

November 3, 2009

MEMORANDUM TO: Edwin M. Hackett, Executive Director
Advisory Committee on Reactor Safeguards
Advisory Committee on Nuclear Waste and Materials

James E. Lyons, Chairman
The Committee to Review Generic Requirements

FROM: William F. Burton, Chief */RA/*
Rulemaking and Guidance Development Branch
Division of New Reactor Licensing
Office of New Reactors

SUBJECT: TRANSMITTAL OF PROPOSED INTERIM STAFF GUIDANCE
DC/COL-ISG-018 TO THE ADVISORY COMMITTEE ON
REACTOR SAFEGUARDS AND THE COMMITTEE TO REVIEW
GENERIC REQUIREMENTS ON DESIGN RELIABILITY
ASSURANCE PROGRAM SECTION 17.4 OF THE STANDARD
REVIEW PLAN FOR THE REVIEW OF SAFETY ANALYSIS
REPORTS FOR NUCLEAR POWER PLANTS (NUREG-0800)

The purpose of this memorandum is to transmit the Proposed Interim Staff Guidance (ISG) on "Design Reliability Assurance Program Section 17.4 of the Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants (NUREG-0800)" for the Advisory Committee on Reactor Safeguards (ACRS) and the Committee to Review Generic Requirements (CRGR) review and consideration.

The U.S. Nuclear Regulatory Commission is issuing its DC/COL-ISG-018 for comments from stakeholders and transmitting in parallel to ACRS and CRGR for information.

Enclosure:
As stated

CONTACT: Ram Subbaratnam, NRO/DNRL
301-415-1478

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Nuclear Regulatory Commission

NRC-2009-0476

Office of New Reactors; Interim Staff Guidance on Design Reliability Assurance Program
Section 17.4 of the Standard Review Plan for the Review of
Safety Analysis Reports for Nuclear Power Plants (NUREG-0800)

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Solicitation of public comment.

SUMMARY: The NRC staff is soliciting public comment on its proposed Interim Staff Guidance (ISG) DC/COL-ISG-018 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML092290791). This ISG revises the guidance provided to the staff in Section 17.4, "Reliability Assurance Program" of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," March 2007 (SRP). This ISG revises the review responsibilities and further clarifies the acceptance criteria and evaluation findings contained in SRP Section 17.4 in support of the NRC reviews of the design certification (DC) and combined license (COL) applications. The NRC staff issues DC/COL-ISGs to facilitate timely implementation of current staff guidance and to facilitate activities associated with review of applications for DCs and COLs by the Office of New Reactors. The NRC staff intends to incorporate the final approved DC/COL-ISG-018 into the next revision of NUREG-0800, SRP Section 17.4 and Regulatory Guide (RG) 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," June 2007.

DATES: Comments must be filed no later than 30 days from the date of publication of this notice in the *Federal Register*. Comments received after this date will be considered, if it is

practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please include Docket ID: **NRC-2009-0476** in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC website and on the Federal rulemaking website at <http://www.Regulations.gov>. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

Federal Rulemaking Website: Go to <http://www.Regulations.gov> and search for documents filed under Docket ID: **NRC-2009-0476**. Address questions about NRC dockets to Carol Gallagher at 301-492-3668; e-mail at Carol.Gallagher@nrc.gov.

Mail comments to: Michael T. Lesar, Chief, Rulemaking and Directives Branch (RDB), Division of Administrative Services, Office of Administration, Mail Stop: TWB-05-B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by fax to RDB at (301) 492-3446.

The NRC ADAMS provides text and image files of NRC's public documents. These documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at <http://www.nrc.gov/reading-rm/adams.html>. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should

contact the NRC Public Document Room reference staff by telephone at 1-800-397-4209, 301-415-4737, or by e-mail at pdr.resource@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Mr. Todd A. Hilsmeier, Project Manager, PRA Licensing Operations Support and Maintenance Branch 2, Division of Safety Systems and Risk Assessment, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC, 20555-0001; telephone 301-415-6788 or e-mail at todd.hilsmeier@nrc.gov.

SUPPLEMENTARY INFORMATION: The agency posts its issued staff guidance in the agency external web page (<http://www.nrc.gov/reading-rm/doc-collections/isg/>).

The NRC staff is issuing this notice to solicit public comments on proposed DC/COL-ISG-018. After the NRC staff considers any public comments, it will make a determination regarding proposed DC/COL-ISG-018.

Dated at Rockville, Maryland, this 22nd day of October 2009.

For the Nuclear Regulatory Commission,

/RA/

William F. Burton, Branch Chief
Rulemaking and Guidance Development Branch
Division of New Reactor Licensing
Office of New Reactors

**Interim Staff Guidance on NUREG-0800 Standard Review Plan
Section 17.4, “Reliability Assurance Program”
DC/COL-ISG-018**

Purpose

The purpose of this interim staff guidance (ISG) is to clarify the U.S. Nuclear Regulatory Commission (NRC) guidance and application of Section 17.4, “Reliability Assurance Program,” of NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants,” March 2007 (SRP). This ISG revises the review responsibilities and clarifies the review and acceptance criteria contained in SRP Section 17.4 in support of NRC reviews of design certification (DC) and combined license (COL) applications.

Background

In March 2007, the NRC issued SRP Section 17.4, which provides guidance to the NRC staff in performing DC and COL application reviews of the reliability assurance program (RAP). This ISG will include the lessons learned and insights gained from these RAP reviews, until the SRP is updated.

The RAP is implemented according to the Commission’s direction provided in the staff requirements memorandum (SRM) dated June 28, 1995, for Item E, “Reliability Assurance Program,” of SECY-95-132, “Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs,” dated May 22, 1995. The RAP applies to those systems, structures, and components (SSCs), both safety-related and non-safety-related that are identified as being risk-significant (or significant contributors to plant safety). The SSCs within the scope of the RAP (referred to hereafter as within-scope SSCs) are identified by using a combination of probabilistic, deterministic, or other methods of analysis, including information obtained from sources such as the probabilistic risk assessment (PRA), severe accident evaluations, industry operating experience, and expert panels.

The purposes of the RAP are to provide reasonable assurance of the following:

- A reactor is designed, constructed, and operated consistent with the key assumptions and risk insights for the within-scope SSCs.
- The within-scope SSCs do not degrade to an unacceptable level of reliability, availability, or condition during plant operations.
- The frequency of transients that challenge these SSCs is minimized.
- The SSCs function is reliable when challenged.

Enclosure

The purposes of the RAP can be achieved by implementing the program in two stages. The first stage applies to reliability assurance activities that occur before initial fuel load and is referred to as the design reliability assurance program (D-RAP). The second stage applies to reliability assurance activities for the operations phase of the plant's life cycle.

The objective of the D-RAP is to ensure that the reactor is designed and constructed consistent with the key assumptions (including reliability and availability assumptions in the PRA, when applicable) and risk insights for the within-scope SSCs. This objective can be achieved through the following:

- Applying the essential elements of D-RAP (i.e., organization, design control, procedures and instructions, records, corrective actions, and audit plans) during design and construction activities. These essential elements ensure that the key assumptions and risk insights are consistent with the reactor design and construction, and that the list of within-scope SSCs is appropriately developed, maintained, and communicated to the appropriate organizations.
- Implementing the appropriate quality assurance (QA) controls related to design and construction (e.g., design, procurement, fabrication, construction, inspection, and testing activities) to provide control over activities affecting the quality of the within-scope SSCs. QA controls for safety-related SSCs are established through Title 10 of the Code of Federal Regulations, the QA requirements 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." The provisions in Part V, "Non-safety-Related SSC Quality Controls," of SRP Section 17.5 address graded QA controls for non-safety-related, within-scope SSCs.

D-RAP can be implemented through the following phases:

- During the DC phase, the DC applicant develops and implements those portions of the D-RAP that apply to the DC. This effort includes (1) describing the details of the D-RAP (e.g., scope, purpose, objectives, framework, and phases of the D-RAP) that will be implemented during the DC and COL phases, (2) applying the essential elements of D-RAP during DC design activities, (3) determining the within-scope SSCs using a combination of probabilistic, deterministic, and other methods of analysis, and (4) implementing the appropriate graded QA controls related to DC design activities for the non-safety-related, within-scope SSCs in accordance with Part V of SRP Section 17.5. Also, the DC applicant proposes non-system-based Tier 1 inspections, tests, analyses, and acceptance criteria (ITAAC) for the COL D-RAP. The NRC verifies the DC applicant's D-RAP, including its implementation during the DC application phase, through the agency's safety evaluation review process, as well as audits.
- During the COL application phase, the COL applicant develops and implements those portions of the D-RAP that apply to the COL. This effort includes (1) applying the essential elements of D-RAP during COL design activities, (2) determining the SSCs in the scope of the COL's plant-specific D-RAP by introducing plant-specific information into the probabilistic, deterministic, and other methods of analysis, and (3) implementing

the appropriate graded QA controls related to COL design activities for the non-safety-related, within-scope SSCs in accordance with Part V of SRP Section 17.5. The NRC verifies the COL applicant's D-RAP, including its implementation during the COL application phase, through the agency's safety evaluation review process, as well as audits.

Also, the COL applicant proposes a process for integrating reliability assurance activities for within-scope SSCs into operational programs to meet the objectives of the RAP during the operations phase. The objectives of the RAP during the operations phase can be accomplished within the following operational programs: (1) maintenance rule program established through 10 CFR Section 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," (2) QA program for safety-related SSCs established through Appendix B to 10 CFR Part 50, (3) graded QA controls for non-safety-related, within-scope SSCs established in accordance with Part V of SRP Section 17.5, and (4) in-service inspection and testing, surveillance testing, and maintenance programs.

- During the COL holder phase prior to initial fuel load, the COL holder is responsible for (1) applying the essential elements of D-RAP during COL design and construction activities, (2) implementing the appropriate graded QA controls related to COL design and construction activities for the non-safety-related, within-scope SSCs in accordance with Part V of SRP Section 17.5, and (3) completing the ITAAC for the D-RAP. The NRC staff verifies implementation of the plant-specific D-RAP during this phase using inspections and audits. Satisfactory completion of the D-RAP ITAAC is verified by using Inspection Manual Chapter 2503, "Construction Inspection Program: Inspections of Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)" (IMC 2503).

The objective of the RAP during the operations phase of the plant's life cycle is to ensure that the reliability and availability of SSCs are maintained commensurate with their risk significance. The COL holder identifies dominant failure modes and integrates reliability assurance activities for within-scope SSCs into operational programs to meet the objectives of the RAP during the operations phase. Performance and condition monitoring is implemented to provide reasonable assurance that these within-scope SSCs do not degrade to an unacceptable level of reliability, availability, or condition. The NRC verifies implementation of reliability assurance activities associated with the operations phase through the use of inspections and audits for the duration of the license.

Issue Discussion

Based on the lessons learned and insights gained from the reviews of DC and COL applications, the NRC staff determined that Section 17.4 of the SRP needs additional clarification. The following summarizes the significant lessons learned and insights gained from these reviews.

- Staff reviews of the methodology for evaluating and identifying the list of within-scope SSCs were often inconsistent due to insufficient acceptance criteria in SRP Section 17.4. Also, these lists of SSCs specified in the applications were, in general, incomplete because the applicants did not consider the full spectrum of risk evaluations considered

in SRP Section 19.0, “Probabilistic Risk Assessment and Severe Accident Evaluation for New Reactors,” and limited the scope of the D-RAP to only risk-significant SSCs modeled in the PRA. The staff addressed this issue during their reviews through the requests for additional information (RAI) process.

- The staff and applicants commonly interpreted the acceptance criteria in SRP Section 17.4 for D-RAP ITAAC as a numerical analysis that would require the estimated reliability of each as-built, within-scope SSC to be at least equal to the reliability assumed in the PRA. However, D-RAP should not solely be based on numerical values because some numerical estimates (e.g., estimated reliability of each as-built, within-scope SSC) may not be available, and additional aspects of D-RAP should be considered in order to address other key assumptions and risk insights. Therefore, implementation of D-RAP should be interpreted as having a process that would control reliability and availability of within-scope SSCs. This process includes implementing the appropriate QA controls to provide control over activities affecting the quality of the within-scope SSCs.
- Staff reviews of the essential elements (i.e., organization, design control, procedures and instructions, records, corrective action, and audit plans) for developing and implementing the D-RAP were inconsistent due to unclear acceptance criteria in SRP Section 17.4. Also, it was not clear to the staff that the COL applications should specify essential elements specific to the COL applicants.

In addition, the roles and responsibilities of individual branches in the Office of New Reactors (NRO) that review the RAP are being revised to reflect the current review responsibilities. This ISG addresses these issues to provide timely updated guidance to the NRC staff to support safety reviews of the RAP, until the SRP is updated.

Rationale

The current version of the SRP does not provide sufficient guidance for performing safety reviews of the RAP and requires changes to the roles and responsibilities of individual branches in NRO that review the RAP. To address these issues, this ISG includes the following changes in SRP Section 17.4:

- (1) Assign PRA staff as primary reviewer, and remove QA staff as primary or secondary reviewer.
- (2) Clarify the following DC and COL acceptance criteria:
 - acceptance criteria related to the scope and purpose of the D-RAP
 - acceptance criteria for the essential elements of D-RAP
 - acceptance criteria on an acceptable methodology for evaluating, identifying, and prioritizing SSCs according to their degree of risk significance (including the use of an expert panel)

- acceptance criteria for the list of within-scope SSCs
- acceptance criteria for how procurement, fabrication, construction, and test specifications for the within-scope SSCs ensure that significant assumptions are realistic and achievable
- acceptance criteria for D-RAP ITAAC, which should provide reasonable assurance that the plant is designed and will be constructed consistent with the key assumptions and risk insights for the within-scope SSCs
- acceptance criteria for COL action items for a DC application
- acceptance criteria for integrating reliability assurance activities for within-scope SSCs into operational programs to meet the objectives of the RAP during plant operation

(3) Clarify the guidance associated with the evaluation findings.

Staff Guidance

This ISG provides additional clarification or changes in the following areas of SRP Section 17.4:

- review responsibilities
- specific areas of review
- SRP acceptance criteria
- evaluation findings

In performing DC and COL application reviews of the RAP in accordance with SRP Section 17.4, the interim staff guidance provided below should supersede the related subsections of SRP Section 17.4.

(1) Review Responsibilities and Specific Areas of Review

- The PRA staff (primary reviewer) is responsible for reviewing all functional areas of the RAP associated with the acceptance criteria provided in Part 2 of this staff guidance.

Also, the discussion provided under the background section of this ISG elaborates on the introduction text provided in Part 1 ("Areas of Review") of SRP Section 17.4.

(2) SRP Acceptance Criteria

The following are the specific acceptance criteria to meet the relevant requirements of the NRC's regulations identified in SRP Section 17.4, Part II ("Acceptance Criteria"), Subsection titled "Requirements." The SRP (as clarified or changed by this ISG) is not a substitute for the NRC's regulations, and compliance with it is not required. However, an applicant is required to identify differences between the design features, analytical

techniques, and procedural measures proposed for its facility and the SRP acceptance criteria (as clarified or changed by this ISG) and evaluate how the proposed alternatives to the acceptance criteria provide acceptable methods for compliance with the NRC regulations.

Section A below applies to a DC application, and Section B applies to a COL application referencing a certified design. Sections A and B together apply to a COL applicant that does not reference a certified design.

A. DC Application

A.1 Description of D-RAP

The application should adequately describe the details of the D-RAP that will be implemented during the DC and COL design and construction activities preceding initial fuel load. This description should include a discussion of the scope, purpose, objectives, framework, and phases of the D-RAP. Also, the application should describe who is responsible for implementing the various phases of the D-RAP. The scope, purpose, and objectives of the D-RAP should be consistent with those described in the background section of this ISG. The information provided in the background section of this ISG can facilitate the acceptability determination of the D-RAP description.

A.2 Essential Elements of D-RAP

The objective of this review is to verify that the applicant has established and applied the appropriate essential elements of D-RAP to support DC design activities. These essential elements ensure that the key assumptions and risk insights are consistent with the design and that the list of within-scope SSCs is appropriately developed, maintained, and communicated to the appropriate organizations. The reviewer should verify that the application adequately addresses the following essential elements of D-RAP. Also, if needed, an audit(s) can be performed to verify that the applicant appropriately applied these essential elements during DC design activities.

a. Organizations

- The application should identify the organizations responsible for establishing the scope of the D-RAP, as well as those that develop, coordinate, or implement D-RAP activities (e.g., those organizations associated with design, PRA, and QA). These include supporting organizations such as architect-engineers if any are involved.
- The application should describe how these organizations interface to ensure that the reactor will be designed consistently with the key assumptions and risk insights.

- The application should describe how these organizations interface in the design change control process for the purpose of updating and providing D-RAP related inputs (e.g., list of within-scope SSCs, PRA models, key assumptions, and risk insights) to account for design changes.
- b. Design Control
- The application should describe the quality controls for identifying within-scope SSCs, including quality controls for the analyses used to identify these SSCs (i.e., probabilistic, deterministic, or other methods of analysis). These quality controls include ensuring that the D-RAP related inputs (e.g., list of within-scope SSCs, PRA models, key assumptions, and risk insights) are maintained or updated, as necessary, and reflect the designed plant. It is acceptable to provide cross-references to the specific sections or chapters of the application that specify these quality controls. For example, describing the quality control of the PRA in Chapter 19 of the application in accordance with the provisions in SRP Section 19.0, “Probabilistic Risk Assessment and Severe Accident Evaluation for New Reactors,” and cross-referencing the description in Section 17.4 would be acceptable.
 - The application should describe the configuration control process for maintaining the list of within-scope SSCs.
 - The application should address how the design control and change processes provide a feedback mechanism for notifying the appropriate organization(s) of changes (e.g., design changes or PRA changes) that could affect the within-scope SSCs or D-RAP related inputs.
- c. The application should describe the controls for procedures and instructions used for developing, coordinating, and implementing D-RAP activities. D-RAP activities should be prescribed by detailed procedures or instructions and accomplished in accordance with these procedures or instructions.
- d. The application should describe the corrective action process applied to D-RAP activities. Corrective action measures should be established to ensure that D-RAP activities determined to be in error, deficient, or nonconforming (e.g., information used to identify within-scope SSCs is determined to be in error, or there is a failure to communicate a key assumption to the design organization) are promptly identified, reported, and corrected.
- e. The application should describe the controls for records associated with D-RAP activities. Records should be prepared and maintained to demonstrate that all requirements for D-RAP activities have been met.
- f. The application should describe the audit plans for conducting audits of D-RAP activities.

A.3 Methodology for Identifying Within-Scope SSCs

The application should describe an acceptable methodology for evaluating, identifying, and prioritizing SSCs according to their degree of risk significance as determined by using a combination of probabilistic, deterministic, or other methods of analysis. This methodology should include, but not limited to, the use of information obtained from the following sources:

- a. risk evaluations that cover the full spectrum of potential events and the range of plant operating modes considered in SRP Section 19.0 (e.g., use of importance measures, risk insights, and key assumptions from internal event risks, fire risks, seismic risks, other external risks, low-power/shutdown risks, severe accident evaluations), which include use of non-PRA type evaluations (e.g., fire-induced vulnerability evaluation or seismic margins analysis) when PRAs have not been performed
- b. industry operating experience
- c. expert panel(s)

The roles and responsibilities of the expert panel(s) should be described since they play an important role in reviewing the information associated with risk-significance determinations and could compensate for the limitations of the PRA. The scope of D-RAP should not be limited to risk-significant SSCs modeled in the PRA. Therefore, SSCs that are not modeled in the PRA should also be evaluated (e.g., by using deterministic or other methods of analysis) for inclusion in D-RAP. The scope of D-RAP should include safety-related and non-safety-related SSCs identified as risk significant (or significant contributors to plant safety) and include those SSCs subject to RTNSS for passive system designs.

A.4 Expert Panel Qualifications

The application should adequately describe the qualification requirements for members of expert panels used. To evaluate and review information associated with determinations of risk-significance, the expert panel should be staffed with plant-knowledgeable members whose expertise includes, at a minimum, PRA, safety analysis, plant operations, maintenance, design engineering, and system engineering. Expert panel members should have a level of knowledge sufficient to evaluate and approve, using both probabilistic and deterministic information, risk significance determinations.

A.5 List of Within-Scope SSCs

The application should contain a complete list of within-scope SSCs based on an acceptable methodology that uses a combination of probabilistic, deterministic, or other methods of analysis. The basis or bases for including each within-scope SSC should be described. The within-scope SSCs should be clearly identified using text descriptions and specific SSC identification numbers, when applicable.

A.6 Process for Determining Dominant Failure Modes

The application should propose an acceptable process for determining dominant failure modes of within-scope SSCs. This process should consider industry experience, analytical models, and applicable requirements (e.g., consideration of operating experience, PRA importance analyses, root cause analyses, failure modes and effects analyses).

A.7 Graded QA Controls Related to DC Design Activities for Non-Safety-Related, Within-Scope SSCs

For the non-safety-related, within-scope SSCs, the application should specify the graded QA controls related to DC design activities in accordance with the provisions in Part V, "Non-safety-Related SSC Quality Controls," of SRP Section 17.5. The review of these graded QA controls is conducted in accordance with Part V of SRP Section 17.5. Section 17.4 of the application should provide cross-references to the specific sections or chapters of the application where these graded QA controls are described.

A.8 ITAAC for D-RAP

The application should specify an ITAAC for the D-RAP that provides reasonable assurance that the plant is designed and will be constructed consistent with the key assumptions and risk insights for the within-scope SSCs. The COL holder would confirm the adequacy of the D-RAP prior to initial fuel load. Acceptance criteria for D-RAP ITAAC would ensure that documentation exists for the following:

- a. for the within-scope SSCs, identification and description of the reliability assurance activities that are accomplished prior to initial fuel load
- b. confirmation that these activities provide reasonable assurance that the plant is designed and constructed consistent with the key assumptions (including reliability and availability assumptions in the PRA, when applicable) and risk insights for the within-scope SSCs

A.9 COL Applicant Action Items

The application should include the following COL action items:

- a. A COL applicant referencing a certified design should update the description of the D-RAP proposed by the DC to include relevant plant-specific information (e.g., design, program, and organizational information). This includes identifying the SSCs within the scope of the plant-specific D-RAP and establishing the essential elements of D-RAP that are applied during the COL design and construction activities prior to initial fuel load.
- b. To support the objectives of the D-RAP during COL design and construction activities, a COL applicant referencing a certified design should specify appropriate graded QA controls for the non-safety-related, within-scope SSCs

in accordance with the provisions in Part V, "Non-safety-Related SSC Quality Controls," of SRP Section 17.5. This includes providing corrective actions for potential design and operational errors that degrade non-safety-related, within-scope SSCs.

- c. A COL applicant referencing a certified design should propose a process for integrating reliability assurance activities for within-scope SSCs into operational programs (e.g., maintenance rule program, QA program, in-service inspection and testing programs, surveillance testing programs, and maintenance programs) to meet the objectives of the RAP during plant operation. The description should also address the (1) establishment of reliability, availability, or condition performance goals for the within-scope SSCs, (2) establishment of performance and condition monitoring requirements to provide reasonable assurance that within-scope SSCs do not degrade to an unacceptable level of reliability, availability, or condition during plant operations, (3) for the non-safety-related, within-scope SSCs, establishment of graded QA controls related to the COL operations phase in accordance with the provisions in Part V of SRP Section 17.5, and (4) use of dominant failure modes of within-scope SSCs in meeting the objectives of the RAP during plant operation.

B. COL Application

B.1 Plant-Specific D-RAP

The applicant should appropriately update the description of the D-RAP proposed by the DC to include relevant COL plant-specific information (e.g., design, program, and organizational information). This includes (1) identifying the SSCs within the scope of the plant-specific D-RAP, and (2) establishing the essential elements of D-RAP (see Section A.2) that are applied during the COL design and construction activities prior to initial fuel load. If needed, an audit(s) can be performed to verify that the applicant appropriately applied the essential elements of D-RAP during design activities in the COL application phase.

B.2 Graded QA Controls Related to COL Design and Construction Activities for Non-Safety-Related, Within-Scope SSCs

For the non-safety-related, within-scope SSCs, the application should specify the graded QA controls related to COL design and construction activities (that include establishing appropriate corrective actions for potential design and operational errors that degrade these SSCs) in accordance with the provisions in Part V, "Non-safety-Related SSC Quality Controls," of SRP Section 17.5. The review of these graded QA controls is conducted in accordance with Part V of SRP Section 17.5. Section 17.4 of the application should provide cross references to the specific sections or chapters of the application where these graded QA controls are described.

B.3 Integration of RAP into Operational Programs

The application should propose an acceptable process for integrating reliability assurance activities for within-scope SSCs into operational programs to meet the objectives of the RAP during plant operation. The application should provide cross-references to the specific sections or chapters of the application where applicable operational programs are described and may also identify other applicable programs, if any (e.g., an RTNSS availability controls program).

The proposed process should also address the following:

- a. Establishment of reliability, availability, or condition performance goals for the within-scope SSCs. Implementation of the maintenance rule following the guidance contained in Regulatory Guide (RG) 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," is one acceptable method for establishing these performance goals, provided that these SSCs are categorized as having high safety significance (HSS).
- b. Establishment of performance and condition monitoring requirements to provide reasonable assurance that within-scope SSCs do not degrade to an unacceptable level of reliability, availability, or condition during plant operations. (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 evaluating equipment reliability and risk significance on the basis of actual equipment, train, or system performance and other operational history.)
- c. For the non-safety-related, within-scope SSCs, establishment of graded QA controls related to the COL operations phase (that include establishing appropriate corrective actions for potential design and operational errors that degrade these SSCs) in accordance with the provisions in Part V, "Non-safety-Related SSC Quality Controls," of SRP Section 17.5. The review of these graded QA controls is conducted in accordance with Part V of SRP Section 17.5.
- d. Use of dominant failure modes of within-scope SSCs, which are determined in accordance with the process established under the referenced DC, in meeting the objectives of the RAP during plant operation. For example, dominant failure modes could be used to identify specific operational reliability assurance activities or strategies (e.g., in-service inspection and testing, surveillance testing, monitoring, and maintenance) to maintain equipment performance consistent with the key assumptions and risk insights for the within-scope SSCs.

One acceptable method for meeting the objectives of the RAP during the operations phase is by implementation of the following operational programs: (1) maintenance rule program consistent with RG 1.160, with the within-scope SSCs being categorized as having HSS, (2) QA program for safety-related SSCs established through Appendix B to 10 CFR Part 50, (3) graded QA controls for

non-safety-related, within-scope SSCs established in accordance with Part V of SRP Section 17.5, and (4) in-service inspection and testing, surveillance testing, and maintenance programs for the within-scope SSCs.

B.4 ITAAC for D-RAP

In accordance with SRP Section 14.3, "Inspections, Tests, Analyses, and Acceptance Criteria," for a COL application referencing a DC, the review should confirm that the D-RAP ITAAC is applied to the design as approved in the DC.

(3) Evaluation Findings

NRC staff should provide a summary description of the applicant's RAP. The NRC staff should also identify the RAP information docketed by the applicant and related NRC audit/inspection reports.

The reviewer verifies that the applicant has provided sufficient information and that the review and calculations (if applicable) support conclusions of the following type to be included in the NRC staff's safety evaluation report (SER). The reviewer also states the bases for those conclusions. The conclusions in the SER should include the following:

- All SRP acceptance criteria (as clarified or changed by this ISG) are satisfied, using the methods described in SRP Section 17.4 (as clarified or changed by this ISG).
- Alternative means of satisfying SRP acceptance criteria, if used, are acceptable.
- Justifications for deviations from SRP acceptance criteria, if used, are acceptable.

For COL reviews, the findings will summarize the NRC staff's evaluation of the process for integrating reliability assurance activities for within-scope SSCs into operational programs and include a description of those operational programs that are not fully described in other sections or chapters of the SER.

For DC and COL reviews, the findings will also summarize the NRC staff's evaluation of requirements and restrictions (e.g., interface requirements) and COL action items relevant to this SRP section.

In addition, to the extent that the review is not discussed in other SER sections, the findings will summarize the NRC staff's evaluation of the ITAAC for D-RAP, including design acceptance criteria, as applicable.

Final Resolution

The NRC staff will subsequently incorporate the contents of this ISG into the next revisions to Section 17.4 of the SRP (NUREG-0800) and appropriate sections of RG 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)."

Applicability

This ISG applies to all DC and COL applications submitted under the requirements of 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." It shall remain in effect until it has been superseded, withdrawn, or incorporated into a revision of the SRP and RG 1.206.

Backfit Determination

The NRC staff has determined that this ISG does not reflect any new NRC staff positions and should not impose any new requirements on the RAP contained in DC and COL application submittals. No backfit is required.

References

1. 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."
2. 10 CFR Section 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants."
3. 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."
4. NRC, "Construction Inspection Program: Inspections of Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)," NRC Inspection Manual, Chapter 2503.
5. NRC, NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)."
6. NRC, RG 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants."
7. NRC, RG 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)."
8. NRC, SECY 95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs (SECY 94-084)," May 22, 1995.