DG-1145, Section C.I.17 - Quality Assurance and Reliability Assurance

I.17 QUALITY ASSURANCE & RELIABILITY ASSURANCE

Consistent with the approach taken in the new update to Chapter 17 of the Standard Review Plan, Sections I.17.1, I.17.1.1, I.17.2, and I.17.3 of this chapter point the reader to Section I.17.5 for the required format and content of a QA program during design, construction, and operation.

I.17.1 Quality Assurance During the Design and Construction Phase

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

I.17.1.1 Early Site Permit Quality Assurance Measures

COL applicants should refer to Section 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 QAPD associated with Early Site Permits, versus other applications, such as Design Certification and COL.

I.17.2 Quality Assurance during the Operations Phase

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

I.17.3 Quality Assurance Program Description

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

I.17.4 Reliability Assurance Program Guidance

I.17.4.1 Reliability Assurance Program (RAP) Introduction and General Requirements

The scope of the RAP includes risk-significant structures, systems, and components (SSCs), both safety related and nonsafety related SSCs, that provide defense in depth or result in significant improvement in the probabilistic risk assessment (PRA) evaluations. The RAP is implemented in two stages. The first stage, the design RAP (D-RAP), applies to reliability assurance activities that occur before the initial fuel load. The objective of the D-RAP is to design reliability into the plant consistent with the NRC-established PRA safety goals. The second stage, the operational RAP (O-RAP), applies to reliability assurance activities for the operations phase of the plant life cycle. The goal of the combined license (COL) applicant's O-RAP is to maintain reliability consistent with the overall safety goals. Individual component reliability values are expected to change throughout the course of plant life because of 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 NRC-established PRA safety goals and deterministic licensing design basis.

The D-RAP is implemented in several phases. The first phase implements the aspects of the program that apply to the design process. During this phase, risk-significant SSCs are identified

for inclusion in the program by using probabilistic, deterministic, and other methods. The design certification applicant performs this phase. The design certification D-RAP is verified via the inspection process and the NRC safety evaluation review process. The second phase is the site-specific phase, which introduces the plant's site-specific SSCs to the D-RAP process. The COL applicant performs this phase. At this stage, the D-RAP is modified or appended based on considerations specific to the site. The COL applicant establishes the PRA importance measures, the expert panel process, and other deterministic methods to determine and maintain the site specific list of SSCs under the scope of RAP. The COL applicant's D-RAP is verified via the inspection process, the NRC safety evaluation review process, and the D-RAP inspection, test, analysis, and acceptance criteria (ITAAC).

The design certification applicant is also responsible for developing D-RAP ITAAC. The design certification D-RAP ITAAC will be verified by the NRC safety evaluation review process. The COL holder is responsible for completing the D-RAP ITAAC. Satisfactory completion of the D-RAP ITAAC is verified by IP 65001, "ITAAC Matrix Inspections."

The COL applicant is responsible for developing and implementing the O-RAP which is an operational program. The applicant's O-RAP is verified via the inspection process, the NRC safety evaluation review process, and the licensing condition process.

The following is intended to provide guidance to applicants. Except in those cases in which the applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the methods described herein will be used by the staff in its evaluation of conformance with Commission regulations.

The provisions of this SRP section apply to reviews of COL applications under 10 CFR Part 52 docketed 6 months or more after the date of issuance of this SRP section.

Any exceptions or alternatives to this SRP section will be reviewed to ensure that they are defined and that an adequate basis exists for their acceptance. When required, the staff will prepare a request for additional information for the applicant and review the response for acceptability.

I.17.4.2 Staff Review of the RAP at COL Application Phase

The following is provided to give the COL applicant insight into staff focus areas during review of the COL application:

1. The staff reviews the process used by the applicant for identifying site-specific risk-significant SSCs and determines if the applicant has properly identified the site-specific risk-significant SSCs.

2. The staff reviews and inspects the applicant's QA controls for developing and implementing the D-RAP.

3. The staff reviews the D-RAP (scope, purpose, objectives, and essential elements).

4. The reviews the O-RAP (scope, purpose, objectives, and essential elements) .

5. The staff's overall acceptance criteria is that the RAP is fully described the COL applicant's Final Safety Analysis Report (FSAR).

I.17.4.3 COL Applicant RAP Information Requirements

The COL applicant should include the following information in the FSAR submittal. The COL applicant should focus information on the site-specific risk-significant SSCs:

I.17.4.3.1 The scope, purpose, objectives and essential elements of the D-RAP.

I.17.4.3.2 A description of the process for identifying and prioritizing SSCs based on risk significance. The description should address the following:

a. The dominant failure modes should be identified and prioritized.

b. Identify the effects associated with those failure modes and subsequent component failure prevention or mitigation.

c. The role industry experience, analytical models, and expert panel contributed in categorizing the safety significance of SSCs.

d. The key assumptions and determinations of risk significance that are derived from probabilistic, deterministic, or other methods that consider operations, maintenance, and monitoring activities for identifying component reliability and failure data.

e. The expert panel qualifications in the areas of personnel knowledgeable in the systems, operations, and maintenance of a plant, and experience necessary to perform the SSC selections.

f. The applicant's use of a combination of PRA importance measures for RAW[1], and RRW[2] or FVI[3].

I.17.4.3.3 A description of the operating experience used to define the significant failure modes and their likely causes and reliability. For example, reliability analyses can be performed using common databases from industry sources such as Institute of Nuclear Power Operations and the Electrical Power Research Institute.

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[1]RAW is the increase in risk if the SSC is assumed to be failed for all failure modes (e.g., failure to start, failure to run). See NUREG/CR-3385 for additional details.

[2]RRW is the decrease in risk if the SSC is assumed to be perfectly reliable for all failure modes (e.g., failure to start, failure to run). See NUREG/CR-3385 for additional details.

[3]FVI is related to RRW on a ratio scale. See NUREG/CR-3385 for additional details.

I.17.4.3.4 The applicant should describe the controls for the RAP. The description should address the following:

a. The organization responsible for formulating and implementing the RAP.

b. The management staff responsible for the design and licensing.

c. The coordination of program activities, including those performed within the design organization as well as work completed by the architect-engineers and other supporting organizations.

d. The risk and reliability organization within the design organization responsible for developing the RAP and access to the design staff.

e. The interface between the risk and reliability organization and the design organization for determining that the performance of risk-significant SSCs relate to the reliability assumptions in the PRA.

(1) How the reliability organization and the design organization manage interface issues.

(2) The risk and reliability organization methods for keeping the design staff cognizant of risk-significant items, program needs, and status.

(3) The risk and reliability organization participation in the design change control process for the purpose of providing RAP related inputs in the design process.

(4) The risk and reliability organization involvement in design reviews.

f. Engineering controls applied for determining SSCs within the scope of the RAP.

g. How procurement and fabrication specifications reflect the reliability values assumed in the PRA.

h. Procedural controls applied to the D-RAP program.

i. Storage and retrieval controls applied to documentation of the RAP program.

j. Corrective action controls applied to RAP SSCs.

k. The process for proposing an alternative design to improve performance in either area. For example, is the revised design reviewed to provide confidence that the current assumptions in the other areas are not violated. When a potential conflict exists between safety goals and other goals, do safety goals take precedence?

l. The proposed design feedback process used to ensure that the design

organization determines that significant design assumptions related to equipment reliability and unavailability are realistic and achievable. Does the design feedback process include the methodology used to consider industry experience, analytical models, and existing requirements for the PRA dominant failure modes?

m. QA requirements implemented during the procurement, fabrication, installation, construction, and testing of risk-significant SSCs.

I.17.4.3.5 A D-RAP ITAAC that provides reasonable assurance that the design of risk-significant SSCs is consistent with their risk analysis assumption. The ITAAC acceptance criteria should ensure that the estimated reliability of each as-built risk-significant SSC is at least equal to the assumed design reliability and that industry experience including operations, maintenance, and monitoring activities were assessed in estimating the reliability of these SSCs.

I.17.4.3.6 Any design and operational information to be used by the COL applicant for plant reliability assurance activities. This information may include possible failure modes and suggestions for failure prevention or mitigation.

I.17.4.3.7 A description of how the O-RAP is integrated into existing programs (e.g., maintenance, surveillance testing, inservice inspection, inservice testing, and QA). The description should address the following:

a. How reliability performance goals for risk-significant SSCs would be established consistent with the existing maintenance and QA processes on the basis of information from the D-RAP.

b. Performance and condition monitoring requirements that provide reasonable assurance that risk-significant SSCs do not degrade to an unacceptable level during plant operation. Implementation of the maintenance rule following the guidance contained in Regulatory Guide 1.160, “Monitoring the Effectiveness of Maintenance at Nuclear Power Plants,” meets the objective of reliability assurance for monitoring and correcting degradation in SSC reliability or availability.

c. The feedback mechanism for periodically reevaluating risk significance on the basis of actual equipment, train, or system performance. (The reliability performance monitoring does not need to statistically verify the numerical values used in the PRA. However, it provides a feedback mechanism for periodically reevaluating risk significance on the basis of actual equipment, train, or system performance.)

d. Any reliability assurance activities incorporated into the maintenance rule, 10 CFR 50.65, the QA, surveillance, inservice inspection, inservice testing, and technical specification allowable outage time programs.

I.17.4.3.8 The administrative processes and procedures for providing corrective actions for

design and operational errors that degrade nonsafety-related, risk-significant SSCs.

I.17.4.3.9 Any maintenance assessments or recommendations for risk-significant SSCs to enhance reliability.

I.17.4.3.10 A licensing condition stating that the O-RAP will be fully implemented prior to loading fuel.

I.17.4.4 NonSafety Systems

Regulatory Treatment of Non-Safety Systems (RTNSS) is a program for nonsafety related SSCs that are important to safety and covers passive plant designs, such as the Westinghouse AP1000. Combined license (COL) applicants should refer to the guidance on nonsafety systems that are safety significant, found in paragraph "Y" of Section 17.5.3 of this chapter.

I.17.5 QUALITY ASSURANCE PROGRAM GUIDANCE

I.17.5.1 Introduction and General Requirements

An applicant is responsible for the establishment and execution of a quality assurance (QA) program applicable to activities during design, construction, pre-operational testing, and operation of the nuclear power plant. An applicant's QA program is executed through a hierarchy of written policies, procedures and instructions. The QA program must be established at the earliest practical time consistent with the schedule for accomplishing an activity. The quality assurance program description (QAPD) should be included in Chapter 17 of the Safety Analysis Report (SAR) or, alternately, as a topical report incorporated by reference in the SAR.

The quality assurance program description is submitted in accordance with the provisions of 10 CFR 50.34 (referenced from 10 CFR 52.79). The program must meet the requirements of Appendix B to 10 CFR Part 50. Although the format of the program description is left to the discretion of the applicant, each of the Appendix B criteria must be addressed in sufficient detail to enable the reviewer to determine whether and how each criteria is satisfied in accordance with 10 CFR 50.34 and the bases documents of SRP Section 17.5. The inspection and survey systems required by §50.55a, "Codes and Standards," of 10 CFR Part 50 may be used in partial fulfillment of these requirements to the extent that they are shown by the description of the QA program to satisfy the applicable Appendix B requirements.

The submittal should describe a comprehensive quality assurance program applicable to design, construction, and operation. For multi-unit sites, the COL applicant should describe the organizational arrangement and functions to meet the needs of the multiple units. The discussion should include the extent to which the arrangement and functions are shared and a descriptions of the divisions and/or controls established to preserve the integrity of individual units and programs.

The objectives of pre-application QA interactions with the NRC are similar to those called for in ESP Inspection Manual Chapter 2501, and those identified in Inspection Procedure 35002-01, Early QA Meeting. Although NRC regulations do not require submittal of a QAPD in a pre-COL application, it is recommended that applicants resolve design and construction QA issues in a

pre-application time frame. Operational QA issues could be deferred to the COL application.

> NOTE: SRP Section 17.5 will be the principle guidance for NRC reviews of QAPD's submitted by applicants. SRP Sections 17.1, 17.2, and 17.3 will not be updated or used by NRC reviewers for new plants.

SRP Section 17.5 describes a standard QA program for DC, ESP, CP, OL, and COL applicants and holders. SRP Section 17.5 is based on ASME Standard NQA-1 (1994 Edition); Regulatory Guide (RG) 1.8, "Qualification and Training of Personnel for Nuclear Power Plants," Revision 3; RG 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3; RG 1.33, "Quality Assurance Program Requirements (Operation)," Revision 2; and NRC Review Standard (RS)-002, "Processing Applications for Early Site Permits."

> NOTE: DC, ESP, and COL applicants are identified as an "applicant"; COL holders are identified as a "holder" throughout this chapter of the regulatory guide.

A QAPD submitted by an ESP applicant applies to site suitability activities and would be reviewed and evaluated by the NRC prior issuing the ESP.

A QAPD submitted by a DC applicant addresses design QA in support of a DC; it would not address activities that occur subsequent to the beginning of construction. The NRC would evaluate the QAPD submitted by the DC applicant prior to approval of the DC.

A QAPD submitted by a COL applicant applies to all phases of a facility's life, including design, construction, and operation. COL applicants referencing a DC must address the COL items identified in Chapter 17 of the referenced generic DCD. A QAPD may be submitted in two phases, the first phase to cover construction QA activities and the second to cover operational QA activities. Where portions of the operational QA program have not been established at the time the SAR is prepared, the description should provide a schedule for implementation and a description of the transition process from the design/construction QA program to the operational QA program. The NRC would evaluate the QAPD for the construction phase prior to issuing the COL; the NRC would evaluate the QAPD for the operational phase prior to authorizing initial fuel loading.

The applicant's QA program(s) should incorporate the most recently NRC-endorsed QA standards. If an applicant chooses not to follow the standardized regulatory guidance in this section, the QAPD should describe specific alternative methods to be used, how these alternatives would be implemented, and the organizations responsible for their implementation. If an applicant elects to propose and justify using the existing QA program for its operating "fleet," QA controls applicable to construction activities must be addressed

Where a QAPD commits to follow the guidance of a regulatory guide, the QAPD should address how the guidance would be applied, the extent of applicability, and the organizational elements responsible for implementing this guidance. The organizational elements should identify those of the applicant, the architect-engineer, the nuclear steam system supplier, the constructor, and the construction manager (if other than the constructor).

If the station incorporates, or plans to incorporate, other nuclear or nonnuclear power

generating facilities, interfaces with the other facilties should be described. The description should include any planned sharing of personnel, a description of their duties, and the proportion of their time expected to be assigned to other units.

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

I.17.5.1.1 General Requirements for QAPD Information to be Provided:

Provide information on the controls to be used for the nuclear power plant, to include a discussion on how the applicable requirements of Appendix B will be satisfied for all phases of a facility's life, including design, construction, operation, and modification. Describe how each of the acceptance criteria is met.

Include an evaluation of the facility against the SRP in effect 6 months prior to the docket date of the application of a new facility. Alternatives to or differences from the SRP must be identified and justified in the application.

Provide a description of the QA program for the design, fabrication, construction, and testing of the structures, systems, and components (SSCs) important to safety.

Provide a description of the controls established to ensure reporting of defects or failures that are determined to be substantial safety hazards. Describe how reportable defects or noncompliances are identified, evaluated, and reported under the 10 CFR Part 50, Appendix B, QA program and how the requirements of 10 CFR Part 21 and 10 CFR 50.55(e) are established to ensure that substantial safety hazards are 1) evaluated, 2) subject to proper corrective action, and 3) identified to the NRC so it can evaluate the adequacy of corrective actions and consider any generic implications.

Provide a description of the controls established to ensure compliance with 10 CFR 50.55a requirements that SSCs be designated, fabricated, erected, constructed, tested, and inspected to quality standards commensurate with the importance of the safety function to be performed.

Provide a description of the controls established to ensure the requirements of 10 CFR 50.34(f)(3)(ii) and (iii) are met, so that:

1) all SSCs important to safety are listed in accordance with Criterion II of Appendix B to 10 CFR Part 50,

2) independence exists between organizations performing checking functions and

those responsible for performing the function,

3) QA is implemented during construction,

4) QA personnel are included in the documented review and concurrence in quality-related procedures,

5) QA personnel are qualified,

6) sizing of the staff is commensurate with its duties and responsibilities,

7) procedures are established for maintenance of as-built documentation,

8) QA maintains a role in design and analysis activities,

9) criteria are established for QA programmatic requirements.

I.17.5.2 Organization of Section I.17.5.3

Section I.17.5.3 of this chapter is organized into the 26 areas (A through Z) listed below. Sections A through X apply to SSCs. Section Y applies only to nonsafety-related SSCs. Sections A through Y apply to COL applicants and COL holders. Section Z applies only to holders of a COL (operational phase). Areas not applicable to DC and ESP applicants are annotated as such in Section 17.5.

A. ORGANIZATION

B. QUALITY ASSURANCE PROGRAM

C. DESIGN CONTROL AND VERIFICATION

D. PROCUREMENT DOCUMENT CONTROL

E. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

F. DOCUMENT CONTROL

G. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

H. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

I. CONTROL OF SPECIAL PROCESSES

J. INSPECTION

K. TEST CONTROL

L. CONTROL OF MEASURING AND TEST EQUIPMENT

M. HANDLING, STORAGE, AND SHIPPING

N. INSPECTION, TEST, AND OPERATING STATUS

O. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

P. CORRECTIVE ACTION

Q. RECORDS

R. AUDITS

S. TRAINING AND QUALIFICATION CRITERIA - QUALITY ASSURANCE (QA)

T. TRAINING AND QUALIFICATION - INSPECTION AND TEST

U. QA PROGRAM COMMITMENTS

V. 10 CFR PART 21 AND 10 CFR 50.55(e) PROGRAMS FOR REPORTING DEFECTS AND NONCOMPLIANCE

W. COMMERCIAL GRADE DEDICATION

X. DIGITAL EQUIPMENT SOFTWARE VERIFICATION AND VALIDATION QUALITY CONTROLS

Y. NONSAFETY-RELATED SSC QUALITY CONTROLS

Z. INDEPENDENT REVIEW

I.17.5.3.A. ORGANIZATION

Provide a written QAPD, issued at the most senior management level, that establishes the quality policy, commits the organization to implement it, and contains information meeting all the detailed requirements of SRP Section 17.5, including:

- A description of requirements that work is accomplished only by personnel qualified in accordance with written procedures, and that implementing procedures are reviewed and approved by the managers responsible for their implementation.

- An organizational description that addresses the organizational structure, functional responsibilities, levels of authority, interfaces and associated responsibilities, for all elements that function under the cognizance of the QA program. (Onsite/offsite, operational, and maintenance organizational elements are not applicable to DC applicants.)
- A description of controls to ensure there is independence between persons and organizations performing activities and those executing verification and audit activities.

- A description of a management position with sufficient authority and organizational freedom to implement the QA program without undue influence from cost and schedule considerations and refer appropriate matters to the top management in a timely manner.

- A description of QA program responsibility and authority to stop unsatisfactory work and control further processing, delivery, installation, or use of

nonconforming items.

- A description of controls to assure proper delegation of responsibility and authority to carry out delegated portions of the program, while retaining licensee responsibility for the program.

I.17.5.3.B. QUALITY ASSURANCE PROGRAM

Provide information in the QAPD that describes the applicant's Quality Assurance Program, including:

- A description of requirements for regular management, QA program participant, and senior management status and adequacy reviews of the QA program.
- A description of the criteria used to identify the items and activities to which the QA program applies, and a list of the SSCs and/or activities under the control of the QA program.
- A description of the requirements for documenting the QA program through written policies, procedures, or instructions
- A description of requirements for ensuring personnel are trained and resources provided before commencing any activity within the scope of the QA program.
- A description of requirements for applicant/holder responsibility for the scope and implementation of an effective QA program and its binding applicability, even to management personnel responsible for costs and schedules.

Provide a commitment that documentation of QA program criteria, applicable SSCs and all activities controlled by the QA program will be established and maintained at the applicant or holder's facility.

I.17.5.3.C. DESIGN CONTROL AND VERIFICATION

Provide a description of the design control program that meets the requirements of SRP Section 17.5.C, including:

- Description of a program with provisions to correctly control design inputs, processes, outputs, changes, interfaces, records, organizational interfaces and documentation of design and design verifications.
- Description of requirements ensuring the final design (approved design output documents and approved changes) identifies the assemblies and/or components that are part of the item being designed.
- Description of design process controls that ensure items and activities are selected and independently verified to ensure they are suitable for their intended application, changes are subject to control measures commensurate with those

applied to the original design, and design information transmitted across interfaces is documented and effectively controlled.

- Description of controls for adequacy of design records, documentation of design inputs, sources and design analyses, design analysis computer programs, design calculations, and the legibility, reproducibility, storage and retrievability of design documents.
- Description of the means by which applicable information derived from experience, as set forth in reports or other documentation, is made available to cognizant design personnel.
- Description of the role of quality assurance in design and analysis activities
- Description of the measures established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the SSCs.
- Description of the controls used to conduct design verification, including requirements for sufficiently detailed documentation relating design inputs to design output products to allow verification, clear identification of the design verifier.
- Description of requirements for documentation of verification methods used, use of alternate calculations to verify appropriateness of inputs, assumptions, calculation methods, and/or computer programs.
- Description of the types of questions used in design verification, including questions verifying:
    - Selection of design inputs
    - Description of assumptions necessary for the design activity
    - Appropriateness of design method(s)
    - Correct incorporation of design inputs
    - Documented specification of design inputs and verification requirements for interfacing organizations
    - Correct verification method(s)
    - Identification of appropriate acceptance criteria, including tolerances
- Description of controls used when design adequacy is verified by qualification tests, including requirements for identification of tests, test conditions, design features tested, documentation of test results, any modifications required as a

result of testing, retests, and model/mockup scaling, verification and error analysis in models/mockups

- Description of controls for assuring completion of verification prior to use of designs, especially prior to irrevocable use, independence of verifier from designer, verification of changes to design, including analysis of effects of changes, and verification of applicability of standardized or previously approved design, with respect to meeting pertinent design inputs, prior to each subsequent application of a design.

I.17.5.3.D. PROCUREMENT DOCUMENT CONTROL

Provide a description of the procurement document control program, including:

- Description of controls to assure applicable technical, regulatory, administrative, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21, “Reporting of Defects and Noncompliance,” and 10 CFR 50.55(e)) are invoked for procurement of items and services.

- Description of the controls to assure procurement documents contain the appropriate information, including administrative items such as submission date as well as:

  - Scope of work statement

  - Specification of technical requirements and description of items or services to be furnished

  - Identification of test, inspection and acceptance requirements for monitoring supplier performance

  - Identification of the supplier’s QA program

  - Access to supplier facilities and records

  - Requirements for documentation submission and reporting of defects and noncompliances

- Description of controls applied to changes to procurement documents, including changes resulting from bid evaluation, negotiations or other actions, and appropriate review of those changes by qualified personnel.

I.17.5.3.E. INSTRUCTIONS, PROCEDURES, AND DRAWINGS (CONTROLLED DOCUMENTS)

Provide a description of controls to assure activities affecting quality are prescribed by and accomplished in accordance with documented instructions, procedures, or drawings, under

suitably controlled conditions.

Provide a description of controls to assure instructions, procedures, and drawings include appropriate quantitative or qualitative acceptance criteria for determining satisfactory completion of the given activity.

I.17.5.3.F. DOCUMENT CONTROL

Describe the program established to control the development, review, approval, issue, use, and revision of documents. Include in the description the following:

- Describe controls to assure the scope of the document control program is defined.
- Describe controls for adequate review and approval of revisions to controlled documents by a knowledgeable, qualified organization, including controls to assure access to pertinent background data or information necessary for approval.
- Describe controls to identify, prepare, review, approve, distribute, and require the use of new and revised controlled copies of instructions and procedural documents and to control superseded documents.
- Describe the means used to ensure controlled documents are adequate, complete and correct prior to distribution and use, including controls to ensure QA review and concurrence on procedures for use on safety related SSCs.
- Describe the requirements for frequency of periodic reviews, or the controls applied if procedure/document reviews will not be done on a periodic (i.e., every 2 year) basis. Include a description of the criteria and measures to ensure changes, revisions and temporary changes receive the appropriate levels of review by knowledgeable personnel. Include a description of controls for processing minor changes not requiring the same levels of review and approval.
- Describe control measures to prevent use of outdated or inappropriate documents, including:

  a. identifying the proper document to be used in performing the activity
  b. coordinating and controlling interface documents
  c. ascertaining that proper documents are being used

- Describe provisions for systematic review and feedback for improvement of procedures in current use.

I.17.5.3.G. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

Provide a description of the quality assurance program established to ensure that purchased items and services, including spare and replacement parts, are of acceptable quality, and are

suitable for their intended purpose. Include in this description the following:

- Describe the provisions for evaluation, selection, and means to assured continued acceptability of qualified suppliers and the products and services they provide.

- Describe provisions for accepting purchased items and services, and for verifying procurement, inspection, and applicable test requirements have been satisfied before using or placing a procured item in service.

- Describe the documentation of procurement activities, demonstrating a systematic approach to the procurement process, identification of procurement methods, and organizational responsibilities. Include a description of the measures used to evaluate and select procurement sources and document the results from these activities.

- Describe the established measures to interface with the supplier and to verify the supplier's performance, including measures to assure clear understanding of purchase order requirements, exchange documented information, evaluate and process changes, modifications and exceptions, conduct document reviews, verifications, surveillance activities and inspections at supplier premises, add or modify design criteria, and firmly establish supplier responsibility for achieving quality requirements.

In cases involving procurement of services only, describe the methods used to accept services from suppliers.

- Describe the controls, requirements, and organizational processes established for reporting, documenting, processing, reviewing, approving and/or correcting supplier nonconformances, including nonconforming items.

- Describe methods used to accept an item or related service from a supplier, and to verify the quality of a product or service. Include in the description the criteria and information that are included in the documentation (e.g., certificates of compliance and conformance, receipt inspection and or test documents) associated with acceptance and verification.

- Describe controls to assure that program requirements apply and are extended to all phases of procurement and levels of suppliers. Include in the description the reviews of procurement documents and changes to them to ensure that documents transmitted to the prospective supplier(s) include appropriate provisions for ensuring that items or services will meet the specified requirements.

- Describe the criteria for use, the processes and controls applied to the means for assuring purchase requirements are met, including surveillance, source verification, receipt inspection, and post-installation testing.

I.17.5.3.H. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

- Describe the controls, methods, and documentation used to assure that items (consumables, items with limited shelf life, materials, parts, and components, including partially fabricated assemblies) are clearly identified, traceable to manufacturing documentation and specifications, and controlled from initial receipt and fabrication up to and including installation and use, to prevent the use of incorrect or defective items. Include a description of provisions to ensure identification of items is consistent with the planned duration and conditions of storage.

I.17.5.3.I CONTROL OF SPECIAL PROCESSES

- Describe the program established to ensure special processes, such as welding, heat treating, and nondestructive examination are properly controlled. Include a description of the criteria used to classify a process as special, the controls for performance of special processes by only properly trained and qualified personnel, and the applicable controls for records and documentation, use of procedures, drawings, instructions, checklists and adherence to applicable codes and standards.

I.17.5.3.J. INSPECTION

Provide a description of controls for an inspection program (source, in-process, final, receipt, maintenance, modification, inservice, and operations). Include in the description the following:

- A description of inspection planning and details required for inspection plans.
- A description of controls for hold points, documentation of inspection results, and action in response to nonconformances.
- A description of controls for inspection records and the information required in inspection records.
- A description of controls for independence of inspectors, activities requiring the use of qualified inspection personnel, management review, and use of instructions, procedures and drawings to control inspections and their results.
- A description of controls for inspection requirements and acceptance criteria.
- A description of controls for inspection and test in light of modifications, repairs, and replacements performed subsequent to the final inspection.

I.17.5.3.K. TEST CONTROL

Describe the test control program for demonstrating that items will perform satisfactorily in service, including:

- A description of controls establishing when tests are required and qualification requirements for test personnel.

- A description of the different types of tests and test procedure structure and controls, including a description of test prerequisites, test conditions, acceptance criteria, mandatory hold points, data gathering, and test equipment requirements.

- A description of controls for documentation and evaluation of test results, including the kinds of information required to be documented in test records.

I.17.5.3.L. CONTROL OF MEASURING AND TEST EQUIPMENT

Describe the measuring and test equipment control program for the calibration, maintenance, and use of measuring and test equipment, including:

- A description of the types of equipment covered by the program and the controls for periodic or pre/post-use calibration of test equipment, including the criteria on which calibration frequency is based.

- A description of controls for use of test equipment, including identification and marking for control of calibration status to prevent use of faulty test equipment and controls for traceability to calibration test data, secondary standards, and applicable nationally recognized (National Institute of Standards and Technology) standards.

- A description of controls for handling and evaluation of test equipment found to be out of calibration and evaluation of the acceptability of SSCs on which the out-of-calibration test equipment had been used.

- A description of controls for calibration procedures including documentation of and checks for test equipment accuracy and tolerances.

- A description of controls for calibration records, including the calibration status of measuring and test equipment.

I.17.5.3.M. HANDLING, STORAGE, AND SHIPPING (NOT APPLICABLE TO DC APPLICANTS)

Provide a description of controls established for package marking and labeling, handling and storage of items to assure adequate identification, maintenance and preservation of items, including:

- A description of controls for items requiring special environments or need for other special controls.

- A description of requirements and controls for special protective measures.

- A description of controls and requirements for development and use of special

procedures for cleaning, handling, storage, packaging, shipping, and receiving.

I.17.5.3.N. INSPECTION, TEST, AND OPERATING STATUS (NOT APPLICABLE TO DC AND ESP APPLICANTS)

Provide a description of the controls for inspection, test, and operating status of items to preclude inadvertent bypassing of inspections and tests and to prevent inadvertent operation, including:

- A description of controls for the application and removal of status indicators and labels for SSCs in the nuclear power plant, including procedures for authority to apply and remove tags, markings, labels, and stamps.
- A description of controls and procedures for independent verification of equipment status controls.
- A description of controls, including procedures and record keeping requirements for installation, removal, independent verification, and status control of temporary modifications.

I.17.5.3.O. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

Provide a description of the controls for nonconforming materials, parts, or components to prevent their inadvertent test, installation, or use, including:

- A description of the controls established to review nonconforming items and disposition them as accepted, rejected, repaired, or reworked, including control of the process by documented procedures, disposition approval by authorized personnel, and documentation of the disposition with appropriate technical justification(s).
- A description of the controls that ensure the design control measures applied to the original design are also applied to design nonconformances that are dispositioned “use-as-is” or “repair,”including the controls for updating applicable records and as-built documentation.

I.17.5.3.P. CORRECTIVE ACTION

Provide a description of the controls for the corrective action (problem identification and resolution) process, including:

- A description of specific responsibilities for executing the program, including the defined responsibilities of performance and verification personnel and the applicant/holder’s retention of overall responsibility for program effectiveness, even when particular responsibilities are delegated.
- A description of the measures in place to foster/encourage timely and accurate identification of all conditions adverse to quality, including the failure to follow

procedures, without fear of negative reaction.

- A description of controls for ensuring conditions adverse to quality are promptly identified, documented, classified, analyzed for cause, corrected and followed up.

- A description of controls for ensuring root causes of significant conditions adverse to quality are determined and eliminated to prevent recurrence, and for ensuring subsequent corrective actions do not nullify prior corrective and preventive actions.

- A description of measures to identify, analyze, and report to appropriate levels of management any adverse trends and significant conditions adverse to quality.

- A description of the controls to assure appropriate response to nonconforming parts issues, design, and design process issues requiring significant design changes.

- A description of the controls to ensure competency, knowledge, and access to pertinent information of personnel involved in the corrective action process, including and especially those assigned to evaluate and determine corrective action/disposition of nonconformances.

I.17.5.3.Q. RECORDS

Provide a description of a records program that ensures adequate documentation of completed work by requiring storage of appropriate records of items and activities, including:

- A description of the procedures, instructions, and other documentation that define, implement, and enforce the records system(s).

- A description of the controls for generation, distribution, use, maintenance, storage and disposition of electronic media. Include a description of the means used to ensure the records are defect free and the implementation of Generic Letter 88-18, “Plant Record Storage on Optical Disks.”

- A description of the controls for the administration, receipt, storage, preservation, transmittal, location, maintenance, distribution, safekeeping, retrieval, and disposition of records, including measures to ensure electronic records are retrievable in human-readable format and are secure and protected, and measures to ensure records are examined for adequacy, legibility, and completeness.

- A description of the required content and controls for design documentation and records, and inspection and test records.

- A description of the training provided to individuals or organizations in charge of electronic records generation, data/media storage, implementation of security measures, migration/regeneration, and recovery.

- A description of the controls to assure that design specifications, test and operational procedures, procurement and other documents specify the records generated, supplied, or maintained.

- A description of the measures taken to identify/certify documents as valid records, classify and appropriately handle records, including electronic records, as lifetime or nonpermanent, and to assure indexing system(s) provide sufficient information to permit identification between the record and the item(s) or activity(ies) to which they apply.

- A description of the controls and retention periods imposed for programmatic and for product nonpermanent records.

- A description of the controls for implementation of electronic record migration/regeneration for electronic records which have standard life expectancies that cannot meet the required retention period.

- A description of the cleanliness, environmental condition, and other storage controls implemented for electronic records.

- A description of the personnel responsibilities, requirements, and other controls implemented for correction of records, including electronic records.

- A description of the personnel responsibilities, requirements, and other controls for implementation of a records receipt control system that assures records are protected and inventoried, and for electronic records, assures an inventory of system applications, record formats, and programs required to process and retrieve electronic records is maintained.

- A description of the controls for training and qualification records.

- A description of the records system audit/inspection process, including the process requirements to ensure electronic records retrievability, integrity, and retention period.

I.17.5.3.R. AUDITS

Provide a description of the responsibilities, procedural requirements, and other controls implementing the audit system, including:

- A description of measures taken to assure personnel responsible for carrying out the audit function, including safety committee activities, audits, and other independent assessments, are cognizant of day-to-day activities so that they can act in a management advisory function.

- A description of the priorities, orientation, and results focus for organizations with responsibilities for independent audit and oversight.

- A description of the controls for use of procedures and qualified personnel in the conduct of the audit function, and the measures to assure access to appropriate levels of management to achieve responsive corrective and preventive action.

- A description of the outside/offsite audit of the individual or organization responsible for verifying QA program implementation activities (not applicable to DC applicants).

- A description of the system of planned and periodic audits, including a discussion of frequency and schedule that assures all elements of an organization's QA program are audited within a 2-year period. Include a description of the minimum scope and focus of audits to assure assessment of the compliance and effectiveness of audited elements of the organization's QA program and of program functions/activities delegated to others, and to demonstrate that audits provide a comprehensive, independent evaluation of activities and procedures.

- A description of the organization's audit planning functions and contents of audit plans.

- A description of QA organization and the audited organization responsibilities, required actions and process steps upon completion of an audit, including the documentation, management review, response to and follow-up of audit results.

- A description of the organization's system for procurement audits to assure the applicable requirements of 10 CFR Part 50, Appendix B, are applied to suppliers of parts, services, software and other products falling under the program. Include a description of exceptions to audit requirements, frequency of audits and criteria/circumstances that would require additional audits, use of third party audits, audit scope, audit report content and documentation requirements, and the scope of documented periodic (annual) evaluations of suppliers.

- A description of QA audit report content, signature, and issuance requirements, and associated process steps.

- A description of the process for periodic records systems audits.

I.17.5.3.S. TRAINING AND QUALIFICATION CRITERIA - QUALITY ASSURANCE

Provide a description of Quality Assurance (QA) training programs and qualification criteria for individuals holding responsibilities for execution and management of the QA program, including:

- A description of the criteria, content, and scope of training programs to ensure that QA personnel achieve and maintain suitable proficiency.

- A description of the education and qualification requirements for the individual assigned to manage the QA program.

- A description of the qualification requirements for individuals responsible for planning, implementing, and maintaining the QA plan, and for lead auditors.

- A description of the requirements, minimum content, and approval of qualification records, and the process for establishing and maintaining the system of records of personnel qualifications for auditors and lead auditors performing audits.

I.17.5.3.T. TRAINING AND QUALIFICATION - INSPECTION AND TEST

Provide a description of the system of requirements, process, and documented procedures for qualification, performance review, and qualification re-evaluation of personnel who perform inspection and test activities, including:

- A description of the education and experience requirements for qualification of Level I, II, and III test and inspection personnel.

- A description of requirements for direct observation and supervision of persons in on-the-job training for qualification as an inspection and test person.

I.17.5.3.U. QA PROGRAM COMMITMENTS

Provide a documented list and description of QA program commitments, including the list of regulatory guides and standards, and their appropriate revision, to which the applicant/holder is committed, consistent with the requirements of SRP Section 17.5.

Note any exceptions or alternatives to the specific criteria in any of these RGs being proposed, and provide adequate justification for these exceptions or alternatives.

I.17.5.3.V. 10 CFR PART 21 AND 10 CFR 50.55(e) PROGRAMS

> NOTE: DC, COL, and ESP applicants are subject to the requirements of 10 CFR Part 21, which address the reporting of defects and noncompliances. Prior to fuel load authorization, COL applicants and holders are subject to the requirements of 10 CFR 50.55(e). However, once the Commission has authorized the loading of fuel, COL holders are subject to the requirements of 10 CFR Part 21.

Provide a description of the program for implementing the requirements of 10 CFR Part 21 AND 10 CFR 50.55(e), including identification, documentation and preliminary evaluation of all non-conforming conditions for "discovery" as defined in 21.3, i.e., to determine whether they should be evaluated under 21.21(a)(1).

- Specifically, describe how the program or process for identification of non-conforming materials, parts or components, under Criterion XV of Appendix B to 10 CFR Part 50, or conditions or significant conditions adverse to quality under Criterion XVI, ensures that nonconformances or conditions are screened for evaluation under Part 21 or 50.55(e), as applicable.
- Describe how the screening process for discovery prior to 21.21(a)(1) evaluation considers:

(1) whether they involve anything that is a basic component in the facility or anything that is to be delivered or offered for use at an NRC-licensed facility as a basic component,
(2) whether the nonconformance constitutes a deviation or failure to comply (with the potential for creating a substantial safety hazard), and
(3) whether any affected goods or services are installed and/or in use and/or have been delivered or offered for use, such that if not, the problem could be corrected before their being delivered or offered for use.

Provide descriptions of the following specific aspects of the Part 21 program:

- A description of how the applicant/holder assures compliance with posting requirements of 10 CFR Part 21 relative to the reporting of defects and non-compliances.

- A description of the requirements and documented process for inclusion of 10 CFR Part 21 requirements in procurement documents for basic components.

- A description of the requirements and documented process for meeting the 10 CFR PART 21 requirements for notification for failures to comply or existence of a defect and its evaluation, including the generation of a written report per 10 CFR 21.21(d)(4), and a description of the criteria used in the evaluation of failures to comply and/or existence of defects in accordance with the regulation.

- A description of the measures to ensure that records necessary to document the applicant's compliance with 10 CFR Part 21 are prepared, maintained, and made available for inspection.

I.17.5.3.W. COMMERCIAL-GRADE DEDICATION (NOT APPLICABLE TO ESP AND DC APPLICANTS)

Provide a description of the commercial-grade dedication program in sufficient detail to demonstrate how it meets the requirements of 10 CFR Part 21 and the applicable requirements of Criteria I though XVIII of 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."

Refer to draft SRP Section 17.5.W for more specific detail on the applicable items within each criterion that must be described as a minimum.

I.17.5.3.X. DIGITAL EQUIPMENT SOFTWARE VERIFICATION AND VALIDATION QUALITY CONTROLS

Provide a description of the controls and measures used to assure the QA program addresses quality controls for digital equipment software (software-based devices) used in safety-related systems, including:

- A description of the measures to ensure digital equipment meets the

requirements of 10 CFR Part 50 Appendix B, including a description of measures within the following areas taken to ensure appropriate quality controls for digital equipment software are established and implemented:

- Organization, including management responsibilities and training and qualification requirements for personnel involved in digital equipment software activities
- QA Program, including procedures for quality controls, supplier quality assurance programs, and verification and validation requirements
- Design Control, including program requirements for (as well as evaluation of vendor programs for) software/hardware configuration control, documented procedures, failure analyses, verification, validation, and testing activities during the software development life cycles, and operating history data.
- Procurement document control and commercial-grade dedication
- Test Control
- Corrective Action
- Audits
- A description of the standards to which the applicant/holder is committed and ensures appropriate suppliers are committed, for digital equipment software verification and validation quality controls, including:

  a. Institute of Electrical and Electronics Engineers (IEEE) Std 1012-1998, “IEEE Standard for Software Verification and Validation,” endorsed by RG 1.168.

  b. Electric Power Research Institute (EPRI) NP-5652, “Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety Related Applications (NCIG-07),” as conditionally endorsed by Generic Letter (GL) 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products,” and with the NRC staff positions promulgated in GL 91-05, “Licensee Procurement and Dedication Programs,” for the procurement of commercial-grade services related to digital equipment.

I.17.5.3.Y. NONSAFETY-RELATED SSC QUALITY CONTROLS (NOT APPLICABLE TO ESP APPLICANTS)

Design Certification Applicant:

Provide a description of any specific measures and controls established within each of the 18 criteria of 10 CFR Part 50, Appendix B, appropriate to risk significant, nonsafety related structures, systems, and components (SSCs).

DG-1145, Section C.I.17 - Quality Assurance and Reliability Assurance

Considering the guidance available in draft SRP Section 17.5.Y., describe and provide justification for any exceptions or alternatives to the specific criteria in draft SRP Section 17.5.Y.

COL Applicant or COL Holder:

> NOTE: The COL applicant or holder need only address aspects of the program not addressed by the DCD applicant).

Describe how the QAPD addresses the documents listed below for risk significant nonsafety related SSCs. Provide a description of and justification for exceptions or alternatives to the specific criteria in any of these documents, with the exception of requirements that are in the design control document (DCD), which would require Commission approval of an exemption:

- The quality requirements for the fire protection system in accordance with Regulatory Position 1.7, “Quality Assurance,” in RG 1.189, “Fire Protection for Operating Nuclear Power Plants.”

- The quality requirements for anticipated transient without scram (ATWS) equipment in accordance with Generic Letter 85-06, “Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related.”

- The quality requirements for station blackout (SBO) equipment in accordance with Regulatory Position 3.5, “Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related,” and Appendix A, “Quality Assurance Guidance for Non-Safety Systems and Equipment,” in RG 1.155, “Station Blackout.”

Describe how the QA requirements for nonsafety related SSCs in the DCD for the design and construction phase, are specified in the QAPD for the operational phase.

Describe how the QAPD addresses cause determinations and corrective actions for design and operational errors that degrade nonsafety-related, risk-significant SSCs.

I.17.5.3.Z. INDEPENDENT REVIEW

This section is applicable to holders of a COL (operational phase).

Provide a description of the program, process, membership and qualification requirements, management review and approval, and other requirements, including the scope and required content of independent reviews, using either the Independent Review Body or Independent Review Committee approaches.

Include in the description of the scope of independent reviews a description of the specific types of reviews, such as propose changes, tests, and experiments, proposed technical specification changes and license amendments, violations, deviations and reportable events, nuclear safety matters, corrective actions for significant conditions adverse to quality, and results of all assessments.

I.17.6 DESCRIPTION OF APPLICANT'S PROGRAM FOR IMPLEMENTATION 10 CFR 50.65, THE MAINTENANCE RULE

1.0 Describe program procedures for Maintenance Rule implementation in accordance with NUMARC 93-01 as endorsed by Regulatory Guide 1.160, including, but not limited to the following areas:

Note 1: Deviations from the guidance in NUMARC 93-01 and RG 1.160 should be explained and justified

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

1.1 Scoping per 10 CFR 50.65(b): List and provide information on the structures, systems, or components (SSCs) within the scope of your proposed Maintenance Rule (MR) program in the format of a full-relational database using the template provided by the NRC. For each SSC in scope, provide the following as database fields:

1.1.1 Specific MR requirement(s) in 50.65(b) that require it to be in scope. Provide a data field for each subparagraph, i.e., (b)(1)(i), (b)(1)(ii), (b)(1)(iii), (b)(2)(i), (b)(2)(ii), (b)(2)(iii)

1.1.2 For each SSC record, indicate in each paragraph (b) field the function(s) that require the SSC to be in scope

1.1.3 For each SSC record, indicate in each paragraph (b) field, as applicable, the failure modes and effects that required the SSC to be in scope

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

1.1.5 Identify each SSC explicitly mentioned in the EOPs (including those mentioned in referenced procedures) that is not in the MR scope. Describe the basis for its exclusion from scope including the basis for its inclusion in the EOPs, the portion of any and all mitigating functions provided, the expectation of reliability in this(ese) application(s), and the means by which operators are alerted (e.g., procedural warnings, cautions, disclaimers, signs, etc.) to reduced assurance or expectation of reliability.

1.2 For each SSC, indicate its reactor safety significance classification (i.e., HSS or LSS) and the basis thereof, including risk metrics and values, IOE, vendor information, and any other factors considered by the expert panel.

1.3 Procedures: Identify and describe the program procedures and documents (including computer software and data) that prescribe or govern scoping, including the items above. Include status in procedural hierarchy, whether treated as safety-related or non-safety-related, level of compliance expected, responsibility for preparation, review, approval, use, compliance oversight, and disposition.

2.0 Monitoring per 10 CFR 50.65(a):

DG-1145, Section C.I.17 - Quality Assurance and Reliability Assurance

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, pseudo-system, train, or plant) of monitoring/tracking.

2.0.1 Identify SSCs or equipment (e.g., circuit breakers, motorized valve actuators, etc.) monitored/tracked at the component level or in special component classes or "pseudo systems" that may involve applications in multiple systems and the bases thereof (e.g. IOE, common failure modes, etc). Explain how the program identifies and treats such SSCs.

2.1 Indicate which SSCs', if any, performance or condition will be monitored initially per paragraph 50.65(a)(1)

2.1.1 For each SSC to be in (a)(1) status, describe the performance monitoring (availability and reliability) or condition monitoring goals and the basis thereof. Discuss the extent to which the goals are commensurate with safety and what IOE was taken into account.

2.1.2 Corrective Action: Provide procedures which require prompt, comprehensive and thorough corrective action that addresses the proximate and ultimate causes of degraded performance or condition, that encompasses the extent of condition, and that institutes preventive measures including changes that may be required in maintenance and/or maintenance support practices, procedures and training.

2.1.3 Although not currently required by the MR, describe the extent to which any (a)(1) goals may be commensurate with radiation safety or offsite release control requirements (non-DBE), i.e., to what extent and how they might be able to adequately monitor the performance or condition of the SSC with respect to any collateral radioactivity control function(s), whether active or passive, that the SSC might have.

2.1.4 Procedures: Identify and describe the program procedures and documents (including computer software and data) that prescribe or govern monitoring under (a)(1), including the items above. Describe how the procedures address disposition of SSCs that do not meet goals, including administration of corrective action. Include status in procedural hierarchy, whether treated as safety-related or non-safety-related, level of compliance expected, responsibility for preparation, review, approval, use, compliance oversight, and disposition.

2.1.5 Policies: Describe any plant management policies, procedures or practices that involve the (a)(1) status of MR SSCs, e.g., for MR staff performance evaluation, etc.

2.2 Identify which SSCs will be tracked to demonstrate effective control of their performance or condition under 50.65(a)(2).

2.2.1 For each SSC to be in (a)(2) status, describe its performance (availability and/or reliability) criteria or condition monitoring criteria and the bases thereof. Discuss the extent to which they are consistent with industry guidance (as endorsed by NRC), commensurate with safety (including PRA insights) and good engineering practice, reasonable and sensible, etc., i.e., achievable and sufficiently sensitive to degraded

performance or condition) such that meeting them could adequately demonstrate effective control of the performance of the SSC through appropriate preventive maintenance and such that the SSC would remain capable of performing its function(s) and not fail in a manner adverse to safety. Deviations from industry guidance should be explained.

2.2.1.1 For each reliability performance criterion, describe how the program defines and determines/identifies and treats functional failures, MR functional failures (MRFFs), maintenance-preventable functional failures (MPFFs), and repetitive MPFFs.

2.2.1.2 For each availability performance criterion, describe how the program defines and tracks availability or unavailability (planned and unplanned), including exceptions and credits and the basis thereof.

2.2.1.3 For each condition monitoring criterion, describe how the program addresses sensing, surveillance, tracking & trending, action levels (predictive maintenance), etc.

2.2.1.3 For each SSC categorized in a "run-to-failure" status, if any, describe the bases and treatment for this categorization, including (a) SSC function(s) and success/failure criteria, (b) ability to detect degradation in performance or condition prior to failure, (c) ability to predict failure based on IOE (e.g., average failure rates, application vulnerabilities, MTBFs, etc.) and vendor information, (d) consequences of failure (modes, effects, safety significance), both with and without prompt detection and correction/repair or replacement, (e) ability promptly to detect failure (e.g., self revealing?), (f) means to ensure prompt identification and resolution, (g) procedures for identification and disposition of excessive failure rates (including vendor interaction).

2.2.2 Performance criteria or condition monitoring criteria under (a)(2), although not currently required by the MR, may be evaluated to determine the extent to which they could also be reasonably expected to demonstrate effective control of any collateral radioactivity control function(s), whether active or passive, that the SSC might have.

2.2.3 Procedures: Identify and describe the program procedures and documents (including computer software and data) that prescribe or govern tracking under (a)(2), including the items above. Describe how procedures govern disposition of SSCs for which effective control of performance or condition is not demonstrated (including not meeting performance criteria or condition monitoring criteria). Address conditions under which the expert panel may justify not placing an SSC in (a)(1) status. Include status in procedural hierarchy, whether treated as safety-related or non-safety-related, level of compliance expected, responsibility for preparation, review, approval, use, compliance oversight, and disposition.

3.0 Periodic Evaluation per 10 CFR 50.65(a)(3):

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 50.65(a)(3).

3.1 Describe how procedures govern the scheduling and timely performance of (a)(3) evaluations

3.2 Documenting, reviewing and approving evaluations, providing and implementing results

3.3 Making adjustments to achieve or restore balance between reliability and availability

3.4 Industry operating experience (IOE)

3.4.1 Obtaining IOE Information, including information from NRC, INPO, EPRI and EPRI-sponsored organizations (e.g., the MRUG, CRMF, CBUGs, etc.), NSSS owners groups, other owners and users groups, and vendors (e.g., the VETIP, or other programs established pursuant to NRC GL 83-28, Section 2.2)

3.4.2 Processing IOE Information, including admin controls, routing/distribution, applicability screening and engineering/technical staff involvement

3.4.3 Implementing/using IOE Information, including corrective action, maintenance, testing and inspection changes, modifications, improvements, procedures, practices, training, qualification and IOE feedback to the processes for safety significance classification, monitoring or tracking type and level determination, goal setting and performance/condition criteria development, procurement engineering (e.g., receipt criteria, commercial-grade dedication), and material handling, storage, issue

4.0 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 accordance with 50.65(a)(4) including, but not limited to the following areas:

4.1 Determination of the scope (or limited scope) of SSCs to be included in (a)(4) risk assessments

4.2 Risk assessment and management during work planning

4.3 Risk assessment and management of emergent conditions and updating risk assessments as maintenance situations and plant conditions and configurations are changed.

4.4 Assessment (quantitative and qualitative capabilities) and management of risk of 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; grid/offsite power reliability for grid-risk-sensitive maintenance activities (respond to or refer to responses to MR-related questions in NRC GL 2006-02), and internal flooding.

4.5 Assessment and management of risk of maintenance activities affecting containment

integrity.

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

4.7 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), in accordance with latest revision of NEI 96-07 as endorsed by latest revision of RG 1.187.

4.8 Risk assessment and management associated with risk-informed technical specifications.

5.0 Maintenance Rule Training and Qualification:

Describe the program, including procedures and documentation, for Maintenance Rule training and qualification of the following personnel:

(Note: While the Maintenance Rule does not require training and qualification, the NRC needs this information to obtain reasonable assurance of consistent compliance.)

5.1 Selection, Training and Qualification of Maintenance Rule Personnel
- 5.1.1 The Maintenance Rule Coordinator
- 5.1.2 The Maintenance Rule Expert Panel

5.2 Training and Qualification of Engineering Personnel
- 5.2.1 System/Component Engineers
- 5.2.2 Procurement Engineers
- 5.2.3 Maintenance Engineers
- 5.2.4 Probabilistic Risk Analysts/Safety Assessors

5.3 Training and Qualification of Maintenance Personnel
- 5.3.1 Work Planners
- 5.3.2 Maintenance Foremen and Shop Supervisors
- 5.3.3 Technicians and Craftsmen

5.4 Training and Qualification of Operations Personnel
- 5.4.1 Shift Supervisors
- 5.4.2 Shift Technical Advisors
- 5.4.3 Senior Reactor Operators
- 5.4.4 Reactor Operators
- 5.4.5 Plant Operators

5.5 Training and Qualification of Licensing Personnel

5.6 Basic Indoctrination of New Personnel

5.7 Management Training

6.0 Maintenance Rule Program and Operational Reliability Assurance Program Interface:

Describe the relationship and interface between MR and ORAP (See Section C.I.17.4), including how functions are coordinated and procedures overlap and/or are cross referenced.

7.0 Maintenance Rule Program Implementation:

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

I.17.7 LIST OF REFERENCES

- 10 CFR Part 21
- 10 CFR Part 50
  - 10 CFR 50.4
  - 10 CFR 50.34(a)(7)
  - 10 CFR 50.34(b)(6)(ii)
  - 10 CFR 50.34(f)(3)(ii)
  - 10 CFR 50.34(f)(3)(iii)
  - 10 CFR 50.34(g)
  - 10 CFR 50.54(a)
  - 10 CFR 50.55(e)(4)
  - 10 CFR 50.55(f)
  - 10 CFR 50.55a(b)(1)(iv)
  - 10 CFR 50.55a(b)(2)(x)
  - 10 CFR 50.55a(b)(3)(I)
  - 10 CFR 50.65
  - 10 CFR Part 50, Appendix B
- 10 CFR Part 52
  - 10 CFR 52.47(a)(1) [cross references to other regulatory requirements]
  - 10 CFR 52.79 [cross references to other regulatory requirements]
  - 10 CFR 52.81 [cross references to other regulatory requirements]
  - 10 CFR 52.83 [cross references to other regulatory requirements]

Regulatory Guidance Documents

- NUREG-0800, “Standard Review Plan”
- RS-002, “Processing Applications for Early Site Permits,” May 2004
- RIS 00-018 “Guidance on Managing Quality Assurance Records in Electronic Media”
- RG 1.189, “Fire Protection for Operating Nuclear Power Plants”
- RG 1.155, “Station Blackout”
- RG 1.26, “Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants”
- RG 1.29, “Seismic Design Classification”
- RG 1.54, “Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants”
- RG 1.97, “Instrumentation for Light-Water Nuclear Power Plants to Assess Plant and Environs Conditions During and Following an Accident”
- RG 1.142 Revision 2, “Safety-Related Concrete Structures for Nuclear Power Plants (Other Than Reactor Vessels and Containments)” (11/01)
- RG 1.143, “Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants”
- RG 1.152, “Criteria for Digital Computers in Safety Systems of Nuclear Power Plants”
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