

**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 **NRC staff's** review responsibilities and clarifies the review and acceptance criteria contained in ~~the SRP~~ **the Standard Review Plan (SRP)**, Section 17.4 in support of NRC reviews of design certification (DC) and combined license (COL) applications.

Background and Description of the Reliability Assurance Program

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, **and is intended to be used by the staff to support safety reviews of the RAP**, until the SRP is updated **to include the guidance in this ISG**.

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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** "RAP SSCs") are identified by using a combination of probabilistic, deterministic, ~~and~~ **and** other methods of analysis **used to identify and quantify risk**, including information obtained from sources such as the probabilistic risk assessment (PRA), severe accident evaluations, industry operating experience, and expert panels.

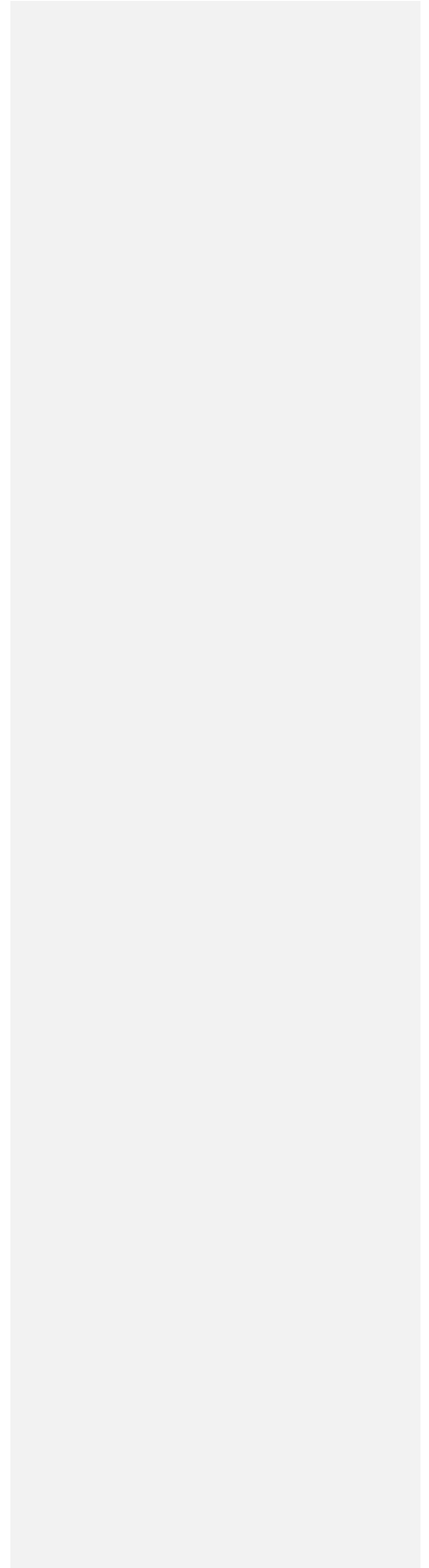
The ~~purpose~~ **purpose** of the RAP ~~is~~ **is** to provide reasonable assurance of the following:

- A ~~plant~~ **reactor plant** is designed, constructed, and operated **in a manner that is** consistent with the **risk insights and** key assumptions ~~and risk insights for~~ (e.g., SSC design, reliability, and availability) from the ~~probabilistic~~ **within-scope** ~~SSCs~~ **probabilistic, deterministic, and other methods of analysis used to identify and quantify risk.**
- The ~~RAP~~ **within-scope** ~~RAP~~ 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.

Enclosure

| ~~•~~ ~~These~~ ~~The~~ ~~These~~ SSCs will function reliably ~~is reliable~~ ~~reliably~~ when challenged.

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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 ~~conducted for~~ **conducted during** the operations phase of the plant's life cycle.

The objective of the D--RAP is to ensure that the ~~plant reactor plant~~ is designed and constructed **in a manner that is** consistent with the **risk insights and key assumptions** (~~including e.g., SSC design, reliability, and availability assumptions in the PRA, when applicable~~) **and risk insights for the within-scope SSCs**) from probabilistic, deterministic, and other methods of analysis used to **identify and quantify risk**. This objective can be achieved through the following:

- ~~Apply~~ **Applying** ~~Apply~~ 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 **are processes and controls that ensure** ~~that the risk insights and key assumptions and risk insights~~ are consistent with the ~~plant reactor plant~~ design and construction, and that the list of ~~RAP within-scope RAP~~ SSCs is appropriately developed, maintained, and communicated to the appropriate organizations.
- ~~Implement~~ **Implementing** ~~Implement~~ the appropriate quality assurance (QA) ~~programs controls programs~~ related to design and construction **activities** (e.g., design, procurement, fabrication, construction, inspection, and testing activities) to provide control over activities affecting the quality of the ~~RAP within-scope RAP~~ SSCs. QA controls for safety-related SSCs are established through Title 10 of the *Code of Federal Regulations, the* (CFR), Part 50, "Domestic Licensing of Production and Utilization Facilities." ~~The QA requirements are~~ **are specified in** 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.~~ SRP Section 17.5, Part V, "Non-safety-Nonsafety-Related SSC Quality Controls," ~~addresses of SRP Section 17.5 address graded addresses~~ QA controls for ~~non-RAP SSCs that are not 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 **in the DC application** 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) **establishing and applying** the essential elements of D-RAP during DC design activities, (3) ~~determining the developing a comprehensive list of RAP SSCs (within- the scope of SSCs of the DC application)~~ using a combination of probabilistic, deterministic, and other methods of analysis **used to identify and quantify risk**, and (4) implementing the appropriate ~~graded~~ QA controls ~~for related to~~ for DC design activities for the non-safety-related, ~~within-scope RAP~~ SSCs in accordance with Part V of SRP Section- 17.5. ~~In~~ **In** ~~addition~~, the DC applicant proposes ~~in non-system based in the DC application a~~ Tier 1 inspections, tests,

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analyses, and acceptance criteria (ITAAC) for the COL D-RAP. The NRC verifies the adequacy of the DC applicant's D-RAP, including its implementation during the DC application phase, through the agency's safety evaluation review process, whichas well aswhich may include 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) establishing and applying the essential elements of D-RAP during COL design activities, (2) determining the developing a comprehensive list of SSCs withininwithin the scope of the COL's plant-specific D-RAP (i.e., the RAP SSCs identified in the DC, updated using COL plant-specific information) by introducing plant-specific information into the probabilistic, deterministic, and other methods of analysis, and (3) implementing the appropriate graded-QA controls forrelated tofor COL design activities for the non-safety-related, within scope RAP SSCs in accordance with Part V of SRP Section- 17.5. The NRC verifies the adequacy of the COL applicant's D-RAP, including its implementation during the COL application phase, through the agency's safety evaluation review process, whichas well aswhich may include audits.

InAddIn addition, the COL applicant proposes in its application a process for integrating RAPreliability assurance activities for within scope SSCsRAP 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) the maintenance rule program established through 10 CFR Section 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," (2) the 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 RAP SSCs established in accordance with Part V of SRP Section 17.5, and (4) their service the inservice inspection and, inservice testing, surveillance testing, and maintenance programs.

- Prior—During the COL holder phase priorPrior to initial fuel load, the COL licenseeholderlicensee is responsible for implementing the D-RAP, which includes (1) applying the essential elements of D-RAP during COL design and construction activities, (2) (which includes updating or maintaining the list of RAP SSCs as changes are made to the plant-specific design and PRA), (2) implementing the appropriate graded-QA controls forrelated tofor COL design and construction activities for the non-safety-related, within scope RAP 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).-RAP.

The objective of the RAP during the operations phase of the plant's life cycle is to ensure that the reliability and availability of RAP SSCs are maintained commensurate with their risk significance. The COL licenseeholderlicensee identifies dominant failure modes and integrates RAPreliability assurance activities for within scope SSCsRAP 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 ~~RAP within scope~~ RAP 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~~ identifying the list of ~~RAP within scope~~ RAP SSCs were often ~~difficult~~ ~~inconsistent~~ difficult due to ~~the insufficient~~ the wording of the acceptance criteria in SRP Section- 17.4. ~~In Also, these~~ In addition, the lists of RAP 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 ~~these issues~~ these issues during ~~the~~ the RAP reviews through ~~the~~ requests for additional information (RAIs ~~RAI~~ process RAIs). Review of the responses to the RAIs provided the staff with new insights. Based on the lessons learned and insights gained from these reviews, the staff developed the clarifications provided in this ISG.
- ~~Both~~ Both the staff and DC 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~~ RAP SSC to be at least equal to the reliability assumed in the PRA. However, ~~D-RAP~~ should not ~~solely~~ be based ~~solely~~ on numerical values. ~~because some numerical estimates (e.g.,~~ For one reason, the estimated reliability of each as-built, ~~within scope~~ RAP SSC) ~~may not be available,~~ and the reliability assumed in the PRA may be highly uncertain. For another, the basis for the estimated reliability of each as-built RAP SSC may be the same as, or very similar to, the basis for the reliability assumed in the PRA. Therefore, only calculating and comparing numerical values may not be useful. Finally, additional aspects of ~~D-RAP~~ should be considered in order to address other risk insights and key assumptions ~~and risk insights~~. Therefore, from probabilistic, deterministic, and other methods of analysis used to identify and quantify risk. The staff concluded that implementation of ~~D-RAP~~ should be ~~interpreted as having~~ a process that would control reliability and availability of ~~RAP within scope~~ RAP SSCs. This process includes implementing the appropriate QA ~~program~~ controls programs to provide control over activities affecting the quality of the ~~RAP within scope~~ RAP SSCs. The staff addressed this issue during the RAP reviews using the RAI process. Based on the lessons learned and insights gained from these reviews, the staff developed the clarifications provided in this ISG.
- 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 ~~often~~ ~~inconsistent~~ often difficult due to ~~unclear~~ the

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wording of the acceptance criteria in SRP- Section 17.4. ~~Also, it was~~ In addition, COL applicants, in general, did not ~~clear to the staff that the COL applications should specify~~ describe the essential elements related to their plant-specific ~~D to the COL applicants~~D-RAP. The staff addressed these issues during the RAP reviews using the RAI process. Based on the lessons learned and insights gained from these reviews, the staff developed the clarifications provided in this ISG.

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 ~~clear~~^{sufficient}~~clear~~ 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 ~~from as primary or secondary reviewer from the RAP review.~~
- (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 ~~RAP within scope~~RAP SSCs
 - acceptance criteria for how procurement, fabrication, construction, and test specifications for the ~~RAP within scope~~RAP 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 ~~infer~~in a DC application
 - acceptance criteria for integrating ~~RAP reliability assurance activities for within scope SSCs~~RAP into operational programs to meet the objectives of the RAP

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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

~~While~~While 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 ~~corresponding~~~~related~~corresponding 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.- In addition, while conducting regulatory audits in accordance with Office Instruction NRO-REG-108, "Regulatory Audits," the PRA staff may identify quality-related issues. If this occurs, then the PRA staff should contact the organization responsible for quality assurance to determine if an inspection should be conducted.

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.

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(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. ~~In~~~~Also~~~~In~~ addition, 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 ~~D-RAP~~ essential elements ~~of D-RAP~~ to support DC design activities. These essential elements ~~are processes and controls that ensure that the risk insights and~~ key assumptions ~~and risk insights from probabilistic, deterministic, and other methods of analysis used to identify and quantify risk~~ are consistent with the ~~plant~~ design and that the list of ~~RAP within scope~~ RAP 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. ~~If~~~~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~~

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a. Organization

- 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 ~~plantreactorplant~~ will be designed ~~inconsistently~~ in a manner that is consistent with the risk insights and key assumptions from ~~and risk insights~~ from probabilistic, deterministic, and other methods of analysis used to identify and quantify risk.
- ~~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.~~

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b. Design Control

- The application should describe ~~how the design quality controls for identifying within scope SSCs, including quality controls for design change control process provides a mechanism to notify the appropriate analyses used to identify these SSCs (i.e., probabilistic, deterministic, or other methods appropriate organizations of plant analysis). These quality controls include ensuring plant changes (e.g., changes to the design, programs, and procedures) that the could affect the RAP SSCs (e.g., the design, operation, testing, and maintenance of these SSCs) or relevant D-RAP related inputs (e.g., the list of RAP within scope RAP SSCs, PRA models, risk insights, and key assumptions, and risk insights) are maintained).~~
- The application should describe how the design change control process provides a mechanism to update relevant D-RAP inputs to account for these plant changes.
- The application should describe how the design change control process provides a mechanism to notify the appropriate organizations of changes to relevant D-RAP inputs.
- The application should describe the quality controls that ensure relevant D-RAP inputs (e.g., list of RAP SSCs, PRA models, risk insights, and key assumptions) meet the predetermined requirements, recommendations, or ~~updated, as necessary, and reflect the designed plant specifications.~~ It is acceptable to ~~cite provide cross references to cite~~ the specific sections or chapters of the application that specify these quality controls. For example, describing the quality ~~controlseontrolcontrols~~ of the PRA in Chapter 19 of the application in accordance with the provisions in SRP Section 19.0,

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“Probabilistic Risk Assessment and Severe Accident Evaluation for New Reactors,” and ~~citing~~~~cross-referencing~~~~citing~~ the description in SRP Section 17.4 would be acceptable.

- The application should describe the configuration control process for maintaining the list of ~~RAP~~~~within-scope~~~~RAP~~ 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., are promptly identified, reported, and corrected. For example, information used to identify RAP~~~~within-scope~~~~RAP~~ SSCs ~~may~~~~is~~~~may be~~ determined to be ~~incorrect~~~~in error~~~~incorrect~~, or there ~~may~~~~is~~~~may be~~ 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 ~~RAP~~ Within Scope ~~RAP~~ SSCs

The application should describe an acceptable methodology for ~~evaluating, identifying, and prioritizing the SSCs within~~ ~~according to their degree within the scope of the risk significance~~ the RAP as determined by using a combination of probabilistic, deterministic, ~~and~~ and other methods of analysis ~~used to identify and quantify risk~~. 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, ~~which includes the use of non-~~ ~~(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~~ includes the ~~use of non-PRA-fault tree/event tree-type risk evaluations (e.g., fire-induced vulnerability evaluation or seismic margins analysis)~~ ~~when PRAs have not been performed~~

For example, identification of RAP SSCs based on: importance measures; risk insights and key assumptions from severe accident evaluations; risk insights and key assumptions from full power and low-power/shutdown PRAs for internal events, fire, seismic, flooding, and other external events; and consideration of SSCs implicitly assumed in important operator actions or initiating events that are significant contributors to risk.

- b. industry operating experience
- c. expert panel(s)

~~The~~ ~~The~~ The scope of 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 for inclusion in RAP (e.g., by using deterministic or other methods of analysis). The scope of RAP should include safety-related and non-safety-related SSCs identified as risk-significant (or significant contributors to plant safety). For passive system designs, RAP should also include all SSCs subject to regulatory treatment of non-safety systems (RTNSS).

A.4 Expert Panel

The application should adequately describe 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.~~

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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-comprise members~~ knowledgeable ~~members of the plant and~~ whose ~~collective~~ 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 ~~risk significance determinations~~ using both probabilistic and deterministic information ~~risk significance determinations~~.

A.5 List of ~~RAP~~ Within-Scope ~~RAP~~ SSCs

The application should contain a ~~comprehensive~~ ~~complete~~ ~~comprehensive~~ list of ~~RAP SSCs~~, within- the scope of ~~SSCs of the DC application~~, based on an acceptable methodology that uses a combination of probabilistic, deterministic, ~~and~~ other methods of analysis ~~used to identify and quantify risk~~. The basis or bases for including each ~~RAP~~ within-scope ~~RAP~~ SSC should be described. ~~The within-scope~~ To communicate the ~~RAP~~ SSCs effectively and accurately to the organizations that implement the D-RAP, the ~~RAP~~ SSCs should be clearly identified using text descriptions and specific SSC identification numbers, when applicable. ~~In addition, the boundaries of the RAP SSCs (e.g., electrical, mechanical, and instrumentation and control boundaries) should be clear to provide a common basis for understanding the RAP SSCs (this is important since the RAP SSCs are subjected to QA controls). For example, it would be acceptable to cite the specific documents where these SSC boundaries are defined (e.g., the section of the application that meets the provisions of SRP Section 3.2.2, "System Quality Group Classification," may describe these boundaries for some RAP SSCs).~~

A.6 Process for Determining Dominant Failure Modes

The application should propose an acceptable process for determining dominant failure modes of ~~RAP~~ within-scope ~~RAP~~ 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).

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

For ~~the non-safety-related, within-scope~~ ~~RAP~~ SSCs, the application should specify the ~~graded~~ QA controls ~~for related to~~ for DC design activities in accordance with the provisions in Part V, "~~Nonsafety~~ ~~Non-safety~~ ~~Nonsafety~~-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 ~~cite~~ ~~provide cross-references to~~ cite the specific sections or chapters of the application where these ~~graded~~ QA controls are described.

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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

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The application should specify an ITAAC for the D-RAP to ensure that appropriate controls are applied to the RAP SSCs early in the COL design phase. The objective is to ensure that the design bases and other requirements have been correctly translated into the detailed design documents used for procurement and construction of every RAP SSC. This is achieved through assurance that appropriate controls were imposed during the development of design products for RAP SSCs. Subsequent activities, including system ITAAC, are predicated on the assumption that those products are correct.

This ITAAC includes all RAP SSCs so that no RAP SSC is overlooked. The staff considers the scope of this ITAAC to be fixed when the COL is issued. Subsequent changes to the list can only occur through D-RAP activities, providing adequate assurance that appropriate controls are applied to SSCs that are added to the scope of RAP. Such modifications may change the particular reliability assurance activities that apply to a particular SSC (e.g., a change in safety classification); the acceptance criterion would simply be met by a different D-RAP activity.

Other inspections are relied upon to provide ongoing confidence that the D-RAP activities are effective (e.g., staff inspections to verify implementation of 10 CFR Part 50, Appendix B requirements as well as staff inspections of quality controls applied to SSCs that are not safety-related). These obviate the need for an ITAAC to confirm that the essential elements of D-RAP are accomplished. Other ITAAC will confirm that the construction is correct and the as-built configuration is consistent with the approved design documents.

An acceptable D-RAP ITAAC would include a design commitment that the design of RAP SSCs is consistent with the risk insights and key assumptions from probabilistic, deterministic, and other methods of analysis used to identify and quantify risk (e.g., SSC design, reliability, and availability). An analysis would demonstrate that the initial design of all RAP SSCs has been completed in accordance with the D-RAP. The staff considers the initial design to be complete when approved for procurement or for construction by the responsible design organization of the licensee. The acceptance criterion for the D-RAP ITAAC should ensure that the initial design of all RAP SSCs identified at the time of the COL issuance has been subject to the applicable reliability assurance activities of the D-RAP. These RAP SSC's are those identified at the time of COL issuance.

A.9 COL-~~Applicant~~ Action Items

The DC 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 ~~site-~~ and plant-specific information (e.g., design, program, ~~procedural~~, and organizational information). This includes identifying the SSCs within the scope of the plant-specific ~~RAPD-RAPRAP~~ (i.e., the RAP SSCs identified in the DC, updated using COL ~~site- and plant-specific information~~) 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~~ RAP SSCs in accordance with the provisions in Part V, "~~NonsafetyNon-~~safetyNonsafety-Related SSC Quality Controls," of SRP Section 17.5. This includes providing corrective actions for potential design and ~~pre-~~operational errors that degrade non-safety-related-~~within-scope~~ RAP SSCs.
- c. A COL applicant referencing a certified design should propose a process for integrating ~~RAPreliability assurance activities for within-scope SSCs~~RAP into operational programs (e.g., maintenance rule program, QA program, ~~inservicein-serviceinservice~~ inspection ~~and, inservice~~ testing ~~programs~~, surveillance testing ~~programs~~, and maintenance programs) to meet the objectives of the RAP during plant operation. The ~~processdescription~~process should also address the (1) establishment of reliability, availability, or condition performance goals for the ~~RAPwithin-scope~~RAP SSCs, (2) establishment of performance and condition monitoring requirements to provide reasonable assurance that ~~RAPwithin-scope~~RAP SSCs do not degrade to an unacceptable level of reliability, availability, or condition during plant operations, (3) for ~~the~~ non-safety-related-~~within-scope~~ RAP SSCs, establishment of ~~graded~~ QA controls ~~forrelated tofor activities during the COL-~~operations phase in accordance with the provisions in Part V of SRP Section- 17.5, and (4) ~~considerationuse~~consideration of dominant failure modes of ~~RAPwithin-~~scopeRAP 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 ~~site- and~~ plant-specific information (e.g., design, program, **procedural**, and organizational information). This includes (1) identifying the SSCs within the scope of the plant-specific ~~D~~-RAP; **(i.e., the RAP SSCs identified in the DC, updated using COL site- and plant-specific information)**, 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. **These essential elements are processes and controls that ensure the plant will be designed and constructed in a manner that is consistent with the risk insights and key assumptions from probabilistic, deterministic, and other methods of analysis used to identify and quantify risk.** 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~~ RAP SSCs

For the non-safety-related, ~~within scope~~ RAP SSCs, the application should specify the ~~graded~~-QA controls ~~for~~ **related to** COL design and construction activities ~~(which that~~ **which** include establishing appropriate corrective actions for potential design and **pre**-operational errors that degrade these SSCs) in accordance with the provisions in Part V, "~~Nonsafety~~~~Non-safety~~~~Nonsafety~~-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.

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B.3 Integration of RAP into Operational Programs

The application should propose an acceptable process for integrating ~~reliability assurance activities for within-scope SSCs~~ RAP into operational programs to meet the objectives of the RAP during ~~plant operation~~ the operations phase. The application should ~~cite~~ provide cross-references to cite 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., ~~aaa~~ RTNSS availability controls program).

The proposed process should also address the following activities:

- a. Establishment of reliability, availability, or condition performance goals for the ~~RAP~~ within-scope RAP 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 ~~RAP~~ within-scope RAP 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 based on ~~the basis of~~ actual equipment, train, or system performance and other operational history.)
- c. For the non-safety-related, ~~within-scope~~ RAP SSCs, establishment of ~~graded~~ QA controls ~~for related to~~ for activities during the ~~COL~~ operations phase (which ~~that~~ which include establishing appropriate corrective actions for potential design and operational errors that degrade these SSCs) in accordance with the provisions in Part V, "Nonsafety ~~Non-safety~~ Nonsafety-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. ~~Consideration~~ Use Consideration of dominant failure modes of ~~RAP~~ within-scope RAP 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~~ ~~in-service~~ ~~in service~~ inspection ~~and~~, ~~in service~~ testing, surveillance testing, monitoring, and maintenance) to maintain equipment performance consistent with the risk insights and key assumptions ~~and risk insights~~ for the ~~RAP~~ within-scope RAP 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 ~~all the within-scope~~ all RAP SSCs being categorized as having HSS, (2) QA program for safety-related SSCs established through Appendix B to 10 CFR Part 50 requirements, (3) ~~graded~~ QA controls for non-safety-related, ~~within-scope~~ RAP SSCs established in accordance with Part V of SRP Section- 17.5, and (4) ~~in-service~~ ~~in-service~~ ~~in-service~~ inspection ~~and, in-service~~ testing, surveillance testing, and maintenance programs for the ~~RAP within-scope~~ RAP SSCs to maintain equipment performance consistent with the risk insights and key assumptions.

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 ~~application specifies the D--RAP ITAAC is applied to the design~~ as approved in the DC. (see Section A.8 of this ISG).

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(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.

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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.

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

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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)."

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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-IMC-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.
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