C.I.17 Quality Assurance and Reliability Assurance

Consistent with the approach taken in the new update to Chapter 17 of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants" (hereafter referred to as the SRP), Sections C.I.17.1, C.I.17.1.1, C.I.17.2, and C.I.17.3 of this chapter point the reader to Section C.I.17.5 for the required format and content of a quality assurance (QA) program during design, construction, and operation.

C.I.17.1 *Quality Assurance During the Design and Construction Phase*

Combined license (COL) applicants should refer to Section C.I.17.5 for a complete discussion of the required format and content of a QA program during design, construction, and operation.

C.I.17.1.1 Early Site Permit Quality Assurance Measures

COL applicants should refer to Section C.I.17.5 for a complete discussion of acceptable format and content of a QA program during design, construction, and operation. This section will identify those aspects of a quality assurance program description (QAPD) associated with early site permits versus other applications, such as design certification and COL.

C.I.17.2 *Quality Assurance During the Operations Phase*

COL applicants should refer to Section C.I.17.5 for a complete discussion of acceptable format and content of a QA program during design, construction, and operation.

C.I.17.3 *Quality Assurance Program Description*

COL applicants should refer to Section C.I.17.5 for a complete discussion of acceptable format and content of a QA program during design, construction, and operation.

C.I.17.4 *Reliability Assurance Program Guidance*

C.I.17.4.1 New Section 17.4 in the Standard Review Plan

The Office of Nuclear Reactor Regulation (NRR) revised the SRP to add the new Section 17.4, "Reliability Assurance Program (RAP)." This new SRP section addresses the Commission's policy for the RAP that is presented in Item E 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 June 28, 1995. Section 17.4 of the SRP is the principal guidance for U.S. Nuclear Regulatory Commission (NRC) reviews of a RAP submitted by a COL applicant.

C.I.17.4.2 Reliability Assurance Program Scope, Stages, and Goals

The RAP applies to those plant structures, systems, and components (SSCs) that are identified as being risk-significant (or significant contributors to plant safety), as determined by using a combination of probabilistic, deterministic, or other methods of analysis, including information obtained from sources such as plant- and site-specific probabilistic risk assessment (PRA), nuclear plant operating experience, relevant component failure databases, and expert panels. The purpose of the RAP is to provide reasonable assurance of the following four considerations:

(1) A reactor is designed, constructed, and operated in a manner that is consistent with the assumptions and risk insights for these risk-significant SSCs.

(2) The risk-significant SSCs do not degrade to an unacceptable level during plant operations.

(3) The frequency of transients that challenge SSCs is minimized.

(4) These SSCs function reliably when challenged.

The RAP is implemented in 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 above, through the reactor design, procurement, fabrication, construction, and preoperational testing activities and programs. The second stage applies to reliability assurance activities for the operations phase of the plant life cycle. The objective during this stage is to ensure that the reliability for the SSCs within the scope of the RAP is maintained during plant operations. Reliability assurance activities are integrated into existing operational programs (e.g., Maintenance Rule, surveillance testing, inservice inspection, inservice testing, and QA). Individual component reliability may change throughout the course of plant life because of a number of factors, including aging and changes in suppliers and technology. Changes in individual component reliability values are acceptable as long as overall plant safety performance is maintained within the licensing basis.

C.I.17.4.3 Reliability Assurance Program Implementation

The RAP is implemented in several phases. The first phase implements the aspects of the program that apply to the reactor design process. The second phase is the site-specific phase, which introduces the plant's site-specific design information to the RAP process. Tier 1 inspection, test, analysis, and acceptance criteria (ITAAC) are required for these phases. The COL applicant establishes the probabilistic, deterministic, and other methods to determine the SSCs under the scope of the RAP and ITAAC. The COL applicant is also responsible for describing how it will integrate reliability assurance activities into existing programs (e.g., Maintenance Rule, surveillance testing, inservice inspection, inservice testing, and QA).

C.I.17.4.4 Reliability Assurance Program Information Needed in a COL Application

The provisions of Title 10, Section 50.34(h) of the *Code of Federal Regulations* (10 CFR 50.34(h)) and 10 CFR 52.79(b) require that COL applicants include an evaluation of the facility against the SRP that is in effect 6 months prior to the docket date of the application of a new facility. A COL applicant should provide the following in Chapter 17 of the safety analysis report in accordance with the provisions in SRP Section 17.4:

- a description of the RAP, including scope, purpose, and objectives
- the deterministic or other methods used for evaluating, identifying, and prioritizing SSCs according to their degree of risk significance (probabilistic/PRA methods and results for evaluating, identifying, and prioritizing SSCs to be addressed in Section C.I.19)
- a prioritized list of SSCs designated as risk-significant based on deterministic or other methods (a prioritized list of SSCs designated as risk-significant based on probabilistic/PRA methods to be addressed in Section C.1.19)
- the quality controls (organization, design control, procedures and instructions, records, corrective action, and audit plans) for developing and implementing the RAP

- how procurement, fabrication, construction, and test specifications for the SSCs within the scope of the RAP ensure that significant assumptions, such as equipment reliability, are realistic and achievable
- how QA requirements are implemented during the procurement, fabrication, construction, and testing of SSCs within the scope of the RAP
- the integration of the RAP into the applicant's existing operational programs (e.g., Maintenance Rule, surveillance testing, inservice testing, inservice inspection, and QA)
- the process for providing corrective action for design and operation errors that degrade nonsafety-related SSCs within the scope of the RAP
- ITAAC for the RAP
- expert panel qualification requirements, if an expert panel is used

If other sections or chapters of the applicant's final safety analysis report (FSAR) provide more detailed information regarding particular aspects of the RAP (e.g., the use of the plant- and site-specific PRA, the methods used in identifying and prioritizing SSCs in accordance with their risk significance), it is acceptable to provide a cross-reference to the specific section or chapter. Describing these aspects of the applicant's RAP in Chapter 17 of the FSAR in accordance with the provisions in SRP Section 17.4 is an acceptable method for meeting the Commission's policy for a RAP in SECY-95-132.

C.I.17.5 *Quality Assurance Program Guidance*

C.I.17.5.1 COL Applicant QA Program Responsibilities

An applicant is responsible for the establishment and implementation of a QA program applicable to activities during design, fabrication, construction, testing, and operation of the nuclear power plant. The content of 10 CFR 50.34, "Contents of Applications; Technical Information" (referenced from 10 CFR 52.79, "Contents of Applications; Technical Information"), describes the minimum QA information that the FSAR must provide.

C.I.17.5.2 Updated SRP Section 17.5 and the QA Program Description

NRR revised the SRP to add the new Section 17.5, "Quality Assurance Program Description—Design Certification, Early Site Permit and New License Applicants." This new SRP section addresses QAPD provisions for COL applicants. NRR reviews and evaluates QAPDs in accordance with the applicable sections of the SRP. Section 17.5 of the SRP is the principal guidance for NRC reviews of a QAPD submitted by a COL applicant. A COL applicant may submit its QAPD in two phases. The first phase could apply to design, fabrication, construction, and testing QA activities, and the second phase could apply to operational QA activities. The requirements for the two phases are fully defined in SRP 17.5. Regardless of the approach, the NRC would review and evaluate QAPDs before issuing the COL. Chapter 17 of the FSAR should incorporate the QAPD (or QAPDs) by reference.

C.I.17.5.3 Evaluation of the QAPD Against the SRP and QAPD Submittal Guidance

COL applicants may use an existing QAPD that the NRC has approved for current use for either or both phases, provided that they identify and justify alternatives to, or differences from, the SRP in effect 6 months prior to the docket date of the application of a new facility.

Chapter 17 of the FSAR should also describe the extent to which the applicant will delegate the work of establishing and implementing the QA program or any part thereof to contractors. The FSAR should clearly delineate those QA functions that are implemented within the applicant's QA organization and those that are delegated to other organizations. The FSAR should describe how the applicant will retain responsibility for, and maintain control over, those portions of the QA program delegated to other organizations. The FSAR should identify the responsible organization and the process for verifying that delegated QA functions are effectively implemented. The FSAR should identify major work interfaces for activities affecting quality and should describe how clear and effective lines of communication between the applicant and its principal contractors are maintained to assure coordination and control of the QA program.

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

For requested information that is not known at the time of COL application, the applicant should explain why it is not known and should estimate when the information will become available.

C.I.17.6.1 Program Procedures

The applicant should describe program procedures for Maintenance Rule implementation in accordance with Nuclear Management and Resources Council (NUMARC) 93-01, "Industry Guidance for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," as endorsed by Regulatory Guide 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," including, but not limited to, the following three areas:

(1) The applicant should explain and justify deviations from the guidance in NUMARC 93-01 and Regulatory Guide 1.160.

(2) While the Maintenance Rule does not require procedures or documentation, the NRC needs this information to obtain reasonable assurance of consistent compliance.

(3) The applicant should include the procedures' status in the procedural hierarchy; whether treated as safety-related or nonsafety-related; level of compliance expected; and responsibility for preparation, review, approval, use, compliance oversight, and disposition. The staff does not desire or require submission of actual procedures or software for review for the COL application.

C.I.17.6.1.1 *Scoping per 10 CFR 50.65(b)*

Applicants should list and provide information on the SSCs within the scope of the proposed Maintenance Rule program to the extent that this information is known at the time of the COL application. For each SSC within scope, provide the following:

(1) Provide specific Maintenance Rule requirements in 10 CFR 50.65(b) that require it to be in scope. Provide data for each subparagraph (i.e., 10 CFR 50.65(b)(1)(I) through 10 CFR 50.65(b)(1)(iii) and 10 CFR 50.65(b)(2)(I) through 10 CFR 50.65 (b)(2)(iii)).

(2) For each SSC, indicate for each applicable paragraph (b) scoping criterion the functions that require the SSC to be in scope.

(3) For each SSC, indicate for each applicable paragraph (b) scoping criterion the failure modes and effects that require the SSC to be in scope, as applicable.

(4) For each SSC scoping function or vulnerability, indicate the functional performance requirements/success criteria and/or functional failure definitions and implications.

C.I.17.6.1.2 *Reactor Safety Significance Classification and Other Factors Considered by the Expert Panel*

Describe the process for safety significance classification (i.e., HSS or LSS) of in-scope SSCs and the bases thereof, including risk metrics/importance measures and values, operating experience, vendor information, and any other factors to be considered by the expert panel.

C.I.17.6.1.3 *Scoping Procedures*

Identify and describe the program procedures and documents (including computer software and data) that prescribe or govern scoping, including the items above.

C.I.17.6.2 Monitoring per 10 CFR 50.65(a) and 10 CFR 50.65(a)(2)

For each SSC, indicate its standby or continuously operating status and associated type (i.e., availability, reliability, or condition) and level (i.e., component, system, pseudosystem, train, or plant) of monitoring/tracking. Describe the process for determining which SSCs' performance or condition will be monitored initially per 10 CFR 50.65(a)(1) and which will be tracked per 10 CFR 50.65(a)(2).

C.I.17.6.3 Periodic Evaluation per 10 CFR 50.65(a)(3)

Identify the plant's refueling cycle. Identify and describe the program procedures and documents (including computer software and data) that prescribe or govern periodic evaluation of the Maintenance Rule program in accordance with 10 CFR 50.65(a)(3). Ensure that this information includes the following four considerations:

(1) using procedures to govern the scheduling and timely performance of 10 CFR 50.65(a)(3) evaluations

(2) documenting, reviewing, and approving evaluations as well as providing and implementing results

(3) making adjustments to achieve or restore balance between reliability and availability

(4) applying industry operating experience, including the following:

C.I.17.6.4 Risk Assessment and Management per 10 CFR 50.65(a)(4)

Identify and describe the program procedures and documents (including computer software and data) that prescribe or govern maintenance risk assessment and management in accordance with 10 CFR 50.65(a)(4), including, but not limited to, the following nine areas:

(1) determination of the scope (or limited scope) of SSCs to be included in 10 CFR 50.65(a)(4) risk assessments

(2) risk assessment and management during work planning

(3) risk assessment and management of emergent conditions and updating risk assessments as maintenance situations and plant conditions and configurations are changed

(4) assessment (quantitative and qualitative capabilities) and management of risk of internal flooding and external events or conditions, including fire (internal, external, and fire-risk-sensitive maintenance activities), severe weather, external flooding, landslides, seismic activity and other natural phenomena, and grid/offsite power reliability for grid-risk-sensitive maintenance

activities (respond to or refer to responses to Maintenance Rule-related questions in NRC Generic Letter2006-02, “Grid Reliability and the Impact on Plant Risk and the Operability of Offsite Power,” dated February 2, 2006)

(5) assessment and management of risk of maintenance activities affecting containment integrity

(6) assessment and management of risk of maintenance activities when at low power or when shut down (including implementation of NUMARC 91-06)

(7) assessment and management of risk associated with the installation of plant modifications and assessment and management of risk associated with temporary modifications in support of maintenance activities (in lieu of screening in accordance with 10 CFR 50.59, “Changes, Tests and Experiments”), in accordance with latest revision of Nuclear Energy Institute (NEI) 96-07, as endorsed by the latest revision of Regulatory Guide 1.187, “Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments”

(8) risk assessment and management associated with risk-informed technical specifications

(9) if known at the time of COL application, the scope and level of the probabilistic risk analysis (e.g., operational modes, Level I or II, internal or external events) and risk assessment tool or process to be used for 10 CFR 50.65(a)(4) risk assessments and its capabilities and limitations (otherwise, this information to be reviewed during inspection)

C.I.17.6.5 Maintenance Rule Training and Qualification

Describe the program, including procedures and documentation, for Maintenance Rule training and qualification consistent with the provisions of Section C.I.13 of this guide as applicable.

C.I.17.6.6 Maintenance Rule Program and Operational Reliability Assurance Program Interface

Describe the relationship and interface between the Maintenance Rule and the Operational Reliability Assurance Program (ORAP) (see Section C.I.17.4), including how functions are coordinated and procedures overlap and/or are cross-referenced. If the Maintenance Rule program SSCs classified as HSS envelop the scope of the ORAP, the Maintenance Rule program is an acceptable method of implementation of the ORAP.

C.I.17.6.7 Maintenance Rule Program Implementation

Describe the plan or process for implementing the Maintenance Rule program as described in the COL application, including sequence and milestones for establishing program elements, and commencing monitoring or tracking of the performance and/or condition of SSCs as they become operational.

C.I.17.7 *References*

Code of Federal Regulations

(1) 10 CFR Part 21, “Reporting of Defects and Noncompliance”

(2) 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities”

(3) 10 CFR Part 52, “Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants”

Regulatory Guidance Documents

(1) NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants"

(2) Review Standard RS-002, "Processing Applications for Early Site Permits"

(3) Regulatory Issue Summary 00-018, "Guidance on Managing Quality Assurance Records in Electronic Media"

(4) Regulatory Guide 1.189, "Fire Protection for Operating Nuclear Power Plants"

(5) Regulatory Guide 1.155, "Station Blackout"

(6) Regulatory Guide 1.26, "Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants"

(7) Regulatory Guide 1.29, "Seismic Design Classification"

(8) Regulatory Guide 1.54, "Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants"

(9) Regulatory Guide 1.97, "Criteria For Accident Monitoring Instrumentation For Nuclear Power Plants"

(10) Regulatory Guide 1.142, "Safety-Related Concrete Structures for Nuclear Power Plants (Other Than Reactor Vessels and Containments)," Revision 2

(11) Regulatory Guide 1.143, "Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants"

(12) Regulatory Guide 1.152, "Criteria for Digital Computers in Safety Systems of Nuclear Power Plants"

(13) Regulatory Guide 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants"

(14) Regulatory Guide 1.168, "Verification, Validation, Reviews, and Audits for Digital Computer Software Uses in Safety Systems of Nuclear Power Plants"

(15) Regulatory Guide 1.169, "Configuration Management Plans for Digital Computer Software Used in Safety Systems of Nuclear Power Plants"

(16) Regulatory Guide 1.170, "Software Test Documentation for Digital Computer Software Used in Safety Systems of Nuclear Power Plants"

(17) Regulatory Guide 1.171, "Software Unit Testing for Digital Computer Software Used in Safety Systems of Nuclear Power Plants"

(18) Regulatory Guide 1.172, "Software Requirements Specifications for Digital Computer Software Used in Safety Systems of Nuclear Power Plants"

(19) Regulatory Guide 1.173, "Developing Software Life Cycle Processes for Digital Computer Software Used in Safety Systems of Nuclear Power Plants"

(20) Regulatory Guide 1.182, "Assessing and Managing Risk Before Maintenance Activities at Nuclear Power Plants"

(21) Regulatory Guide 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities"

(22) Regulatory Guide 4.15, “Quality Assurance for Radiological Monitoring Programs (Normal Operations)—Effluent Streams and the Environment”

(23) Regulatory Guide 7.10, “Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material”

(24) NUMARC 93-01, “Industry Guidance for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants”

(25) Section 11, “Assessment of Risk Resulting from Performance of Maintenance Activities,” of NUMARC 93-01, Revision, February 22, 2000

(26) NUREG-1070, “NRC Policy on Future Reactor Design”

(27) NUREG-1462, “Final Safety Evaluation Report Related to the Certification of the System 80+ Design”

(28) NUREG-1503, “Final Safety Evaluation Report Related to the Certification of the Advanced Boiling Water Reactor Design”

(29) NUREG-1512, “Final Safety Evaluation Report Related to the Certification of the AP600 Standard Design”

(30) NUREG-1793, “Final Safety Evaluation Report Related to the Certification of the AP1000 Standard Design”

(31) NUREG/CR-3385, “Measures of Risk Importance and Their Applications”

Generic Letters

(1) Generic Letter 83-28, “Required Actions Based on Generic Implications of Salem ATWS Events”

(2) Generic Letter 85-06, “Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related”

(3) Generic Letter 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products”

(4) Generic Letter 91-05, “Licensee Commercial-Grade Procurement and Dedication Programs”

(5) Generic Letter 2006-02, “Grid Reliability and the Impact on Plant Risk and the Operability of Offsite Power”

Commission Papers

(1) SECY-89-013, “Design Requirements Related to the Evolutionary Advanced Light-Water Reactors (ALWR)”

(2) SECY-93-087, “Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor Designs”

(3) SECY-94-084, “Policy and Technical Issues Associated with Regulatory Treatment of Non-Safety Systems in Passive Plant Designs” and related Staff Requirements Memorandum

(4) SECY-95-132, “Policy and Technical Issues Associated with Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs”