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17 QUALITY ASSURANCE AND RELIABILITY ASSURANCE

The Quality Assurance (QA) measures for nuclear power plants apply to the design certification of the U.S. EPR. The QA Program (QAP) is based on the eighteen-point criteria of 10 CFR 50, Appendix B, and ANSI/ASME NQA-1-1994. The Reliability Assurance (RA) measures and the Reliability Assurance Program (RAP) for nuclear power plants applies to the systems, structures, and components (SSC) that are identified as risk-significant (or significant contributors to plant safety) as determined by using probabilistic, deterministic, and other methods of analysis, including information obtained from sources such as the plant-specific and site-specific probabilistic risk analysis (PRA), industry operating experience, relevant component failure databases and expert panels. Implementing the RAP will enhance safety by focusing on design resources for risk-significant SSC and on maintaining the reliability of such SSC during the design and operation stages of the plant.

Chapter 17 of the Calvert Cliffs Nuclear Power Plant (CCNPP) Unit 3 Final Safety Analysis Report (FSAR) provides information on the QA measures implemented during design, construction, and operation of CCNPP Unit 3, as well as details of the RA program and implementation of the maintenance rule. This chapter describes the U.S. Nuclear Regulatory Commission (NRC) staff's evaluation of the QA and RA measures that UniStar Nuclear Development, LLC, on behalf of Calvert Cliffs 3 Nuclear Project, LLC and UniStar Nuclear Operating Services, LLC (hereafter collectively known as UniStar or the combined license (COL) applicant) is implementing for the Calvert Cliffs Nuclear Power Plant (CCNPP) Unit 3. It includes the staff's evaluations of the QA measures implemented during design, construction, and operations; the details of the RA program; and the implementation of the maintenance rule. The staff's review of Chapter 17 of the COL FSAR is coordinated closely with the staff's review of the U.S. EPR FSAR, Tier 2, Chapter 17. In Chapter 17 of the COL FSAR, the COL applicant incorporates by reference U.S. EPR FSAR Tier 2, Chapter 17 with no departures (See Section 1.1 of this report), and, as explained below, supplements certain sections of Chapter 17 of the COL application (COLA). These supplemented sections are specifically identified and evaluated below.

17.1 Quality Assurance During Design

COL FSAR Section 17.1 incorporates by reference, with no departures or supplements, U.S. EPR FSAR Tier 2, Section 17. The staff reviewed the COL application and checked the referenced sections of the U.S. EPR FSAR to ensure that all COL information items and supplemental information required to be provided by the COL applicant relating to QA during design have been addressed in the COL application. The staff's review confirmed that the COL applicant has adequately addressed U.S. EPR FSAR Tier 2, Section 17 and there are no outstanding issues related to this subsection.

The staff is reviewing the COL information incorporated by reference from the U.S. EPR FSAR Tier 2, Section 17.1 on Docket No. 52-020. The results of the staff's technical evaluation of the COL information incorporated by reference from the U.S. EPR regarding quality assurance during design will be documented in the staff's safety evaluation report (SER) on the U.S. EPR FSAR. The staff's SER on the U.S. EPR FSAR is not yet complete. **RAI 222, Question 01-05 is being tracked as an open item** as part of this Chapter. The staff will update Section 17.1 of this report to reflect the final disposition of the U.S. EPR design certification application.

17.2 Quality Assurance During the Operations Phase

COL FSAR Section 17.2 incorporates by reference U.S. EPR FSAR Tier 2, Section 17.2, with no departures, and, as explained below, addressed COL information items as identified in U.S. EPR FSAR Tier 2, Section 17.2.

COL Information Items

COL Information Item 17.2-1, in COL FSAR Section 17.2, "Quality Assurance During the Operations Phase," directs a COL applicant that references the U.S. EPR design certification to provide the QA Programs associated with the construction and operations phase.

To address this COL information item, the COL applicant indicated that this information is provided in the COL FSAR Section 17.5.

The staff reviewed COL FSAR Sections 17.2 and 17.5 and the referenced sections of the U.S. EPR FSAR section to ensure that the information contained therein satisfies the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 52.79(d), "Contents of applications; technical information in final safety analysis report," and that any supplemental information to be provided by the COL applicant has been addressed in the COL application. The information provided in COL FSAR Section 17.5 establishes the licensing basis of the CCNPP Unit 3 plant for this section.

The regulatory basis for the review of the information incorporated by reference and the supplemental information presented in this application, as well as the staff's conclusion related to QA during the construction and operations phase, is documented in Section 17.5 of this report.

17.3 Quality Assurance Program Description

COL FSAR Section 17.3 incorporates by reference, with no departures or supplements, U.S. EPR FSAR Tier 2, Section 17. The staff reviewed the application and checked the referenced sections of the U.S. EPR FSAR to ensure that all COL information items and supplemental information required to be provided by the COL applicant regarding the QA program description have been addressed in the COL application. The staff's review confirmed that COL applicant has adequately addressed U.S. EPR FSAR Tier 2, Section 17.3 and there are no outstanding issue related to this section.

The staff is reviewing the COL information in the U.S. EPR FSAR Tier 2, Section 17.3 on Docket No. 52-020. The results of the staff's technical evaluation of the COL information incorporated by reference from the U.S. EPR regarding quality assurance program description will be documented in the staff's SER on the design certification application for the U.S. EPR. The staff will update Section 17.3 of this report to reflect the final disposition of the U.S. EPR design certification application.

17.4 Reliability Assurance Program

17.4.1 Introduction

COL FSAR Section 17.4 which addresses the Reliability Assurance Program (RAP), incorporates U.S. EPR FSAR Tier 2, Section 17.4 with no departures, and as explained below, addresses COL information items identified in U.S. EPR FSAR Tier 2, Section 17.4.

In COL FSAR Section 17.4, the COL applicant describes the RAP as follows:

The RAP applies to the structures, systems, and components (SSCs) that are identified as risk-significant or significant contributors to plant safety. The purposes of the RAP are to provide reasonable assurance that:

- An advanced reactor is designed, constructed, and operated in a manner that conforms to 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 are minimized
- The SSCs function reliably when challenged

The risk-significant SSCs are determined by using probabilistic, deterministic, and other methods of analysis including information obtained from probabilistic risk assessments (PRAs), industry operating experience, relevant component failure databases, and expert panels. The CCNPP Unit 3 RAP includes two stages. The first stage applies to reliability assurance activities that occur before the initial fuel load. The goal of the RAP during this stage is to ensure that the reactor design meets the considerations identified earlier through the reactor design, procurement, fabrication, construction, and preoperational testing activities and programs. The second stage applies to RA activities for the operations phase of the plant life cycle. The objective during this stage is to ensure that the reliability and availability of the SSCs within the scope of the RAP are maintained during plant operations.

17.4.2 Summary of Application

COL FSAR Section 17.4 incorporates by reference U.S. EPR FSAR Tier 2, Section 17.4, with no departures.

COL Information Items

COL Information Item 17.4-1, in COL FSAR Section 17.4.2, “Reliability Assurance Program Implementation,” directs a COL applicant that references the U.S. EPR design certification to identify the site-specific SSCs within the scope of the RAP.

COL Information Item 17.4-2, in COL FSAR Section 17.4.4, “Reliability Assurance Program Information Needed in a COL Application,” directs a COL applicant that references the U.S. EPR design certification to provide the information requested in regulatory guide (RG) 1.206, Section C.I.17.4.4.

17.4.3 Regulatory Basis

The regulatory basis for acceptance of the information incorporated by reference in COL FSAR Section 17.4 is addressed within the staff's final safety evaluation report (FSER) on U.S. EPR FSAR Tier 2, Chapter 17.

17.4.4 Technical Evaluation

The staff reviewed COL FSAR Section 17.4 based on the associated acceptance criteria, which are described and explained in NUREG-0800, Section 17.4, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," (hereafter referred to as NUREG-0800 or the SRP).

The acceptance criteria for RAP information being reviewed in the COL FSAR are described and explained in the following documents:

1. RAP is implemented per the Commission policy in the Staff Requirements Memorandum (SRM), June 28, 1995.

2. SECY-95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs (SECY-94-084)," May 22, 1995, Item E, which outlines the recommendations for the RAP.

The staff reviewed COL FSAR Section 17.4, and checked the referenced sections of the U.S. EPR FSAR to ensure that all COL information items and supplemental information required to be provided by the COL applicant regarding the RAP have been addressed in the COL application. The staff's review confirmed that COL applicant has adequately addressed U.S. EPR FSAR Tier 2, Section 17.4 and there are no outstanding issues related to this subsection. U.S. EPR FSAR, Tier 2, Section 17.4 is being reviewed by the staff under Docket No. 52-020. The staff's technical evaluation of the COL information incorporated by reference from the U.S. EPR regarding the RAP will be documented in the staff's FSER on the U.S. EPR FSAR.

COL Information Items

COL Information Item 17.4-1, in COL FSAR Section 17.4.2, "Reliability Assurance Program Implementation," directs a COL applicant that references the U.S. EPR design certification to identify the site-specific SSCs within the scope of the RAP.

In COL FSAR Section 17.4.2, the COL applicant stated that the U.S. EPR design-specific probabilistic risk assessment (PRA) represents and bounds the U.S. EPR plant proposed at the CCNPP Unit 3 site, and the COL applicant will utilize the U.S. EPR design-specific PRA model, without modification, as the plant-specific PRA for CCNPP Unit 3. COL FSAR Table 17.4-1 specifies the components identified by the PRA for consideration within the scope of RAP. Because the COL applicant concluded that the U.S. EPR design-specific PRA sufficiently captures site and plant parameters, no changes to the design-specific internal events PRA are necessary when considering specific site and plant parameters. Accordingly, the COL applicant concluded that SSCs identified for consideration within the RAP during the design certification review are all included in the site-specific RAP scope.

As discussed in Section 19.4 of this report, the staff reviewed COL Information Item 19.0-1, in COL FSAR, Chapter 19, "Probabilistic Risk Assessment and Severe Accident Evaluation,"

Section 19.0, which directs the COL applicant to either confirm that the PRA in the design certification bounds the site-specific design information and any design changes or departures, or update the PRA to reflect the site-specific design information and any design changes or departures. As discussed in Section 19.4 of this report, the staff finds that the COL applicant has adequately addressed COL Information Item 19.0-1, and the staff finds that it is appropriate to incorporate all SSCs in the design certification D-RAP list into the site-specific scope of RAP. Based on the discussion above, the staff has determined that the COL applicant has properly identified and incorporated the risk-significant SSCs into the site-specific RAP scope as specified in COL FSAR Tables 17.4-1.

It was unclear whether deterministic insights had been considered in the selection of site-specific SSCs within the scope of the RAP per the SSC determination process in SRP Section 17.4. Thus, in RAI 61, Question 17.04-2, the staff requested that the COL applicant discuss the method used and indicate the SSCs identified as in the scope of the RAP by deterministic insights and their bases. In a June 30, 2009, response to RAI 61, Question 17.04-2, regarding consideration of the deterministic insights in the selection of risk-significant SSCs, the COL applicant stated that, in addition to the systems identified by PRA, an expert panel reviewed the plant design for CCNPP Unit 3 to deterministically identify other systems to be included within the scope of the RAP. COL FSAR Table 17.4-2 indicates the systems and structures in the RAP incorporated by the expert panel.

In RAI 268, Question 17.04-22, issued by the staff in the U.S. EPR standard design certification review, the staff requested that the design certification applicant provide further justification for excluding the fire water distribution system (FWDS), sprinkler system (SPRS), spray deluge system (SDS), and core melt stabilization system (CMSS), from the scope of the design reliability assurance program (D-RAP). In an October 30, 2009, response to RAI 268, Question 17.04-22, the design certification applicant proposed revising the U.S. EPR FSAR Tier 2, Table 17.4-2 to incorporate these and other SSCs in the D-RAP, and included a markup of the proposed revision.

The staff finds that the SSCs itemized in COL FSAR Table 17.4-2 do not appear to match the SSCs identified by the design certification applicant in the October 30, 2009, response to RAI 268, Question 17.04-22 in the U.S. EPR design certification review. The staff finds that COL FSAR Table 17.4-2 excludes several risk-significant systems (i.e., fire water distribution system, sprinkler system, spray deluge system, core melt stabilization system, etc.), from the scope of the RAP. RAI 61, Question 17.04-2 is closed, but the issues it addressed are unresolved. Thus, in RAI 194, Question 17.04-4, the staff requested that the COL applicant explain why Table 17-4-2 excludes several risk-significant systems. **RAI 194, Question 17.04-4 is being tracked as an open item**.

To address COL Information Item 17.4-1, the COL applicant also qualitatively evaluated the site-specific systems for consideration in the RAP using the following deterministic criteria:

- Contribution to the initiators
- Implicit contribution to the core damage frequency (CDF)
- Implicit contribution to the large release frequency (LRF)
- Contribution to seismic margin analysis, performance history/operating experience of the component

- Technical Specifications considerations for the component
- Detection of component failures
- Effect of component failure on the other systems

Site-specific systems to be included in the RAP, as a result of the qualitative screening, are provided in COL FSAR Table 17.4-3.

The COL applicant did not specify the risk-significance systems boundaries identified in the scope of the RAP. Thus, in RAI 224, Question 17.04-5, the staff requested that the COL applicant describe the system boundary of the risk-significant systems identified in the COL FSAR Table 17.4-2, "Design Certification Scope Systems Included within RAP," and COL FSAR Table 17.4-3, "Site Specific Systems Included within RAP." **RAI 224, Question 17.04-5 is being tracked as an open item**.

In RAI 224, Question 17.04-6, the staff requested that the COL applicant provide the rationale for the criteria used for selecting the expert panel provided in COL FSAR Section 17.4.4.1.3, "Expert Panel." **RAI 224, Question 17.04-6 is being tracked as an open item**.

In RAI 224, Question 17.04-7, the staff requested that the COL applicant provide the rationale for the deterministic categorization process provided in COL FSAR Section 17.4.4.1.4.2, "Deterministic Risk Ranking," especially, the classification of weighted score range of 0-40 as a low safety or no risk significance. **RAI 224, Question 17.04-7 is being tracked as an open item**.

In RAI 224, Question 17.04-9, the staff requested that the COL applicant justify the exclusion of the following systems from the scope of D-RAP.

- Normal Heat Sink (NHS)
- Startup and Shutdown System (SSS)
- Auxiliary Cooling Water System (ACWS)
- Closed Cooling Water System (CLCWS)
- Raw Water Supply System (RWSS)

RAI 224, Question 17.04-9 is being tracked as an open item.

At this time the staff has insufficient information to conclude whether the COL applicant has adequately addressed COL Information Item 17.04-1.

COL Information Item 17.4-2, in COL FSAR Section 17.4, "Reliability Assurance Program Information Needed in a COL Application," directs a COL applicant that references the U.S. EPR design certification to provide the information requested in RG 1.206, Section C.I.17.4.4.

COL FSAR Sections 17.4.4.1 through 17.4.4.9, supplement U.S. EPR FSAR Tier 2, Section 17.4, which is incorporated by reference in the COL FSAR, with no departures.

The staff reviewed COL FSAR Section 17.4 and checked the referenced sections of the U.S. EPR FSAR to ensure that all COL information items and supplemental information required to be provided by the COL applicant regarding the RAP have been addressed in the COL application. The staff determined that the COL applicant addressed RAP information in conformance with the provisions in SRP Section 17.4 and RG 1.206, Section C.I.17.4.4, "Reliability Assurance Program Information Needed in a COL Application."

In COL FSAR Section 17.4.4.2, the COL applicant did not clearly describe how the reliability and availability assumptions are translated into verifiable attributes. Thus, in RAI 194, Question 17.04-3, the staff requested that the COL applicant describe in detail how the reliability and availability assumptions are translated into verifiable attributes as stated in COL FSAR Section 17.4.4.2. **RAI 194, Question 17.04-3 is being tracked as an open item**.

COL FSAR Section 17.4.4.4.1, "Performance Goal," states that, "the performance monitoring criteria are established consistent with the reliability and availability assumptions used in the PRA." The COL applicant did not describe the performance monitoring criteria for those risk-significant SSCs that were identified by the deterministic process. Thus, in RAI 224, Question 17.04-8, the staff requested that the applicant describe the performance criteria and goals for those risk-significant SSCs identified by the deterministic categorization methods (e.g., not modeled in the PRA). **RAI 224, Question 17.04-8 is being tracked as an open item**.

At this time the staff has insufficient information to conclude whether the COL applicant has adequately addressed COL Information Item 17.04-2.

17.4.5 Post Combined License Activities

There are no post combined license activities related to this section.

17.4.6 Conclusions

The staff reviewed COL FSAR Section 17.4, and checked the referenced sections of the U.S. EPR FSAR. The staff's review confirmed that the COL applicant has addressed the required information relating to the RAP with the exception of the SSCs specified in COL FSAR Table 17.4-2 and the reliability and availability assumptions. However, as a result of the open items, the staff is unable to finalize its conclusions on the RAP.

The staff is reviewing the COL information incorporated by reference from the U.S. EPR FSAR on Docket No. 52-020. The results of the staff's technical evaluation of the COL information incorporated by reference from the U.S. EPR regarding the Reliability Assurance Program will be documented in the staff's SER on the design certification application for the U.S. EPR. The staff will update this report to reflect the final disposition of the U.S. EPR design certification application.

17.5 Quality Assurance Program Description

COL FSAR Section 17.5, which provides a discussion of the Quality Assurance Program (QAP) to be implemented by the COL applicant at CCNPP Unit 3, incorporates U.S. EPR FSAR Tier 2, Section 17.5 with no departures, and as explained below, addresses COL information items identified in U.S. EPR FSAR Tier 2, Section 17.5.

17.5.1 Introduction

UniStar Nuclear Topical Report (TR) No. UN-TR-06-001-A, "Quality Assurance Program Description," Revision 0 (UN-TR-06-001-A, Revision 0), which was approved by the NRC on March 14, 2007, is the COL applicant's Quality Assurance Program Description (QAPD) for CCNPP Unit 3. The QAPD conforms to the criteria in 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," and the guidance in American Society for Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-1994, "Quality Assurance Requirements for Nuclear Applications."

17.5.2 Summary of Application

COL FSAR Section 17.5 incorporates by reference U.S. EPR FSAR Tier 2, Chapter 17, with no departures.

COL Information Items

COL Information Item 17.2-1, in COL FSAR Section 17.5, "Quality Assurance During the Operations Phase," directs a COL applicant that references the U.S. EPR design certification to provide the Quality Assurance Programs associated with the construction and operations phase.

The COL applicant has incorporated by reference UN-TR-06-001-A, Revision 0, as approved by the staff and as described in Section 17.5.1 of this report. The COL applicant indicates that UN-TR-06-001-A, Revision 0, is to be considered as a supplement to the U.S. EPR FSAR information. The COL applicant further commits that the requirements of this QAPD will apply during siting, design, fabrication, construction (including pre-operational testing), operation (including testing), maintenance, and modification of CCNPP Unit 3. The COL applicant further commits that changes to the QAPD will be made in accordance with 10 CFR 50.54(a)(3), "Conditions of licenses," and 10 CFR 50.55(f)(4), "Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses."

17.5.3 Regulatory Basis

The regulatory basis for acceptance of the COL information incorporated by reference from the U.S. EPR FSAR is addressed in the staff's FSER on the U.S. EPR FSAR.

The regulatory basis for the supplemental information the COL applicant included in this section is addressed in the staff's SER approving UN-TR-06-001-A, Revision 0, as referenced above.

17.5.4 Technical Evaluation

The staff reviewed COL FSAR Section 17.5 and checked the referenced sections of the U.S. EPR FSAR to ensure that all COL information items and supplemental information required to be provided by the COL applicant regarding the QAPD have been addressed in the COL application. The staff determined that the COL applicant has addressed all of the required information relating to this section. U.S. EPR FSAR Tier 2, Section 17.5 is being reviewed by the staff under Docket No. 52-020. The staff's technical evaluation of the COL information incorporated by reference from the U.S. EPR regarding the quality assurance program description will be documented in the staff's SER on the U.S. EPR design certification

application. The staff will update this report to reflect the final disposition of the U.S. EPR design certification application.

COL Information Items

COL Information Item 17.2-1, in COL FSAR Section 17.2, "Quality Assurance During the Operations Phase," directs a COL applicant that references the U.S. EPR design certification to provide the QAPs associated with the construction and operations phase.

As noted in Section 17.5-1 of this report, the staff previously reviewed and approved UN-TR-06-001-A, Revision 0, QAPD as conforming to NRC requirements and SRP Section 17.5. As part of the review of COL FSAR Chapter 17, the staff confirmed that COL FSAR Section 17.5 incorporates UN-TR-06-001-A, Revision 0, without exception, for control of activities affecting quality during the siting, design, fabrication, construction, operation, maintenance, and modification of the COL FSAR.

In RAI 7, Questions 17.5-1 and 17.5-2, the staff requested that the COL applicant provide additional information regarding its commitment to RG 1.26, "Quality Group Classifications and Standards for Water, Steam, and Radioactive-Waste-Containing Components of Nuclear Power Plants," Revision 4, March 2007; RG 1.29, "Seismic Design Classification," Revision 4, March 2007; and RG 1.37, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants," Revision 1, March 2007, in UN-TR-06-001-A, Revision 0. In a September 10, 2008, response to RAI 7, Questions 17.5-1 and 17.5-2, the COL applicant indicated that revisions would be made to UN-TR-06-001-A, to conform to the current revisions of the RGs. In a September 11, 2008, response, the COL applicant submitted UN-TR-06-001-A, Revision 1, for staff review and approval. The staff reviewed UN-TR-06-001-A, Revision 1, and confirmed that the COL applicant had adequately addressed the staff's issues identified in RAI 7, Questions 17.5-1 and 17.5-2. The staff considers RAI 7 resolved.

The staff also prepared additional requests for information regarding the COL applicant's use of certain terminology in the Calvert Cliffs COL application (RAI 120, Question 17.5-5), the addition of a commitment to 10 CFR 50.55(e) in UN TR-06-001-A, Revision 1 (RAI 120, Question 17.5-3), and the COL applicant's lack of an explicit commitment to follow the guidance in RG 1.33 in the UN-TR-06-001-A, Revision 1 (RAI 120, Question 17.5-4). In a July 29, 2009, response, the COL applicant addressed RAI 120, Question 17.5-3, by proposing to remove the redundant requirements from UN-TR-06-001-A that suppliers of basic components adhere to 10 CFR 50.55(e) in addition to 10 CFR Part 21. The staff finds that the COL applicant's proposal will adequately address issues concerning redundant requirements. **RAI 120, Question 17.5-3 is being tracked as a confirmatory item**.

To address RAI 120, Question 17.5-4, the applicant also proposed to revise UN-TR-06-001-A to include an explicit commitment to follow the guidance in RG 1.33, and to implement and comply with the RGs in accordance with ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications." The staff finds that the COL applicant's response does not adequately address RAI 120, Question 17.5-4 because ASME NQA-1-1994, only addresses QA requirements during design and construction, not during operations. The staff considers RAI 120, Question 17.5-4 closed, but the issues it raised are still unresolved. Therefore, the staff issued RAI 200, Question 17.5-6 to request that the COL applicant commit to following the guidance in RG 1.33 and revise UN-TR-06-001-A accordingly. **RAI 200, Question 17.5-6 is being tracked as an open item**.

The COL applicant's July 29, 2009, response to RAI 120, Question 17.5-5, did not address the staff's concern regarding terminology, but the COL applicant later revised the title of COL FSAR Section 17.5 to refer to the "Quality Assurance Program Description," rather than to refer to this program as "guidance." Therefore, the staff finds that COL FSAR, Section 17.5, Revision 6, uses appropriate terminology and the staff considers RAI 120, Question 17.5-5 resolved.

The staff intends to conduct an inspection of the COL applicant's implementation of its QAPD with respect to control of QA-related activities before COL issuance for CCNPP Unit 3. This inspection will be documented in an inspection report and will be described in Section 17.5 of this report, prior to COL issuance.

17.5.5 Post Combined License Activities

There are no post combined license activities related to this section.

17.5.6 Conclusions

The staff reviewed the COL application and checked the referenced sections of the U.S. EPR FSAR. The staff's review confirmed that with the exception of the open and confirmatory items described above, the COL applicant addressed the required information relating to the QAPD, and there is no outstanding information expected to be addressed in the COL FSAR related to this section.

The staff is reviewing the COL information incorporated by reference from the U.S. EPR FSAR on Docket No. 52-020. The results of the staff's technical evaluation of the COL information incorporated by reference from the U.S. EPR regarding the quality assurance program description will be documented in the staff's SER on the design certification application for the U.S. EPR. The staff will update this report to reflect the final disposition of the U.S. EPR design certification application.

On the basis of its review, the staff concludes that, with the exception of the open items discussed above, the COL applicant's QAPD provides adequate guidance for establishing a QA program that conforms to applicable NRC regulations and industry standards and can be used for the siting, design, fabrication, construction, operation, maintenance, and modification activities related to CCNPP Unit 3. However, as a result of the open items, the staff is unable to finalize its conclusions on the QAPD in accordance with the requirements of 10 CFR Part 50, Appendix B and the guidance of SRP Section 17.5 as the basis for evaluating the acceptability of the CCNPP Unit 3 QAPD provided in COL FSAR Chapter 17.

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 program for Maintenance Rule implementation based on the requirements of 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." Implementation of the program for the Maintenance Rule is also based on the guidance in Nuclear Management and Resources Council (NUMARC) 93-01, "Industry Guidance for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," as endorsed by

RG 1.160, “Monitoring the Effectiveness of Maintenance at Nuclear Power Plants,” Revision 2, March 1997, and the guidance contained in the February 22, 2000, revision to NUMARC 93-01, Section 11.0 as endorsed by RG 1.182, “Assessing and Managing Risk Before Maintenance Activities at Nuclear Power Plants,” May 2000.

17.6.2 Summary of Application

COL FSAR Section 17.6 incorporates by reference U.S. EPR FSAR Tier 2, Section 17.6, with no departures.

COL Information Items

COL Information Item 17.6-1, in COL FSAR Section 17.6.1, “Scoping per 10 CFR 50.65(b),” directs a COL applicant that references the U.S. EPR design certification to describe the process for determining which plant SSCs will be included in the scope of the Maintenance Rule Program in accordance with 10 CFR 50.65(b). This COL information item requires the program description to identify that additional SSC functions may be added 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.

To address this COL information item, the COL applicant stated that maintenance rule scoping per 10 CFR 50.65(b) is described in Section 17.7.1.1. COL FSAR Chapter 17, Revision 6, does not contain a Section 17.7.1.1. In COL FSAR Section 17.7, the COL applicant incorporated by reference, with no supplements, the Maintenance Rule Program description included in TR Nuclear Energy Institute (NEI) 07-02A, “Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52,” Revision 0, March 2008 (NEI 07-02A), in COL FSAR Section 17.7.

COL Information Item 17.6-2, in COL FSAR Section 17.6.2, “Monitoring per 10 CFR 50.65(a),” directs a COL applicant that references the U.S. EPR design certification to 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).

To address this COL information item, the COL applicant stated that preventative maintenance per 10 CFR 50.65(a)(2) is described in Section 17.7.1.3. COL FSAR Chapter 17, Revision 6 does not have a Section 17.7.1.3. In COL FSAR Section 17.7, the COL applicant incorporates by reference the Maintenance Rule Program description included in NEI 07-02A. The COL applicant further states that the text of the template provided in NEI 07-02A is generically numbered as “17.X.” The template is incorporated by reference into COL FSAR Section 17.7 by changing the numbering from “17.X” to “17.7.”

COL Information Item 17.6-3, in COL FSAR Section 17.6.2, “Monitoring per 10 CFR Section 50.65(a),” directs a COL applicant that references the U.S. EPR design certification to provide a program description for monitoring SSCs in accordance with 10 CFR 50.65(a)(1).

To address this COL information item, the COL applicant stated that monitoring and corrective action per 10 CFR 50.65(a)(1) is described in Section 17.7.1.2. COL FSAR Chapter 17, Revision 6 does not have a Section 17.7.1.3. In COL FSAR Section 17.7, the COL applicant incorporates by reference the Maintenance Rule Program description included in NEI 07-02A.

The COL applicant further states that the text of the template provided in NEI 07-02A is generically numbered as “17.X.” The template is incorporated by reference into COL FSAR Section 17.7 by changing the numbering from “17.X” to “17.7.”

COL Information Item 17.6-4, in COL FSAR Section 17.6.3, “Periodic Evaluation per 10 CFR Section 50.65(a)(2),” directs a COL applicant that references the U.S. EPR design certification to identify and describe the program for periodic evaluation of the Maintenance Rule Program in accordance with 10 CFR 50.65(a)(3).

To address this COL information item, the COL applicant stated that periodic evaluation of monitoring and preventative maintenance per 10 CFR 50.65(a)(3) is described in COL FSAR Section 17.7.1.4. COL FSAR Chapter 17, Revision 6 does not have a Section 17.7.1.4. In COL FSAR Section 17.7, the COL applicant incorporates by reference the Maintenance Rule Program description included in NEI 07-02A. The COL applicant further states that the text of the template provided in NEI 07-02A is generically numbered as “17.X.” The template is incorporated by reference into COL FSAR Section 17.7 by changing the numbering from “17.X” to “17.7.”

COL Information Item 17.6-5, in COL FSAR Section 17.6.4, “Risk Assessment and Management per 10 CFR 50.65(a)(4),” directs a COL applicant that references the U.S. EPR design certification to 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 must address how removing SC from service will be evaluated. For qualitative risk assessments, the program description must explain how the risk assessment and management program will preserve plant-specific key safety functions.

To address this COL information item, the COL applicant stated that risk assessment and risk management per 10 CFR 50.65(a)(4) is described in COL FSAR Section 17.7.1.5. COL FSAR Chapter 17, Revision 6 does not have a Section 17.7.1.5. In COL FSAR Section 17.7, the COL applicant incorporates by reference the Maintenance Rule Program description included in NEI 07-02A. The COL applicant further states that the text of the template provided in NEI 07-02A is generically numbered as “17.X.” The template is incorporated by reference into COL FSAR Section 17.7 by changing the numbering from “17.X” to “17.7.”

COL Information Item 17.6-6, in COL FSAR Section 17.6.5, “Maintenance Rule Training and Qualification,” directs a COL applicant that references the U.S. EPR design certification to describe the program for selection, training, and qualification of personnel with Maintenance-Rule-related responsibilities conforming to the provisions of COL FSAR Section 13.2, “Training,” 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.

To address this COL information item, the COL applicant stated that maintenance rule training and qualification is described in COL FSAR Section 17.7.2. COL FSAR Chapter 17, Revision 6 does not have a Section 17.7.2. In COL FSAR Section 17.7, the COL applicant incorporates by reference the Maintenance Rule Program description included in NEI 07-02A. The COL applicant further states that the text of the template provided in NEI 07-02A is generically numbered as “17.X.” The template is incorporated by reference into COL FSAR Section 17.7 by changing the numbering from “17.X” to “17.7.” Descriptions of the programs listed in

NEI 07-02A, Subsection 17.X.3 are provided in the Maintenance Programs (Section 13.5.2.2.6) of the COL FSAR.

COL Information Item 17.6-7, in COL FSAR Section 17.6-6, "Maintenance Rule Program Role in Implementation of Reliability Assurance Program (RAP) in the Operations Phase," directs a COL applicant that references the U.S. EPR design certification to describe the relationship and interface between Maintenance Rule Program and the RAP.

To address this COL information item, the COL applicant stated that Maintenance Rule Program relationship with RA activities is described in COL FSAR Section 17.7.5. COL FSAR Chapter 17, Revision 6, does not have a Section 17.7.5. In COL FSAR Section 17.7, the COL applicant incorporates by reference the Maintenance Rule Program description included in NEI 07-02A. The COL applicant further states that the text of the template provided in NEI 07-02A is generically numbered as "17.X." The template is incorporated by reference into COL FSAR Section 17.7 by changing the numbering from "17.X" to "17.7." In Section 17.X.1.1.b of NEI 07-02A, the "D-RAP" (Reliability Assurance Program for the Design Phase) is defined to be located in COL FSAR "17.Y." The D-RAP is included in COL FSAR Section 17.4. The template is incorporated by reference into this COL FSAR section by changing the numbering from "17.Y" to "17.4."

COL Information Item 17.6-8, in COL FSAR Section 17.6.7, "Maintenance Rule Program Implementation," directs a COL applicant that references the U.S. EPR design certification to describe the plan or process for implementing the Maintenance Rule Program as described in the COL FSAR, which includes establishing program elements through sequence and milestones and monitoring or tracking the performance and/or condition of SSCs as they become operational. This COL information item also requires that the Maintenance Rule Program will be implemented by the time that fuel load is authorized.

To address this COL information item, the COL applicant stated that the Maintenance Rule Program implementation is described in COL FSAR Section 17.7.5. COL FSAR Chapter 17, Revision 6 does not have a Section 17.7.5. In COL FSAR Section 17.7, the COL applicant incorporates by reference the Maintenance Rule Program description included in NEI 07-02A. The COL applicant further states that the text of the template provided in NEI 07-02A is generically numbered as "17.X." The template is incorporated by reference into COL FSAR Section 17.7 by changing the numbering from "17.X" to "17.7."

COL Information Item 17.6-9, in COL FSAR Section 17.6, "Description of Applicant's Program for Implementation of 10 CFR 50.65, The Maintenance Rule," directs a COL applicant that references the U.S. EPR design certification to describe the program for Maintenance Rule implementation.

To address this COL information item, the COL applicant stated that the COL applicant stated that the Maintenance Rule Program description included in NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," Revision 0, March 2008, is incorporated by reference with supplements in COL FSAR Section 17.7. In COL FSAR Section 17.7, the COL applicant incorporates by reference the Maintenance Rule Program description included in NEI 07-02A. The COL applicant further states that the text of the template provided in NEI 07-02A is generically numbered as "17.X." The template is incorporated by reference into COL FSAR Section 17.7 by changing the numbering from "17.X" to "17.7."

17.6.3 Regulatory Basis

The regulatory basis for acceptance of the COL information incorporated by reference from the U.S. EPR FSAR is addressed within the staff's FSER on the U.S. EPR FSAR.

17.6.4 Technical Evaluation

The staff reviewed COL FSAR Section 17.6 and checked the referenced sections of the U.S. EPR FSAR to ensure that COL information items and supplemental information required to be provided by the COL applicant regarding the description of COL applicant's program for Implementation of 10 CFR 50.65, the Maintenance Rule, have been addressed in the COL application. The staff's review confirmed that the COL information contained in the application and incorporated by reference from the U.S. EPR addresses all of the required information relating to this section. U.S. EPR FSAR Tier 2, Section 17.6 is being reviewed by the staff under Docket No. 52-020. The staff's technical evaluation of the COL information incorporated by reference from the U.S. EPR regarding Maintenance Rule implementation will be documented in the staff's SER on the U.S. EPR design certification application. The staff will update this report to reflect the final disposition of the U.S. EPR design certification application.

The staff reviewed conformance of COL FSAR Sections 17.6 and 17.7, which incorporates by reference NEI 07-02A, to the guidance in RG 1.206, Section C.I.17.6, "Description of the Applicant's Program for Implementation of 10 CFR 50.65, the Maintenance Rule," to ensure that the combination of NEI 07-02A and the information in the COL FSAR represents all of the information required to be included in the COL FSAR regarding the Maintenance Rule Program.

The staff has endorsed NEI 07-02A and approved the template presented in NEI 07-02A for the Maintenance Rule Program. The staff concluded that NEI 07-02A provides an acceptable method for COL applicants to comply with the requirement in 10 CFR 52.79(a)(15) that COL FSARs contain a description of the Maintenance Rule Program, and its implementation, for monitoring the effectiveness of maintenance to meet the requirements of 10 CFR 50.65 and satisfy the acceptance criteria of SRP Section 17.6.

As part of the staff's review of the U.S. EPR design certification application, in RAI 226, Question 17.06-2, the staff requested that the U.S. EPR design certification applicant include a COL information item on industry operating experience (IOE) as described in NEI 07-02A. In a June 23, 2009, response to RAI 226, Question 17.06-2, the U.S. EPR design certification applicant agreed to add a description of IOE to the U.S. EPR FSAR Tier 2, Section 17.6.7, and Table 1.8-2.

According to NEI 07-02A Section 17.4, the Maintenance Rule Program should utilize IOE, where appropriate, for scoping, performance/condition criteria development, monitoring, goal-setting, corrective action, training, program assessment and maintenance and procurement activities. In RAI 62, Question 17.06-1, the staff requested that the COL applicant comply with the requirement in NEI 07-02A, Section 17.4 to account for IOE. In a December 4, 2009, response to RAI 62, Question 17.06-1, the COL applicant proposed to revise the COL FSAR to incorporate by reference from NEI 07-02A, Section 17.4 the requirement to account for IOE as requested in RAI 62, Question 17.06-1. **RAI 62, Question 17.06-1 is being tracked as a confirmatory item**.

The staff's review of the COL applicant's December 4, 2009, response to RAI 62, Question 17.06-1 determined that while the COL applicant proposes an acceptable means of complying with the requirement to incorporate IOE in the Maintenance Rule Program, the section numbers and COL information item numbers presented in the COL FSAR, Section 17.6, Revision 6, do not appear to conform to the most recent revision to the U.S. EPR FSAR. As a result, the staff issued RAI 192, Question, 17.06-2, requesting that the COL applicant provide clarification. However, the staff considers the changes requested by RAI 192, Question 17.06-2 to be editorial, which should have no impact on the technical contents of COL FSAR Section 17.6. **RAI 192, Question 17.06-2 is being tracked as an open item**.

17.6.5 Post Combined License Activities

NEI 07-02A template specifies that the Maintenance Rule Program documents will be developed and maintained and the Maintenance Rule Program implemented by the time that fuel load is authorized (i.e., by the time the staff makes the finding required in 10 CFR 52.103(g), "Operation under a combined license"). The staff's position is that implementation of an acceptable Maintenance Rule Program may occur in advance of the staff's 10 CFR 52.103(g) finding, with components being monitored or tracked as they become available. As described in RG 1.206, Section C.IV.4, "Operational Programs," the staff intends to inspect operational programs and their implementation as they are developed and put into place.

Pursuant to 10 CFR § 52.79(a)(15), a COL applicant must include in the COL application a description of the program, and its implementation, for monitoring the effectiveness of maintenance necessary to meet the requirements of 10 CFR § 50.65. The COL application should fully describe this program, as defined in SECY-05-0197, "Review of Operational Programs in a Combined License Application and Generic Emergency Planning Inspections, Tests, Analyses, and Acceptance Criteria," which was approved by the Commission in an SRM dated February 22, 2006. In addition, as discussed in SECY 05-0197, the COL applicant should provide implementation and readiness milestones for this program.

COL FSAR Table 13.4-1 lists the Maintenance Rule program, and states that the program will be implemented prior to the authorization to load fuel pursuant to 10 CFR 52.103(g), in accordance with 10 CFR 50.65(a)(1).

In RAI 228, Question 17.06-3, the staff requested that the COL applicant provide, as discussed in SECY 05-0197, the implementation and readiness milestones for this program. **RAI 228, Question 17.06-3 is being tracked as an open item**.

17.6.6 Conclusions

The staff reviewed COL FSAR Section 17.6, and checked the referenced sections of the U.S. EPR FSAR. With the exception of the open and confirmatory items discussed above, the staff confirmed that the COL applicant has fully addressed the required information relating to the Maintenance Rule Program by including an additional COL FSAR Section 17.7, "Maintenance Rule Program," which indicates that the entire NEI 07-02A guidance document template is incorporated. However, as a result of the open item, the staff is unable to finalize its conclusions on the Maintenance Rule Program.

The staff is reviewing the COL information incorporated by reference from the U.S. EPR FSAR on Docket No. 52-020. The results of the staff's technical evaluation of the COL information incorporated by reference from the U.S. EPR regarding the Maintenance Rule Program will be documented in the staff's SER on the design certification application for the U.S. EPR. The staff will update this report to reflect the final disposition of the U.S. EPR design certification application.

17.7 Maintenance Rule Program

This section of the COL FSAR has been added as a supplement to the COL information items required to be included in the COL application by an applicant that references the design certification for the U.S. EPR FSAR. COL FSAR Section 17.7 incorporates by reference the Maintenance Rule Program description included in NEI 07-02A.

The supplemental information provided in this section has been evaluated in Section 17.6 of this report.