endorsed by the staff.

The specific areas of review are as follows:

- Scoping in accordance with 10 CFR 50.65(b)
- Monitoring in accordance with 10 CFR 50.65(a)
- Periodic evaluation in accordance with 10 CFR 50.65(a)(3)
- Maintenance risk assessment and management in accordance with 10 CFR 50.65(a)(4)

17.6.2 Summary of Application

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

FSAR Tier 2: The applicant has provided a FSAR Tier 2 description of the MR program in Section 17.6, summarized here in part, as follows:

The applicant states that the COL applicant referencing the U.S. EPR design certification will describe the program for MR implementation.

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

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

17.6.3 Regulatory Basis

The relevant requirements of NRC regulations for this area of review, and the associated acceptance criteria, are given in Section 17.6 of NUREG-0800 and are summarized below. Review interfaces with other SRP sections also 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. 10 CFR 52.79(a)(15), which requires that a COL FSAR contain a description of the program, and its implementation, for monitoring the effectiveness of maintenance necessary to meet the requirements of 10 CFR 50.65.

Acceptance criteria adequate to meet the above requirements include:

1. NUMARC 93-01 as endorsed by RG 1.160 represents an acceptable approach for implementing a MR Program in accordance with 10 CFR 50.65. For Section 50.65(a)(4), the guidance contained in the February 22, 2000, revision to Section 11 of NUMARC 93-01, as endorsed and modified by RG 1.182, is effective until superseded by subsequent NRC guidance.

2. The staff has endorsed NEI 07–02A, as an acceptable template guidance for presenting the MR information in accordance with the acceptance criteria of NUREG-0800, Section 17.6.

17.6.4 Technical Evaluation

The staff has reviewed FSAR Tier 2, Section 17.6 in accordance with the guidance in NUREG-0800, Section 17.6. The applicant is not required to address the requirements of the MR, as this is an operational program not required for design certification, and no outstanding information is expected to be addressed in the FSAR related to this program.

The staff determined that FSAR Tier 2, Section 17.6 does not include a COL Information Item on industry operating experience (IOE) as described in NEI 07-02A guidance and its safety evaluation, dated January 2008. In a June 23, 2009, response to RAI 226, Question 17.06-2, the applicant agreed to add a description of IOE to FSAR Tier 2, Section 17.6.7, and FSAR Tier 2, Table 1.8-2. The staff has reviewed the proposed FSAR markup and finds it to be acceptable since it completely addressed all principal functions associated with the MR program. **RAI 226, Question 17.06-2 is being tracked as a confirmatory item** to ensure that the FSAR is revised accordingly.

FSAR Tier 2, Section 17.6.7 and FSAR Tier 2, Table 1.8-2, Item 17.6-8 state that:

"A COL applicant that references the U.S. EPR design will describe the plan or process for implementing the MR Program as described in the COL application, which includes establishing program elements through sequence and milestones and monitoring or tracking the performance and/or condition of SSC as they become operational. The MR Program will be implemented by the time that fuel load is authorized."

The staff agrees that the plan or process for implementing the MR program is the responsibility of the COL applicant referencing the U.S. EPR design. The COL applicant shall implement the MR program, at the latest, by the time of fuel load. (i.e., by the time the Commission makes the finding required in 10 CFR 52.103(g)). Implementation of an acceptable MR program may occur in advance of the Commission's 10 CFR 52.103(g) finding, with components being monitored or tracked as they become available.

17.6.5 Combined License Information Items

FSAR Tier 2, Table 17.6-1 provides a list of MR related COL information item numbers and descriptions from FSAR Tier 2, Table 1.8-2:

Table 17.6-1 U.S. EPR Combined License Information Items

Item No.	Description	FSAR Tier 2 Section	Action Required by COL Applicant	Action Required by COL Holder
17.6-1	A COL applicant that references the U.S. EPR design certification will describe the process for determining which plant SSCs will be included in the scope of the MR Program in accordance with 10 CFR 50.65(b). The program description will identify that additional SSC functions may be added to or subtracted from the Maintenance Rule scope prior to fuel load, when additional information is developed {e.g., emergency operating procedures (EOP)}, and after the license is issued.	17.6.1	Y	
17.6-2	A COL applicant that references the U.S. EPR design certification will provide the process for determining which SSCs within the scope of the MR Program will be tracked to demonstrate effective control of their performance or condition in accordance with 10 CFR 50.65(a)(2).	17.6.2	Y	
17.6-3	A COL applicant that references the U.S. EPR design certification will provide a program description for monitoring SSCs in accordance with 10 CFR 50.65(a)(1).	17.6.2	Y	
17.6-4	A COL applicant that references the U.S. EPR design certification will identify and describe the program for periodic evaluation of the MR Program in	17.6.3	Y	

Item No.	Description	FSAR Tier 2 Section	Action Required by COL Applicant	Action Required by COL Holder
	accordance with 10 CFR 50.65(a)(3).			
17.6-5	A COL applicant that references the U.S. EPR design certification will describe the program for maintenance risk assessment and management in accordance with 10 CFR 50.65(a)(4). Since the removal of multiple SSCs from service can lead to a loss of MR functions, the program description will address how removing SSCs from service will be evaluated. For qualitative risk assessments, the program description will explain how the risk assessment and management program will preserve plant-specific key safety functions.	17.6.4	Y	
17.6-6	A COL applicant that references the U.S. EPR design certification will describe the program for selection, training, and qualification of personnel with MR-related responsibilities consistent with the provisions of FSAR Tier 2, Section 13.2, as applicable. Training will be commensurate with MR responsibilities, including MR Program administration, the expert panel process, operations, engineering, maintenance, licensing, and plant management.	17.6.5	Y	
17.6-7	A COL applicant that references the U.S. EPR design certification will describe the relationship and interface between MR Program and the RAP.	17.6.6	Y	
17.6-8	A COL applicant that references the U.S. EPR design certification will describe the plan or process for implementing the MR Program as described in the COL application, which includes establishing program elements through sequence and milestones and monitoring or tracking the performance and/or condition of SSCs as they become operational. The MR Program will be implemented by the time	17.6.7	Y	

Item No.	Description	FSAR Tier 2 Section	Action Required by COL Applicant	Action Required by COL Holder
	that fuel load is authorized.			
17.6-9	A COL applicant that references the U.S. EPR design certification will describe the program for MR implementation.	17.6	Y	

17.6.6 Conclusions

As set forth above, the staff has reviewed FSAR Tier 2, Section 17.6, and confirmed that the applicant has addressed the information relating to the MR program. The staff agrees with the design certification application that the COL applicant is responsible for developing and implementing the MR program pursuant to the requirements of 10 CFR 52.79(a) and 10 CFR 50.65. Thus, except for the confirmatory item discussed above, the staff concludes that the relevant information presented within FSAR Tier 2, Section 17.6 is acceptable.