

Safety Evaluation Report With No 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 4, "AREVA NP Inc., Quality Assurance Plan (QAP) for Design Certification of the U.S. EPR Topical Report," December 13, 2012. 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 Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, Appendix B 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).

FSAR Tier 2, Sections 17.1, 17.2, 17.3, and 17.5 addresses the Quality Assurance Program (QAP) for the U.S. EPR. FSAR Tier 2, Section 17.4 addresses the Design Reliability Assurance Program (D-RAP)_ for the U.S. EPR. FSAR Tier 2, Section 17.6 addresses the U.S. EPR Maintenance Rule Program.

17.1 Quality Assurance During Design

FSAR Tier 2, Section 17.1 addresses the quality assurance (QA) program during design. The information regarding QA during the design of 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.

17.2 Quality Assurance During the Operations Phases

FSAR Tier 2, Section 17.2 addresses the QA program during the construction and operations phases of the plant. 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 in its COL application. 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
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

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

17.5 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. The AREVA U.S. EPR QAPD is described by reference in the AREVA NP (AREVA) Topical Report ANP-10266, Revision 4, "AREVA NP, Inc., Quality Assurance Plan (QAP) for Design Certification of the U.S. EPR Topical Report," December 13, 2012. The incorporation of Topical Report ANP-10266, Revision 4 into AREVA's Design Certification application is discussed in the technical evaluation section below. 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

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

FSAR Tier 2: The applicant has provided in FSAR Tier 2 a description of the QAP in Section 17.5, summarized here, in part.

The QAP for the U.S. EPR is addressed in AREVA NP Topical Report Number ANP-10266, Revision 1, "AREVA NP Inc. Quality Assurance Plan (QAP) for Design Certification of the U.S. EPR Topical Report," April 2007. This topical report was approved by the staff's April 26, 2007, Safety Evaluation Report (SER). The QAP is based on the 18-point criteria of 10 CFR Part 50, Appendix B, and American National Standards Institute (ANSI)/ASME NQA-1-1994. Consistent with Standard Review Plan (SRP) Section 17.5, Section I, design certification does not include fabrication, erection, installation, or operations.

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 relevant requirements of NRC regulations for these areas of review, and the associated acceptance criteria are given in NUREG-800, Section 17.5, the SRP, and are summarized below. Review interfaces with other SRP sections can be found in NUREG-0800, Section 17. The regulatory basis of the information described in the AREVA NP Topical Report ANP-10266, Revision 1, is addressed within the staff's SER related to the topical report and is dated April 26,

2007. On December 13, 2012, AREVA submitted Topical Report ANP-10266, Revision 4 to the staff for review and approval. In an April 9, 2014, letter to AREVA, the staff approved ANP-10266, Revision 4.

Specifically, the NRC's regulatory requirements related to quality assurance programs are set forth in 10 CFR 52.47(a)(19), and 10 CFR Part 50, Appendix B.

10 CFR 52.47(a)(19) requires, in part, that a design certification application contain a description of the quality assurance program applied to the design of the structures, systems, and components of the facility. 10 CFR Part 50, Appendix B sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant shall include a discussion of how the applicable requirements of 10 CFR Part 50, Appendix B were satisfied.

10 CFR Part 50, Appendix B specifies 18 quality assurance (QA) criteria that must be addressed in the QAPD. 10 CFR Part 50, Appendix B establishes QA requirements for the design, fabrication, construction, and testing of SSCs of the facility. The requirements of 10 CFR Part 50, 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.

The acceptance criteria to meet the above requirements are listed in NUREG-0800, Section 17.5, Subsection II, "Acceptance Criteria."

17.5.4 Technical Evaluation

In an April 26, 2007, letter, the staff issued an SER that approved the QAPD in the applicant's topical report for the U.S. EPR design certification activities, ANP-10266, Revision 1. Subsequently, in a December 13, 2012, letter to the staff, the applicant submitted a revised QAPD (ANP-10266, Revision 4) for staff review and approval. In an April 9, 2014, letter, the staff issued a Supplemental SER that approved the revised QAPD (ANP-10266, Revision 4) for the U.S. EPR design certification activities on the basis that the changes to the QAPD did not constitute any reductions in commitments from the staff's previously approved version. Specifically, the staff evaluated the AREVA QAPD to verify that it meets NRC 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 verified that FSAR Tier 2, Revision 6, Section 17.5 incorporates ANP-10266, Revision 4, without exception, for control of activities affecting quality during the design certification of the U.S. EPR, and is therefore, acceptable.

As documented in the staff's SER for the AREVA topical report, ANP-10266, Revision 1, 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 Regulatory Guide (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 AREVA Topical Report ANP-10266, Revision 1 does not commit to the regulatory guidance provided in RG 1.37, Revision 1. The staff noted that AREVA Topical Report ANP-10266, Revision 1, 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 the applicant revise FSAR Tier 2, Section 1.9, Table 1.9-2 and the AREVA Topical Report ANP-10266, Revision 1, to show conformance and commitment to RG 1.37, Revision 1. In a July 24, 2008, response to RAI 38, Question 17.5-1, 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 reviewed the revision to FSAR Tier 2, Table 1.9-2 and finds the applicant's conformance to RG 1.37, Revision 1 is applicable to FSAR Tier 2, Section 17.5 and is acceptable. In addition, the applicant proposed to revise Topical Report ANP-10266 to commit to RG 1.37, Revision 1 and to delete the reference to 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-10266, Revision 1, and finds it acceptable because the revisions now commit to RG 1.37, Revision 1. The staff reviewed Revision 6 of FSAR Tier 2 and Revision 4 of Topical Report ANP-10266 and confirmed that the proposed changes have been incorporated. Therefore, the staff considers RAI 38, Question 17.5-1 resolved.

Staff Inspection of U.S. EPR QAPD Implementation

From June 28, 2010, through July 1, 2010, the staff conducted a limited scope inspection at the AREVA office in Lynchburg, VA, as documented in inspection report No. 05200020.2010-202, August 12, 2010. The purpose of the NRC inspection was to verify that QA processes and procedures were effectively implemented regarding the U.S. EPR design certification application. During this inspection, the NRC inspectors identified a violation of NRC requirements related to the QA program. AREVA responded to the Notice of Violation (NOV) in an August 30, 2010, letter. AREVA identified its actions to correct and prevent recurrence of the violations and noted that compliance was achieved. The staff finds the letter responsive to the NOV.

The staff conducted a limited scope inspection at the AREVA office in Charlotte, NC, from April 29, 2013, through May 3, 2013. The NRC inspector findings are documented in Inspection Report No. 052000020/2013-201, June 13, 2013. The purpose of the inspection was to review QA program implementation and focused primarily on the control and use of MTR System for Analysis of Soil-Structure Interaction (MTR/SASSI) software used for seismic analysis and design of safety-related U.S. EPR structures. The NRC inspectors identified a violation of NRC QA requirements specifically related to design control and commercial grade dedication. AREVA responded to the NOV in a July 6, 2013, letter and provided additional information in an August 23, 2013, letter. The staff finds the letters responsive to the NOV.

From September 9 through September 12, 2013, the staff conducted a limited scope inspection of the quality assurance program implementation focused on the use of RELAP5/MOD2-B&W and GOTHIC Methodology for large and small break loss-of-coolant accident analyses. AREVA is using the results of these analyses in the containment design analyses included in the U.S. EPR design certification application. The NRC inspectors documented its findings in Inspection Report No. 05200020/2013-203, November 26, 2013. The NRC inspectors identified a violation of NRC QA requirements related to corrective actions. Specifically, AREVA failed to evaluate the extent of condition for input errors in the RELAPS/MOD2-B&W input decks developed for a large break loss-of-coolant accident analysis and evaluate the extent of condition for the programmatic issue of open design change reviews that were suspended.

The applicant responded to the NOV in a December 20, 2013, letter. The NRC inspectors requested additional information in a letter dated January 27, 2014. AREVA responded in a letter dated March 28, 2014 and the staff found the letter responsive to the NOV in a letter dated April 1, 2014.

At this time, there are no outstanding review items associated with this SER related to these inspections.

17.5.5 Combined License Information Items

The staff did not identify any COL information items to be included in FSAR Tier 2, Table 1.8-2 for the QA program.

17.5.6 Conclusions

As discussed above, the staff completed its review of FSAR Tier 2, Section 17.5, and confirmed that the applicant fully addressed the information related to the AREVA QAPD. The staff used the requirements of 10 CFR Part 50, Appendix B, 10 CFR 52.47(a)(19), and the guidance of SRP Section 17.5 as the bases for evaluating the acceptability of the AREVA QAPD. The staff concluded, for the reasons set forth above, that the AREVA QAPD is acceptable to establish a QA program in accordance with applicable NRC regulations and industry standards for design certification activities. Therefore, the staff finds that the relevant information presented within FSAR Tier 2, Section 17.5 acceptable.

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 Maintenance Rule (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." NUMARC 93-01, Section 11.0, 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 Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," provides a template for presenting MR information for COL applicants and is also endorsed by the staff. As discussed in the SRP, since the MR program is an operational program, it would be specifically addressed in a COL application.

The specific areas of review for COL information items include:

- 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)
- MR training and qualification
- MR program role in implementation of Reliability Assurance Program (RAP) in the operations phase
- MR program relationship with industry operating experience activities
- MR program implementation

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 stated that the COL applicant referencing the U.S. EPR design certification will describe the program for MR implementation. The applicant identified nine COL information items relevant to MR program.

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 NUREG-0800, Section 17.6, and are summarized below. Review interfaces with other SRP sections also can be found in NUREG-0800, Section 17.6.

1. 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants"
2. 10 CFR 52.79(a)(15), as it relates to the requirement 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.
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 reviewed FSAR Tier 2, Section 17.6, in accordance with the guidance in NUREG-0800, Section 17.6. As mentioned in SRP Section 17.6.2, the MR program is an operational program to be addressed in a COL application, and thus, the design certification applicant is not required to address the requirements of the MR. Therefore, no specific information is expected to be addressed in the U.S. EPR FSAR related to this program.

FSAR Tier 2, Section 17.6.8 states:

A COL applicant that references the U.S. EPR design certification will describe the plan or process for implementing the Maintenance Rule Program 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.

Based on the guidance provided in the SRP, the staff agrees with the design certification applicant that the plan or process for implementing the MR program is the responsibility of the COL applicant who references 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 NRC makes the finding required in 10 CFR 52.103(g)). Implementation of an acceptable MR program may occur in advance of the NRC's 10 CFR 52.103(g) finding, with plant SSCs being monitored or tracked as they become available.

For each COL application referencing the U.S. EPR design, the applicant identified nine COL information items relevant to the MR program as listed in Table 17.6-1 of this report. The staff reviewed these nine COL information items and finds that they all have been developed in a manner consistent with the SRP and the template provided in NEI 07-02A. Therefore, the staff concludes that the COL information items relevant to the MR program are complete and acceptable.

17.6.5 Combined License Information Items

Table 17.6-1 below reproduces the MR program-related COL information descriptions provided in FSAR Tier 2, Table 1.8-2, "U.S. EPR Combined License Information Items." These information items provide guidance for developing and implementing a MR program that is consistent with the requirements in 10 CFR 50.65 and with guidance in NEI 07-02A, which has been endorsed by the staff. For these reasons, the staff finds these COL information items acceptable.

Table 17.6-1 U.S. EPR Combined License Information Items Relevant to MR Program

Item No.	Description	FSAR Tier 2 Section
17.6-1	A COL applicant that references the U.S. EPR design certification will describe the process for determining which plant structures, systems, and components (SSCs) will be included in the scope of	17.6.1

Item No.	Description	FSAR Tier 2 Section
	the Maintenance Rule Program in accordance with 10 CFR 50.65(b). The program description will identify that additional SSCs 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, or EOP), and after the license is issued.	
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 Maintenance Rule 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
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
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 Maintenance Rule Program in accordance with 10 CFR 50.65(a)(3).	17.6.3
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 Maintenance Rule 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
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 Maintenance Rule-related responsibilities consistent with the provisions of Section 13.2, as applicable. Training will be commensurate with maintenance rule responsibilities, including Maintenance Rule Program administration, the expert panel process, operations, engineering, maintenance, licensing, and plant management.	17.6.5

Item No.	Description	FSAR Tier 2 Section
17.6-7	A COL applicant that references the U.S. EPR design certification will describe the relationship and interface between the Maintenance Rule Program and the Reliability Assurance Program.	17.6.6
17.6-8	A COL applicant that references the U.S. EPR design certification will describe the plan or process for implementing the Maintenance Rule Program 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.	17.6.7
17.6-9	A COL applicant that references the U.S. EPR design certification will describe the program for Maintenance Rule implementation.	17.6

17.6.6 Conclusions

As set forth above, the staff reviewed FSAR Tier 2, Section 17.6, and confirmed that the applicant has addressed the information relating to the MR program, in conformance to the guidance provided in the SRP. The staff agrees with the U.S. EPR design certification application that the COL applicant who references the U.S. EPR design is responsible for developing and implementing the MR program pursuant to the requirements of 10 CFR 52.79(a) and 10 CFR 50.65 and fully describing it in its COL application. Therefore, the staff finds the relevant information presented within FSAR Tier 2, Section 17.6 acceptable.