

17 QUALITY ASSURANCE AND RELIABILITY ASSURANCE

Chapter 17, “Quality Assurance and Reliability Assurance,” of this safety evaluation report (SER) describes the results of the review by the staff of the U.S. Nuclear Regulatory Commission (NRC or Commission), hereinafter referred to as the staff, of Chapter 17 of the Design Control Document (DCD), for the design certification (DC) of the Advanced Power Reactor 1400 (APR1400), submitted by Korea Electric Power Corporation (KEPCO) and Korea Hydro & Nuclear Power Co., Ltd (KHNP), hereinafter referred to as the applicant.

DCD Tier 2 Chapter 17 discusses the quality assurance (QA) during the design phase, QA during the construction and operation phases, the QA program (QAP), the reliability assurance program (RAP), and the QAP description (QAPD) for the DC. It also discusses the position of KHNP, the DC applicant, regarding a combined license (COL) applicant’s responsibility for developing a QAP for the construction and operations phase and a program for implementation of Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.65, “Requirements for monitoring the effectiveness of maintenance at nuclear power plants,” in Section 17.6. The QAP described in Sections 17.1, “Quality Assurance during the Design Certification Phase”, 17.2, “Quality Assurance during the Operations Phase”, 17.3, “Quality Assurance Program Description”, and 17.5, “Quality Assurance Program Description – Design Certification”, of Chapter 17 of DCD Tier 2 is applicable for QA during the APR1400 standard plant design activities. The RAP described in Section 17.4 of DCD Tier 2 applies to those structures, systems, and components (SSCs) that are identified as being risk-significant or significant contributors to plant safety.

17.0 Quality Assurance and Reliability Assurance

The KHNP QAP used for the APR1400 DC is described in KHNP APR1400-K-Q-TR-11005, Revision 5, “Quality Assurance Program Description (QAPD) for the APR1400 Design Certification,” dated May 2, 2016 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16123A404), which was approved by the staff on October 6, 2016 (ML16265A505). Accordingly, KHNP published the accepted version of the document as APR1400-K-Q-TR-11005-A, Revision 2, for the APR1400 DC (ML18085B044). The accepted version of the topical report added an “-A” (designated accepted) following the report identification number. APR1400-K-Q-TR-11005-A, Revision 2, included the changes that the staff reviewed and accepted in APR1400-K-Q-TR-11005, Revision 5. The KHNP QAP topical report covers the activities associated with the certification of the APR1400 design. The QAP is based on the applicable portions of both Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” to 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” and the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-2008 and NQA-1a-2009 Addenda, “Quality Assurance Requirements for Nuclear Applications,” relevant to the APR1400 DCD Tier 2.

17.1 Quality Assurance during the Design Certification Phase

17.1.1 Introduction

The KHNP QAP for the APR1400 during the DC phase is described in DCD Tier 2 Section 17.1. The staff reviewed DCD Tier 2 Section 17.1 in accordance with Section 17.5, “Quality Assurance Program Description – Design Certification, Early Site Permit and New License

Applicants,” of NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition” (SRP), and that evaluation is in Section 17.5 of this SER.

17.1.2 Summary of Application

The KHNP QAP during the DC phase of the APR1400 is described in Section 17.5.

DCD Tier 2 Section 17.1 states that “[the] COL applicant is to establish and implement a QA program that is applicable to site-specific design activities during the plant construction and operation phases.” However, this apparent COL item did not have a COL item number. The staff issued a request for additional information (RAI) 64-8042, Question 17.01-1 (ML15190A286), which requested the addition of a COL item number for tracking purposes for COL items in DCD Tier 2 Section 17.1. The applicant responded (ML15217A634) that DCD Tier 2 Section 17.1, will be revised to include a COL item number for tracking purposes. The applicant issued DCD Revision 1 (ML17096A321), which provided a COL item number for the COL item. This action adequately addressed Confirmatory Item 17.1.1. The staff considers the RAI response acceptable; therefore, Confirmatory Item 17.1.1, is resolved and closed.

Table 17.1 Combined License Information Items Identified in the DCD

Item No.	Description	Section
COL 17.1 (1)	The COL applicant is to establish and implement a QA program that is applicable to site-specific design activities during the plant construction and operation phases.	17.1.1

17.2 Quality Assurance during the Operations Phase

DCD Tier 2 Section 17.2 states that “[t]he COL applicant is to establish and implement a QA program that is applicable to site-specific design activities during the plant construction and operation phases.” However, this apparent COL item did not have a COL item number. The staff issued RAI 65-8043, Question 17.02-1 (ML15190A287), requesting the addition of a COL item number for tracking purposes for COL items in DCD Tier 2 Section 17.2. The applicant responded (ML15217A637) that DCD Tier 2 Section 17.2, will be revised to include a COL item number for tracking purposes. The applicant issued the APR1400 DCD Revision 1 (ML17096A321), which adequately addressed Confirmatory Item 17.2.1. Specifically, the applicant included a COL item number for the COL item. The staff determined that this information is acceptable because the QA for Operations will be reviewed at the COL stage in accordance with SRP Section 17.5. The staff considers the RAI response acceptable and Confirmatory Item 17.2.1, is resolved and closed.

Table 17.2 Combined License Information Items Identified in the DCD

Item No.	Description	Section
COL 17.2(1)	The COL applicant is to establish and implement a QA program that is applicable to site-specific design activities during the plant construction and operation phases.	17.2.1

17.3 Quality Assurance Program Description

The KHNP's QAP description during the DC phase of the APR1400 is described in DCD Tier 2 Section 17.5.

The COL applicant is to establish and implement a QAP that is applicable to site-specific design activities during the plant construction and operation phases. The staff reviewed DCD Tier 2 Section 17.3, in accordance with SRP Section 17.5. That evaluation is in Section 17.5 of this SER.

The staff issued RAI 66-8044, Question 17.03-1 (ML15190A289), requesting the applicant to provide an addition of a COL item number for tracking purposes for COL items in Section 17.3. In its response to RAI 66-8044, Question 17.03-1 (ML15217A641), the applicant stated that the DCD Tier 2 Section 17.3 will be revised to include a COL item number for tracking purposes. The applicant issued DCD Revision 1 (ML17096A321), which adequately addressed Confirmatory Item 17.3.1. Specifically, the applicant included a COL item number for the COL item. The staff considers the RAI response acceptable; therefore, Confirmatory Item 17.3.1, is resolved and closed.

Table 17.3 Combined License Information Items Identified in the DCD

Item No.	Description	Section
COL 17.3(1)	The COL applicant is to establish and implement a QA program that is applicable to site-specific design activities during the plant construction and operation phases.	17.3.1

17.4 Reliability Assurance Program

17.4.1 Introduction

The RAP applies to the 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. 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 design-specific and plant-specific probabilistic risk assessments (PRAs), 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 SRM and SECY are available in ML003761550). The purposes of the RAP are to assure the following:

- An advanced reactor [including advanced light-water reactors] 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.

17.4.2 Summary of Application

DCD Tier 1: A description of the Design Reliability Assurance Program (D-RAP) is provided in DCD Tier 1 Section 2.13 "Design Reliability Assurance Program." The inspections, tests, analyses, and acceptance criteria (ITAAC) for the D-RAP is provided in DCD Tier 1 Table 2.13-1 "Design Reliability Assurance Program ITAAC," which indicates that an analysis will be performed to verify that the initial design of all RAP SSCs (for procurement and installation) is completed in accordance with the D-RAP.

DCD Tier 2: The applicant provided a DCD Tier 2 discussion of the RAP program including an outline of the first stage of RAP implementation (also known as D-RAP). The procedures for identification and prioritization of SSCs are discussed together with the use of expert panels. Using the program described, the applicant identified RAP SSC's and COL items. The applicant developed the RAP in conformance with the guidance in SRP Section 17.4, "Reliability Assurance Program (RAP)," Revision 1, and described the RAP for the APR1400 as a two-stage process in its DCD Tier 2 Section 17.4. The first stage applies prior to initial fuel load, and is referred to as D-RAP. This stage is implemented through the ITAAC before initial fuel load. The second stage applies to reliability assurance activities during the operations phase of the plant life cycle. The applicant did not describe this stage, leaving it to be addressed in the COL application phase.

17.4.3 Regulatory Basis

The relevant requirements of NRC regulations for this area of review, and the associated acceptance criteria, are listed in SRP Section 17.4, Revision 1, 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 DC must contain proposed ITAAC that are necessary and sufficient to provide reasonable assurance that, if the tests, inspections, and analyses are performed, and the acceptance criteria are met, a plant that references the design is built and will operate in accordance with the DC, the provisions of the Atomic Energy Act of 1954, as amended, and NRC regulations.

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 COL who references the certified design.

17.4.4 Technical Evaluation

SRP Section 17.4, Revision 1, Section II, “Acceptance Criteria” states the following:

... an applicant is required to identify differences between the design features, analytical techniques, and procedural measures proposed for its facility and the SRP acceptance criteria and evaluate how the proposed alternatives to the SRP acceptance criteria provide acceptable methods of compliance with the NRC regulations.

The staff reviewed DCD Tier 2 Section 17.4, “Reliability Assurance Program,” and found that, although DCD Table 1.9-2, “APR1400 Conformance with the Standard Review Plan,” referenced SRP Section 17.4, Revision 1, as being used to develop the RAP, the DCD information seemed to match closely the guidance provided in Revision 0 of SRP Section 17.4, which is outdated and superseded by Revision 1. The applicant did not identify differences between its RAP and the SRP acceptance criteria. Furthermore, DCD Tier 2 Section 17.4 discusses: a) essential elements of RAP instead of programmatic controls and processes for RAP in the operations phase, and b) development/integration of operational RAP, which is not included in the SRP Section 17.4, Revision 1 guidance. Therefore, the staff issued RAI 316-8305, Question 17.04-1 (ML15321A167), to address this issue. In its response to RAI 316-8305, Question 17.04-1 (ML16239A283), the applicant did not completely address the issues identified in the staff’s question. During a public teleconference (ML16274A253) with the applicant on September 27, 2016, the staff provided the applicant feedback and the applicant committed to revise its response to comply with the guidance in SRP Section 17.4, Revision 1. On January 31, 2018, the applicant submitted a revised version of DCD Tier 2 Section 17.4 (ML18031A561). The revised version was developed in compliance with SRP Section 17.4, Revision 1. Based on the review of DCD, Revision 3, which is the latest revision, the staff has confirmed incorporation of the changes described above. The staff considers the RAI response acceptable and the RAI, is resolved and closed.

The SRP prescribes elements of an acceptable RAP program. The applicant opted to propose a RAP program that is in conformance with the SRP and did not define alternative approaches to developing its RAP program. Therefore, the staff reviewed the revised submittal of DCD Tier 2 Section 17.4 and audited the APR1400 RAP Notebook in accordance with the guidance provided in SRP Section 17.4, Revision 1, and SECY-95-132 to determine whether the APR1400 RAP adequately considered the following attributes:

- Describe the RAP program in sufficient detail.
- Identify and characterize SSCs in the RAP list.
- Define an appropriate ITAAC for RAP SSCs.
- Provide applicable COL items.

Description of Design Reliability Assurance Program

The staff verified that the applicant included a description of the details of the D-RAP that will be implemented during the DC and COL design and construction activities preceding initial fuel load. This description included a discussion of the scope, purpose, objectives, framework, and those activities that will occur in the two phases of the D-RAP (i.e. DC and detailed plant design following issuance of a COL). The staff confirmed that the scope, purpose, and objectives of the applicant's D-RAP are consistent with those described in Subsection I of SRP Section 17.4, Revision 1. Based on its review as described above, the staff finds the description of the D-RAP to be acceptable.

Programmatic Controls of Design Reliability Assurance Program

The staff verified that the applicant has established and applied the appropriate D-RAP programmatic controls to support DC design activities. Consistent with guidance in SRP Section 17.4, Revision 1, the programmatic controls established by the applicant address organization responsibilities, design control activities, procedures and instructions, records control, corrective actions, and audit plans. Based on its review as described above, the staff finds that the applicant has established adequate programmatic controls for the D-RAP.

Methodology for Identifying SSC within the Scope of the D-RAP

The staff verified that the applicant's methodology for identifying the SSCs within the scope of the RAP is based on information obtained from a combination of analysis methods to identify and quantify risk. The staff observed that the methodology provides an objective and replicable approach to identify SSCs within the scope of the RAP. The applicant's methodology is consistent with accepted industry practice for identifying risk-significant SSCs, as discussed in Regulatory Guide (RG) 1.200, "An Approach For Determining The Technical Adequacy Of Probabilistic Risk Assessment Results For Risk-Informed Activities." This methodology is consistent with that described in SRP Section 17.4, Revision 1, as confirmed by the staff audit of the APR1400 RAP Notebook (ML18253A034), as noted, above. Based on its review, as described above, the staff finds that the applicant has established an adequate methodology for identifying RAP SSCs.

Expert Panel

The staff verified that the applicant adequately described the roles, responsibilities, and qualification requirements of the expert panel and its members. The staff finds the described minimum expertise of the expert panel with knowledge of the plant design to be consistent with SRP Section 17.4, Revision 1. The staff verified, during review of the expert panel meeting minutes, that the applicant adequately implemented the RAP program requirements in the make-up of the expert panel. Based on its review as described above, the staff finds the description and implementation of the expert panel to be acceptable.

SSC within the Scope of the Reliability Assurance Program

Overall, the staff verified that the application contained a comprehensive list of RAP SSCs based on the methodology for identifying and characterizing SSCs within the scope of the RAP. The staff audited the RAP notebook, which included the expert panel meeting minutes. Consistent with the proposed RAP program, the expert panel reviewed a combination of information, including results of probabilistic and deterministic analyses, and relied on the expert

panel members' experience with the APR1400 design to account for the limitations of the PRA or SSCs not modeled in the PRA. During the audit, the staff observed that the PRA results described in DCD Chapter 19, identified the failure of the in-containment refueling water storage tank (IRWST) sump due to plugging to be very risk significant and, based on the applicant's methodology, should have been provided to the expert panel to be considered for inclusion in the RAP list. The applicant subsequently conducted a second expert panel to review the issue, which resulted in the IRWST sump being added to the RAP list. The staff observed that the applicant's methodology does not automatically include PRA risk important SSCs in the RAP list; rather, the expert panel reviews the RAP list and excludes some SSCs from the list after documenting its rationale. The staff evaluated the replicability of this process and finds it to be reasonable because the SSCs excluded from the RAP list are very close to the risk important threshold established. In addition, these excluded SSCs are safety-related, which ensures that they will be adequately designed, procured, and constructed. This is acceptable, because the applicant applied the approach consistently and documented its basis for excluding the SSCs. The RAP list sufficiently identified the RAP SSCs and the basis for including each SSC. Consistent with SRP Section 17.4, Revision 1, the staff finds that the applicant appropriately cited the section of the DCD that describes SSC boundaries. Based on its review, as described above, the staff finds the RAP SSCs list to be acceptable.

Process for Determining Dominant Failure Modes

The staff verified that the application describes a proposed process for determining dominant failure modes of RAP SSCs. Consistent with guidance in SRP Section 17.4, Revision 1, the applicant's proposed process for determining dominant failure modes incorporates consideration of insights from the PRA model, analytical methods, and IOE. The process described by the applicant is consistent with the guidance for an acceptable process described in SRP Section 17.4, Revision 1, and therefore is acceptable.

Quality Assurance Associated with Design Activities

The staff verified that the applicant specified where the QA controls for DC design activities are described. The applicant cited the specific section of the DCD that describes QA controls applied to non-safety-related RAP SSCs. The QA controls are evaluated in the staff's SER of DCD Section 17.5. These controls are consistent with staff's expectations for QA controls described in SRP Section 17.4, Revision 1, and are therefore acceptable.

ITAAC for Design Reliability Assurance Program

The staff verified that the applicant included an ITAAC for the D-RAP in Tier 1 of the DCD. The D-RAP ITAAC specified a design commitment along with an analysis method, and acceptance criterion that is consistent with the guidance described in SRP Section 17.4, Revision 1. The staff finds the ITAAC will ensure that appropriate controls are applied to all RAP SSCs early in the COL application phase. Based on its review, as described above, the staff finds the applicant has established an adequate ITAAC for the D-RAP.

17.4.5 Combined License Information Items

The SRP Section 17.4, Revision 1, Section II, "Acceptance Criteria," states the following "The DC application should include the following COL items...."

The staff reviewed APR1400 DCD, Section 17.4, “Reliability Assurance Program,” and found that the section did not include the COL items listed in the SRP Section 17.4 acceptance criteria, nor did it justify the COL items selected. For example, SRP Section 17.4 specifically identifies three COL items to be addressed by the COL applicant. However, DCD Section 17.4 was missing one of those items, which expects the COL applicant to address appropriate QA controls for non-safety-related SSCs. In addition, the applicant’s COL items did not address SRP guidance for the COL applicant to consider dominant failure modes of RAP SSC’s in meeting the objectives of the RAP during plant operations. Therefore, the staff issued RAI 316-8305, Question 17.04-2 (ML15321A167), to address this issue. The applicant provided a response to the RAI 316-8305, Question 17.04-2 (ML16239A283), that the staff found to be inadequate. During a public teleconference with the applicant on September 27, 2016 (ML16274A253), the staff provided feedback on the applicant’s response, and the applicant committed to include the three SRP Section 17.4, Revision 1, COL items, with its revised response. On May 24, 2017, RAI 316-8305, Question 17.04-2, was subsequently subsumed into and tracked by RAI 316-8305, Question 17.04-1. On January 31, 2018, the applicant submitted a revised version of DCD Tier 2 Section 17.4 (ML18031A561). The applicant included the three SRP Section 17.4, Revision 1, COL items, shown below, in DCD, Revision 3, with no amendments.

Table 17.4 Combined License Information Items Identified in the DCD

Item No.	Description	Section
COL 17.4(1)	An updated description of the D-RAP to include relevant site- and plant specific information (e.g., design, program, procedural, and organizational information). This includes identifying the SSCs within the scope of the plant-specific RAP (i.e., the RAP SSCs identified in the DC, updated using COL site- and plant-specific information) and establishing the programmatic controls of D-RAP to be applied during the COL design and construction activities prior to initial fuel load.	17.4.4
COL 17.4(2)	Appropriate QA controls for the non-safety-related RAP SSCs in accordance with the provisions in Part V, “Non-safety-Related SSC Quality Controls,” of SRP Section 17.5. This includes providing corrective actions for potential design and pre-operational errors that could degrade non-safety-related RAP SSCs. These controls are not applicable to SSCs that are not on the RAP list.	17.4.4

Item No.	Description	Section
COL 17.4(3)	The process for integrating the RAP into operational programs (e.g., maintenance rule program, QA program, inservice inspection, inservice testing, surveillance testing, and maintenance programs). The process should also address the (1) establishment of reliability, availability, or condition performance goals for the RAP SSCs, (2) establishment of performance and condition monitoring requirements to provide reasonable assurance that RAP SSCs do not degrade to an unacceptable level of reliability, availability, or condition during plant operations, (3) for non-safety-related RAP SSCs, establishment of QA controls for activities during the operations phase in accordance with the provisions in Part V of SRP Section 17.5, and (4) consideration of dominant failure modes of RAP SSCs in meeting the objectives of the RAP during plant operation.	17.4.4

The above COL items will ensure that the COL applicant considers site-specific information, establishes QA controls for the RAP, and provides a process for integrating the RAP into operational programs in its application. The staff finds the COL items acceptable because they were directly from SRP Section 17.4, Revision 1, which is an acceptable method to demonstrate compliance with Commission policy. The staff concludes that no additional COL items relevant to the APR1400 RAP are necessary.

17.4.6 Conclusion

As discussed above, the staff reviewed DCD Tier 1 Section 2.13, and DCD Tier 2 Section 17.4, in accordance with Item E of SECY-95-132 and SRP Section 17.4, Revision 1, and concludes that the APR1400 RAP program as developed, described, and to be implemented is acceptable.

17.5 Quality Assurance Program Description – Design Certification

17.5.1 Introduction

The QAP for the APR1400 DC is described in APR1400-K-Q-TR-11005-A, Revision 2, “KHNP Quality Assurance Program Description (QAPD) for the APR1400 Design Certification,” dated October 6, 2016. The QAPD incorporates the requirements of ASME NQA-1-2008 and NQA-1a-2009 Addenda as endorsed by the NRC in RG 1.28, “Quality Assurance Program Criteria (Design and Construction),” Revision 4, dated June 2010.

The purpose of the QAPD is to meet the requirements of 10 CFR Part 50, Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” by implementing ASME NQA-1-2008, and NQA-1a-2009 Addenda, “Quality Assurance Program Requirements for Nuclear Facilities,” as endorsed by RG 1.28, Revision 4.

17.5.2 Summary of Application

The KHNP APR1400 QAPD referenced in the APR1400 DCD provides for control of KHNP activities that affect the quality of safety-related nuclear plant SSCs and includes all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service. The QAPD may also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where other NRC guidance establishes program requirements.

The KHNP QAPD is the top-level policy document that establishes the manner in which quality is to be achieved and presents KHNP's overall philosophy regarding achievement and assurance of quality. KHNP's implementing documents assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAPD.

Table 17.5 Combined License Information Items Identified in the DCD

Item No.	Description	Section
COL 17.5(1)	The COL applicant is to establish and implement a QA program that is applicable to site-specific design activities related to the plant construction and operation phases.	17.5.1

17.5.3 Regulatory Basis

The Commission's regulatory requirements related to QAP for standard DC are set forth in 10 CFR 52.47(a)(19) and Appendix B to 10 CFR Part 50 (Appendix B).

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

Appendix B establishes QA requirements for the design, fabrication, construction, and testing of SSCs for the facility. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying SSCs.

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

The staff reviewed the KHNP QAPD as described in APR1400-K-Q-TR-11005, Revision 5, and issued SER, "Acceptance of Advanced Power Reactor 1400 APR1400-K-Q-TR-11005,

Revision 5, KHNP Quality Assurance Program Description for the APR1400 Design Certification” (ML18085B044). Specifically, the staff evaluated the KHNP QAPD to verify that it meets NRC regulations by following the guidance in SRP Section 17.5. KHNP subsequently issued the approved version of the KHNP QAPD topical report, designated as APR1400-K-Q-TR-11005-A, Revision 2. The staff verified that the approved version of the topical report was consistent with the version accepted by the staff. The staff also verified that APR1400 DCD Tier 2, Revision 2, Section 17.5, incorporates APR1400-K-Q-TR-11005-A, Revision 2, without exception, for control of activities affecting quality during the DC of the APR1400 and is therefore, acceptable.

Staff Inspection of APR1400 QAPD Implementation

NRC Inspection Manual Chapter 2502 provides staff guidance to perform a post-docketing QAP inspection. This post-docketing QAP inspection provides the staff with reasonable assurance that the QAP has been adequately implemented. This objective is consistent with regulations that govern all stages of the licensing process and will verify whether activities affecting quality are conducted under the appropriate provisions of Appendix B to 10 CFR Part 50. The staff conducted an implementation inspection on May 22-26, 2017 of KHNP’s QAP to ensure that the applicant’s program will provide reasonable assurance that SSCs will perform the intended safety function. The inspection was being tracked as Open Item 17.5.1.

The NRC issued Inspection Report (IR) 05200010/2005-201(ML17171A237), dated May 22-26, 2017, documenting the inspection. During this inspection, the staff found that the implementation of the KHNP’s QAPD failed to meet certain NRC requirements and cited four nonconformances. Specifically, the staff found that KHNP failed to implement measures for control of design interfaces and for coordination among participating design organizations as required by the KHNP’s QAPD. KHNP requirements from the APR1400 Design Control Document (DCD) were not adequately translated into the design specifications developed by design organizations. In addition, KHNP failed to identify conditions adverse to quality for NRC audit findings and requests for information related to the review of the APR1400 DC application. KHNP also failed to ensure that audits were performed by personnel not having direct responsibilities in the areas being audited.

KHNP responded to IR 05200010/2005-201 by letter dated August 9, 2017 (ML17237B985), and provided appropriate corrective and preventive actions for the cited nonconformances. The staff concluded that KHNP’s QAPD has established an acceptable QAP in accordance with applicable NRC regulations and industry standards for DC activities. Therefore, Open Item 17.5.1, is closed.

17.5.5 Conclusion

As discussed above, the staff completed its review of APR1400 DCD Tier 2 Section 17.5, and confirmed that the applicant fully addressed the information related to the KHNP 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 KHNP’s QAPD. The staff finds the APR1400 DCD meets the applicable criteria of 10 CFR Part 50, Appendix B, as outlined by 10 CFR 52.47(a)(19).

17.6 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." 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 in Revised Safety Evaluation by the Office of New Reactors for Topical Report NEI 07-02, Revision 3, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52", dated January 24, 2008 (ML073650081).

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)(1) and (2).
- 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).

The applicant developed the MR program in conformance with the guidance in SRP Section 17.6, and described it in its DCD Section 17.6.

17.6.2 Summary of Application

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

DCD Tier 2: The applicant's DCD Tier 2 description states that the COL applicant is responsible for the establishment and implementation of a MR according to 10 CFR 50.65. It included a COL item for the COL applicant to include in its FSAR a description of the MR program and its implementation.

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

Technical Specifications (TS): There are no TS 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 SRP Section 17.6 and are summarized below. Review interfaces with other SRP sections can also be found in SRP Section 17.6.

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

2. Section 52.79(a)(15) of 10 CFR, 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 the following.

1. NUMARC 93-01, as endorsed by RG 1.160, represents an acceptable approach for implementing a MR program in compliance with 10 CFR 50.65.
2. The staff has endorsed NEI 07-02A as an acceptable template guidance for presenting the MR information in conformance with the acceptance criteria of SRP Section 17.6.

17.6.4 Technical Evaluation

The staff reviewed APR1400 DCD Tier 2 Section 17.6, in accordance with the guidance in SRP Section 17.6, "Maintenance Rule." Per the SRP guidance, the DC applicant is not required to address the requirements of the MR, as this is an operational program not required during the DC stage, and thus no outstanding information is expected to be addressed in the DCD related to this program.

The staff concludes that the plan or process for implementing the MR program is the responsibility of the COL applicant referencing the APR1400 design.

17.6.5 Combined License Information Items

The MR-related COL item established in the APR1400 DCD Tier 2 Section 17.6.1, is shown below.

Table 17.6 Combined License Information Items Identified in the DCD

Item No.	Description	Section
COL 17.6(1)	The COL applicant is to provide in its FSAR a description of the MR program and a plan for implementing it, to meet the requirements of 10 CFR 50.65.	17.6.1

The staff finds that the COL item conforms to the guidance provided in SRP Section 17.6 to have the COL applicant referencing the APR1400 design to provide the description of the MR program and implementation in its FSAR. Therefore, the COL Item 17.6(1) above is acceptable.

17.6.6 Conclusion

As set forth above, the staff has reviewed the DCD Tier 2 Section 17.6, and confirmed that the applicant has fully addressed the information relevant to the MR program. The staff agrees with the DC application that the COL applicant is responsible for developing and implementing the MR program pursuant to the requirements of 10 CFR 52.79(a)(15) and 10 CFR 50.65. Thus, the staff concludes that the MR information presented within DCD Tier 2 Section 17.6, is acceptable.