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Advanced Nuclear Technology: Design Reliability Assurance Program Implementation Guidance

2011 TECHNICAL REPORT

Advanced Nuclear Technology: Design Reliability Assurance Program Implementation Guidance

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EPRI Project Manager
K. Barry

ELECTRIC POWER RESEARCH INSTITUTE

3420 Hillview Avenue
Palo Alto, CA 94304-1338
USA

PO Box 10412
Palo Alto, CA 94303-0813
USA

800.313.3774
650.855.2121

askepri@epri.com

www.epri.com

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THE FOLLOWING ORGANIZATION, UNDER CONTRACT TO EPRI, PREPARED THIS REPORT:

ETRANCO, Inc.

NOTE

For further information about EPRI, call the EPRI Customer Assistance Center at 800.313.3774 or e-mail askepri@epri.com.

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The following organization, under contract to the Electric Power Research Institute (EPRI), prepared this report:

ETRANCO Inc.
2430 Hyde Street
San Francisco, CA 94109

Principal Investigators
G. Hughes
G. Zimmerman

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Kenneth	Baity	Babcock & Wilcox Co.
William	Culp	Fluor Enterprises, Inc.
Robert	Gamberg	Duke Energy Carolinas
Jairus	Greene	Mitsubishi Nuclear Energy Systems, Inc.
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James	Jackson	Southern Nuclear Operating Co.
Thomas	Jackson	Southern Nuclear Operating Co.
Joey	Kenley	Southern Nuclear Operating Co.
John	McEntire	AREVA NP Inc. (USA)
Sara	Misic	Babcock & Wilcox Co.
Philippe	Montigny	UniStar Nuclear Energy
John	Moran	Tennessee Valley Authority (TVA)
David	Noxon	AREVA NP Inc. (USA)
Patrick	O'Regan	Electric Power Research Institute (EPRI)
Vish	Patel	Southern Nuclear Operating Co.
Mark	Paul	Dominion Generation

Andrew	Rowland	International TechneGroup, Inc.
Futoshi	Tanaka	Mitsubishi Nuclear Energy Systems, Inc.
Kelli	Voelsing	Electric Power Research Institute (EPRI)
Richard	Wachowiak	Electric Power Research Institute (EPRI)
Russell	Wells	AREVA NP Inc. (USA)
Konstantine	Xoinis	Tennessee Valley Authority (TVA)

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Abstract

Applicants and licensees for design certification (DC) or a combined operating license (COL) are required to establish and implement a design reliability assurance program (D-RAP). The NRC has developed guidance on the program, yet considerable variability may exist. This report describes the details (essential elements) of the D-RAP, including scope, purpose, objectives, framework, and phases of the program. The D-RAP is implemented during the DC or COL period of licensing and during construction leading to turnover, at fuel loading, to the operational programs or Maintenance Rule organization. This report also discusses how to apply the essential elements of D-RAP during the design activities.

Keywords
Design reliability assurance program
D-RAP
Maintenance Rule
O-RAP

Executive Summary

Applicants and licensees for design certification (DC) or a combined operating license (COL) are required to establish and implement a design reliability assurance program (D-RAP). The NRC has developed guidance on the program, yet considerable variability may exist. This report describes the details (essential elements) of the D-RAP, including scope, purpose, objectives, framework, and phases of the program. The D-RAP is implemented during the DC or COL period of licensing and during construction leading to turnover, at fuel loading, to the operational programs or Maintenance Rule organization. This report also discusses how to apply the essential elements of D-RAP during the design activities.

The methodology for categorizing structures, systems, and components (SSCs) to determine those that are within scope and those that are out of scope is discussed. The function of an Expert Panel in the categorization process is described, with information presented about the panel's membership, organization, and responsibilities.

The report identifies the programs that require or involve SSC categorization and treatment, including deterministic criteria, the Maintenance Rule, reliability programs such as AP-913, and the graded quality assurance voluntary program, 10CFR50.69. (Even where this program is not adopted, the guidance provided in 10CFR50.69 is useful in defining the D-RAP scope and in establishing the appropriate treatment for SSCs determined to be within scope.)

Although there are many ways to execute the D-RAP program, it is expected that an applicant or licensee will seek to achieve a simplified implementation of these various programs. The identification of similarities will allow users to achieve the desired SSC reliability and treatment through careful integration of these activities, with reduced cost and impact-enhanced compliance.

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Section 1: Introduction

1.1 Purpose

Applicants and licensees for Design Certification (DCs) or Combined Operating Licenses (COL) are required to establish and implement a Design Reliability Assurance Program (D-RAP) in accordance with NUREG-0800, Standard Review Plan (SRP), Section 17.4. The NRC has developed guidance on the program yet considerable variability may exist. This report benefits from a survey of industry and two workshops supported by key industry personnel involved in D-RAP to develop and present an approach for scoping and treatment of within-scope Structures, Systems, and Components (SSCs), and a typical method of implementing a D-RAP.

The purpose of this report is to:

A. Describe the details (essential elements) of the D-RAP (e.g., scope, purpose, objectives, framework, and phases of the D-RAP) that will be implemented during the DC or COL period of licensing, and during construction leading to turnover at the time of fuel load to the operational program or Maintenance Rule organization.

B. Describe the methods for determining the within-scope SSCs using a combination of probabilistic and deterministic methods of analysis. This includes discussing the workings of a D-RAP Expert Panel.

C. Discuss a reasonable method for addressing the evolving design of a new plant during the post-COL period and the evolving PRA results that will arise as the plant develops additional PRA studies or updates and finalizes a PRA that meets the requirements of 10CFR50.71(h)(1) (i.e., a PRA that meets all standards in effect one year before fuel load).

D. Discuss guidelines for implementing the appropriate graded QA controls related to design activities for the non-safety-related, within-scope SSCs in accordance with Part V, Nonsafety-Related SSC Quality Controls, of NUREG 0800, Standard Review Plan (SRP), Section 17.5.

E. Discuss the Inspection, Testing, Analyses, and Acceptance Criteria (ITAAC) and provide recommendations for closure at fuel load.

F. Address the transition from design stage to operating stage and the operational program reliability assurance activities, which may be addressed by simply turning the information over to existing plant organizations and programs such as the maintenance rule team for continuation during operation.

1.2 Regulatory Guidance

Regulatory Guidance is specified in NUREG-0800, Standard Review Plan (SRP) Section 17.4, "Reliability Assurance Program," and clarified in the Interim Staff Guidance on Standard Review Plan, Section 17.4, (DC/COL-ISG-18). Both documents are discussed in more detail in Section 2.2 (ISG-18 is included as Appendix A.)

1.3 Report Scope

This report seeks to set forth the key insights and practices related to the implementation of a program to comply with the D-RAP requirements in Section 17.4 of the SRP, NUREG-0800, as described in guidance provided by the NRC in ISG-18. This report seeks to provide information to those who may seek to implement the key aspects of ISG-18 in a reasonable fashion given the other requirements and programs impacting the selection of SSCs for treatment and the resultant treatment to be applied.

D-RAP is a program to define those SSCs that are safety significant so that appropriate controls can be applied to the procurement, installation, testing, and operation of those SSCs. They may be Safety Related or Not Safety Related. For those that are Safety Related there are no additional treatment actions beyond Safety Related requirements. For those that are Not Safety Related some additional treatment is required. As a result this report focuses mostly on the addition of Non Safety Related SSCs to the list of SSCs requiring treatment.

The D-RAP program represents a necessary element (for new plants under 10CFR52) of the actions to define SSC requirements. To achieve efficiency and consistency the report discusses possible ways for these programs to be rationalized or combined in an effective approach. Key programs involved in SSC review and determination are indicated in Figure 1-1.

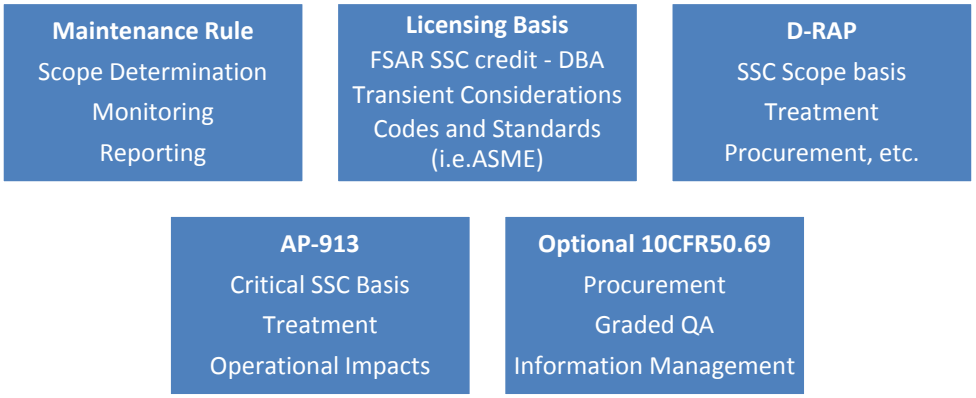

Figure 1-1
Programs (Required and Optional) Involving SSC Treatment

Each of these programs involves, to one degree or another, developing a set of criteria, making a determination of scope and treatment, and maintaining that information for plant construction and operation. Simplification and consistency is likely to be a high priority in implementation of these programs.

Of these programs, it is noted that the D-RAP is very similar to the optional 10CFR50.69 program in defining and treating SSC scope through use of an Expert Panel and including consideration of both PRA importance measures and deterministic criteria. In 10CFR50.69, the definition of RISC-2 components – not safety-related, but safety-significant – generally matches the part of the D-RAP scope description, which includes SSCs also defined as non safety related but safety significant SSCs. Likewise 10CFR50.69 RISC-1 components are Safety Related and Safety Significant which are also defined identically in D-RAP but for which neither 10CFR50.69 nor D-RAP applies any special or adjusted treatment. The relationship to 10CFR50.69 is not a requirement but the guidance for implementing 10CFR50.69 is plentiful, addresses the Expert Panel as well as scope determination processes, and offers a key set of insights into the development of a D-RAP. Elements of the implementing programs for 10CFR50.69 have been referenced and used by licensees in responding to NRC RAIs.

A new plant applicant or license holder is not required to adopt 10CFR50.69 as this remains a voluntary program. The comparison and use of guidance from 10CFR50.69 in this report does not endorse such a program, but does suggest that benefit can be obtained from the work already done in this area. Further, a subsequent decision to implement 10CFR50.69 would be simplified by using 10CFR50.69 guidance during the D-RAP implementation. In addition the focus is on SSCs requiring additional special treatment which are limited to RISC-2 type components.

Similarly, as shown above in Figure 1-1, this report notes that the Maintenance Rule, which may be implemented along with a reliability program such as INPO AP-913, requires classification of SSCs. INPO AP-913 uses different language

to define critical SSCs. These may also be part of the set of integrated requirements that plants face in achieving both compliance and high reliability. Achieving congruence among these programs is a desirable result of the implementation of the elements of each.

Since there is already a great deal of work completed by these other programs, this report relies on guidance in several other existing reports that are used to implement specified NRC regulations or meet industry standards for excellence. For instance, whether or not an applicant or licensee chooses to implement 10CFR50.69 or the 10CFR50.69 Risk Informed Safety Categorization methodology, the following documents may be useful in the effort to develop and implement a successful D-RAP program:

- NEI 00-04, "10CFR50.69 SSC Categorization Guidelines,"
- EPRI 1015099, "Option 2, 10CFR50.69 Special Treatment Guidelines," and ASME Code Case N-660,
- EPRI 1009748, "Guidance for Accident Function Assessment for RISC-3 Applications, Alternate Treatment to Environmental Qualification for RISC-3 Applications,"
- EPRI 1011783, "Risk Informed Safety Categorization (RISC-3) Seismic Assessment Guidelines,"
- EPRI 1021415,"Equipment Reliability for New Nuclear Plant Projects: Industry Recommendations for Design."
- EPRI 1021416, "Equipment Reliability for New Nuclear Plant Projects: Industry Recommendations for Procurement."
- EPRI 1021413, "Equipment Reliability for New Nuclear Plant Projects: Industry Recommendations for Storage, Construction, and Testing."

1.4 Acronyms and Abbreviations

APR	Advanced Power Reactor
CDF	Core Damage Frequency
COL	Combined License (10CFR52.1 Definition)
cROP	Construction Reactor Oversight Program
DC	Design Certification
DID	Defense In Depth: the application of deterministic and operational features that compensate for events that have a high degree of uncertainty with significant consequences to public health and safety.
D-RAP	Design Reliability Assurance Program
F-V	Fussel-Vessely

HSS	High Safety Significance
IDP	Integrated Decision-Making Panel
INPO	Institute of Nuclear Power Operations
ISI	Inservice Inspection
ISG	Interim Staff Guidance
IST	Inservice Testing
ITAAC	Inspections, Tests, Analyses, and Acceptance Criteria
LERF	Large Early Release Frequency
LSS	Low Safety Significance
M-Rule	Maintenance Rule (10CFR50.65)
NEI	Nuclear Energy Institute
OQAP	Operational Quality Assurance Program
PM	Preventive Maintenance
PRA	Probabilistic Risk Assessment
RAW	Risk Achievement Worth
RCOLA	Reference Combined Operating License Application
RISC	Risk Informed Safety Categorization
RRW	Risk Reduction Worth
RTNSS	Regulatory Treatment for Non Safety-related Systems
SECY	Written papers prepared by NRC Staff for Commissioners on specific issues
SRM	Staff Requirements Memorandum
SRP	Standard Review Plan
SSAR	Standard Safety Analysis Report
SSC	Structures, Systems, and Components
URD	Utility Requirements Document

Section 2: Background

2.1 General

Historically, the reliability of safety-related SSCs has been assured by implementation of several requirements and programs, i.e., a Quality Assurance (QA) Program involving quality control during design, procurement, construction, and operation; a startup and preoperational testing program; the Maintenance Rule (M-Rule) and periodic inspections and testing, e.g., Inservice Inspection (ISI) and Technical Specification Surveillance.

Generally, non-safety-related SSCs are not included in these existing programs although some have been incorporated into Technical Specification Surveillances and Administrative Requirements. With the advent of risk assessment techniques and methodologies, some non-safety-related SSCs have been found to be important to safety and the issue of adequate confidence in their performance has arisen. Likewise the PRA analyses have shown that in many cases the Safety Related SSCs are actually not safety significant. The D-RAP program does not address, add or change requirements for Safety Related SSCs. It does require special treatment for Non Safety Related but risk significant SSCs. In 10CFR50.69 Safety Related SSCs are divided into safety significant requiring full treatment and non safety significant for reduced treatment.

Applicants for DC/COL under 10CFR52 are required to provide evidence of the implementation of a D-RAP for design and construction in accordance with SRP 17.4 and using ISG-18 or an equivalent. The D-RAP defines and addresses SSCs that are identified as being significant contributors to plant safety by using a combination of probabilistic and deterministic methods of analysis. These are called "Within-scope." Supplemental activities associated with the design, procurement, and construction/installation of non-safety related but important to safety (e.g., safety significant) SSCs are also defined The D-RAP is described in Section 17.4 of the DC or COL Application FSAR and the applicant either adopts the guidance in ISG-18 or provides a justification for the different approach taken.

The NRC in ISG-18 separated Reliability Assurance (RA) into two phases: a design phase RAP (D-RAP) and an operations phase. The operations phase is generally viewed as implementation of existing programs such as the Maintenance Rule.

The M-Rule, 10CFR50.65, requires a licensee to demonstrate reasonable assurance that SSCs within the scope of the M-Rule are capable of fulfilling their intended functions over the plant lifetime, including design, procurement, and construction/installation. The M-Rule requires licensees to determine those SSCs that are subject to the monitoring program of the rule. The methodologies for determining those SSCs subject to the rule are similar to D-RAP criteria and can be deterministic or probabilistic but have to be identified and described.

10CFR50.69 is a voluntary regulatory program that if implemented requires SSCs to be categorized into the appropriate Risk Informed Safety Category (RISC) depending upon their safety significance determined using probabilistic and deterministic methods. The categorization must be performed by an Integrated Decision-Making Panel (IDP). The discussion of the IDP closely tracks the requirements for the Expert panel of D-RAP. The four RISC categories are identified in Table 2-1.

Table 2-1
Categorization of SSCs in Accordance with 10CFR50.69

RISC-1 Safety Related Safety Significant	RISC-2 Non Safety Related Safety Significant
RISC-3 Safety Related Not Safety Significant	RISC-4 Non Safety Related Not Safety Significant

2.2 Regulatory Requirements Applicable to D-RAP

There is a long regulatory history regarding D-RAP and its applicability to new plant licensing. This section discusses the most recent guidance and the preceding history.

2.2.1 Recent Regulatory Guidance In ISG-18

The early effort to establish the program is discussed below. The early implementation has been described by the NRC as in need of additional clarification. This is the reason for the development and issuance of ISG-18.

Some applicants focused more on the numerical reliability than the NRC intended. This is addressed in NUREG-0800, Section 17.4.B.4.b which states' "The reliability performance monitoring does not need to statistically verify the numerical values. However, it provides a feedback mechanism for periodically evaluating equipment reliability on the basis of actual equipment, train, or system performance and other operational history."

In addition, the establishment of within-scope SSCs was described by the NRC as lacking consistency. Through ISG-18 the NRC has sought to clarify the intent of the requirement and issued regulatory guidance and engaged in more

detailed reviews to clarify the program and its intent. To some degree this clarification is still occurring as reviews are conducted, ITAAC discussed, and the NRC Staff Evaluation Reports are being written.

ISG-18 is guidance and need not be adopted, yet it is generally referenced and used as a guide by current license applications.

ISG-18 is the most current and detailed defining document for D-RAP and provides detailed guidance for the development of a D-RAP. The final version of ISG-18 was issued in July, 2011.

ISG-18 (provided as Appendix A) states that:

> "The purpose of the RAP is to provide reasonable assurance of the following:
>
> 1. A plant is designed, constructed, and operated in a manner that is consistent with the risk insights and key assumptions (e.g., SSC design, reliability, and availability) from the probabilistic, deterministic, and other methods of analysis used to identify and quantify risk.
> 2. The RAP SSCs do not degrade to an unacceptable level of reliability, availability, or condition during plant operations.
> 3. The frequency of transients that challenge these SSCs is minimized.
> 4. These SSCs will function reliably when challenged."

It also states that:

- "The RAP applies to those systems, structures, and components (SSCs), both safety-related and non-safety-related that are identified as being -safety significant (or significant contributors to plant safety)."
- "The SSCs within the scope of the RAP are identified by using a combination of probabilistic, deterministic, and 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 application should describe the configuration control process for maintaining the list of RAP SSCs.
- "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 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."
- "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."

D-RAP should include 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-fault tree/event tree-type risk evaluations (e.g. fire-induced vulnerability evaluation or seismic margins analysis).

2.2.2 Regulatory History

The Reliability Assurance Program (RAP) first appeared in SECY-89-013, "Design Requirements Related to the Evolutionary Advanced Light Water Reactors (ALWRS)," dated January 19, 1989, as a proposed method to "… ensure that the reliability of those systems, structures, and components (assumed in analyses) will be maintained throughout plant life. Therefore, a program to ensure design reliability must be provided as part of the FDA [Final Design Approval] application."

On April 2, 1993, in SECY-93-087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Design," the NRC Staff provided an interim regulatory position on D-RAP "… as a non-system generic Tier I requirement with no associated ITAAC," and "…the conceptual framework, program structure, and essential elements, should be provided in the SSAR." The SECY paper also stated that the SSAR should "…1) identify and prioritize a list of -safety significant SSCs based on the design certification PRA and other sources, (2) ensure that the vendor's design organization determines that significant design assumptions, such as equipment reliability and unavailability, are realistic and achievable, (3) provide input to the procurement process for obtaining equipment that satisfies the design reliability assumptions, and (4) provide these design assumptions as input to the COL for consideration in the operational reliability assurance program (O-RAP)."

Subsequently, in SECY-94-084, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems [RTNSS] in Passive Plant Designs," dated March 28, 1994, the Staff provided a Final Position on RAP, item E., as follows:

> "The staff's position is, for design certification of all ALWRs, a RAP applicable to design certification (D-RAP) should be required, and for a COL application that references a certified design, a RAP plan (augmented D-RAP and O-RAP) and inspections, tests, analyses, and acceptance criteria (ITAAC) should be required. The SSAR should

include the details of the D-RAP, including the conceptual framework, program structure, and essential elements. The SSAR for the D-RAP should also (1) identify, prioritize, and list the safety significant SSCs based on the design certification PRA, deterministic methods, such as, but not limited to, nuclear plant operating experience and relevant component failure data bases; (2) ensure that the design certification applicant's design organization determines that significant design assumptions, such as equipment reliability and unavailability, are realistic and achievable; (3) include design assumption information for the equipment procurement process; and (4) provide these design assumptions to the COL for consideration in the O-RAP."

The Commissioners provided comments on Regulatory Treatment of Non-Safety Systems (RTNSS) and directed the Staff to provide additional guidance on RTNSS and RAP.

SECY-95-132, "Policy and Technical Issues Associated With the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs (SECY-94-084), Responses to Staff Requirements Memorandum (SRM) on SECY-94-084 dated May 22, 1995, Item A Regulatory Treatment of Non-Safety Systems (RTNSS)," the Commission (with all Commissioners agreeing) approved the staff's recommendation on RTNSS with the caveat that the Westinghouse comments on the graded-safety classifications and requirements for I&C systems as stated in the attachment to NTD-NRC-94-4145, should be accommodated. In addition, the Staff provided additional clarification and interpretation in applying RTNSS and RAP.

The SRM approved a design reliability assurance program (D-RAP) subject to resolution of the recommendation by the Office of the General Counsel (OGC) to implement the D-RAP using the inspections, tests, analyses, and acceptance criteria (ITAAC) process. The SRM disapproved the staff's proposal that an operational reliability assurance program (O-RAP) be continued for the life of the combined license (COL). In response to the instructions of the SRM, the staff modified SECY-94-084 to: 1) revise the statement of purpose of the reliability assurance program; 2) require the use of the maintenance rule methodology for performance monitoring so that industry design reliability assumptions are not translated into new regulatory requirements; 3) require the D-RAP to be verified using the ITAAC process; 4) remove the requirement that a separate O-RAP exist for the life of the plant; and 5) incorporate the objective of the O-RAP into existing programs. These clarifications are reflected in the revised text of SECY-94-084.

NUREG-0800, Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition, Section 17.4, was revised in March 2007 to add Section 17.4, Reliability Assurance Program. SRP Section 17.4 states:

> "The RAP applies to those systems, structures, and components (SSCs) that are identified as being significant contributors to plant safety as determined by using probabilistic/PRA, deterministic, or other methods of analysis, including information obtained from sources such as the plant- and site-specific PRA, industry operating experience, relevant component failure data bases, and expert panels. The purposes of the RAP are to provide reasonable assurance that:
>
> 1. a reactor is designed, constructed, and operated in a manner that is consistent with the assumptions and risk insights for these SSCs,
> 2. these SSCs do not degrade to an unacceptable level during plant operations,
> 3. the frequency of transients that challenge SSCs is minimized, and
> 4. these SSCs function reliably when challenged."

Interim Staff Guidance (ISG)-18: In 2009, the NRC provided additional regulatory requirements and guidance in ISG-18, which was issued for industry review. ISG-18 was finalized in March 2011 and further defines NRC Staff roles and responsibilities, provides relevant discussion issues for Staff consideration, identifies specific elements required for implementation of RAP, and clarifies various aspects of SRP 17.4 as described in Section 2.2.1 above.

Additional Regulations: Two other regulations are also directly or indirectly applicable to the incorporation and implementation of D-RAP:

> 10CFR50.65, Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants, establishes the requirements for maintaining SSCs at operating nuclear power plants, and ensuring their reliability. The NRC directed the staff to require the operations reliability assurance programs to incorporate and comply with 10CFR50.65.
>
> 10CFR50.69, Risk-Informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power Reactors. Application of this regulation is voluntary but the guidance for categorization of SSCs can be useful in the scoping of a D-RAP.

Additional Guidance: NRC Regulatory Guide 1.201, Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance, was issued in 2006. Regulatory Guide 1.201 endorses NEI 00-04 for Categorization of SSCs with limitations and caveats but is also a useful reference for the categorization process.

Section 3: D-RAP Description

3.1 General

A general description of the D-RAP Process is provided in Figure 3-1. ISG-18 provides guidance for the format and the key elements of a D-RAP and provides a description of the minimum information necessary to develop, implement, and describe the D-RAP. A copy of ISG-18 is provided as Appendix A.

There are basically two phases to the implementation of a D-RAP: the scoping phase and the treatment phase. The scoping phase involves the categorization of SSCs, which determines those SSCs that are within-scope of the D-RAP. The treatment phase involves the application of appropriate rules, regulations, codes, and standards to ensure the within-scope SSCs will maintain their function during the life of the plant.

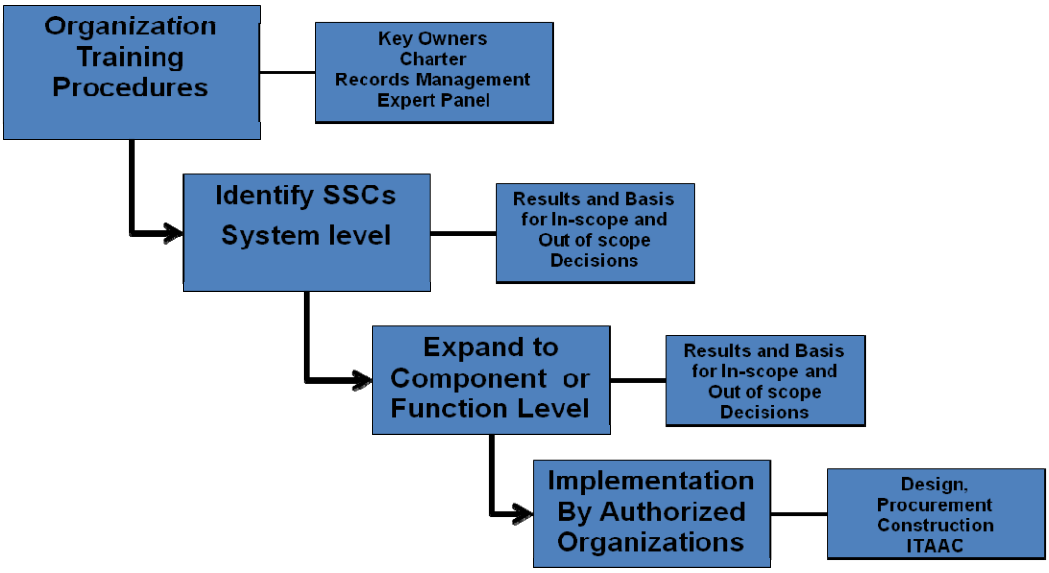

Figure 3-1
Overview of the D-RAP Process

3.2 Key D-RAP Elements

The D-RAP key elements identified in ISG-18 are to be described in the Standard Safety Analysis Report (SSAR) and defined in a procedure or instruction that establishes the D-RAP (referred to as a charter). The initial element of the D-RAP is a general description. ISG-18 states that the "description should include a discussion of the scope, purpose, objectives, framework, and phases of the D-RAP," and "… who is responsible for implementing the various phases of the D-RAP." Defining the program involves addressing the various activities in both the SSAR and D-RAP charter. The D-RAP key elements are:

- Organization

  An important feature of the D-RAP is a description of the organizations involved in establishing and implementing the various activities of the D-RAP. The description of the organization summarizes the responsibilities of each organization involved in establishing the scope and implementing the D-RAP. If Working Groups are created to perform initial categorization, they should be described by membership, roles, and responsibilities. Interfaces between the various organizations should be described.

- Design Control

  Identification of the process for reviewing and considering design changes and the impact on the PRA and D-RAP scope determination is critical for implementation of the D-RAP. A description of the process for updating the PRA during design and construction as well as how changes to the PRA are evaluated for effects on the D-RAP is important. Prior to fuel load the licensee is expected to have evidence that the D-RAP scope determination is correct, documented, and effectively implemented in the various activities of procurement, installation, and testing.

- Procedures and Instructions

  The procedures and instructions that implement the D-RAP for the organizations and processes involved are also important elements of the D-RAP. It is expected that a charter will exist and that organizational responsibilities developed and implemented in accordance with the established charter.

- Corrective Action Processes

  The D-RAP program is expected to be within the Corrective Action Program to assure that all activities are subject to self-identification of problems and correction.

- Records

  The process and method for creating records of D-RAP activities and record keeping are described in the SSAR and D-RAP charter or implementing procedures.

- Audits

  Audits are a part of the implementation of the oversight by the QA Program that ensures the D-RAP activities are conducted in accordance with the charter.

- Methodology for Identifying In-Scope SSCs

  The methodology for identifying within-scope SSCs is discussed in Section 5. The approach used by the applicant or licensee is a key element described in the SSAR and charter for the D-RAP.

- Expert Panel

  The Expert Panel is described in detail in Section 4 below. The purpose of the Expert Panel [Integrated Decision-Making Panel (IDP) in 10CFR50.69] is to determine the Scope of the D-RAP Program by considering both PRA insights and deterministic inputs in an integrated fashion. A procedure that describes the membership of the Expert Panel, their roles and responsibilities, the minimum qualifications of the members, the reporting responsibilities of the Expert Panel, how meetings are conducted and recorded, how decisions are made, and the minimum frequency of meetings (see Section 4 below) is necessary.

- List of Within-Scope SSCs

  A list of the SSCs that are determined to be within-scope are provided in the D-RAP and SSAR. This list is expected to evolve during design and with upgrades to the PRA.

- Graded QA Controls Related to DC Design Activities for Non-Safety-Related, Within-Scope SSCs. These are described in 17.5 of the SRP, NUREG -0800.

- ITAAC for D-RAP

  The ITAAC for the D-RAP provides reasonable assurance that the plant is designed in a manner that is consistent with the key assumptions and risk insights for the within-scope SSCs. Acceptance criteria for D-RAP ITAAC would ensure that documentation exists that:

  - Identifies the SSCs within the scope of the D-RAP
  - Shows that quality requirements for the safety related safety significant SSCs are identified in documents approved for procurement and construction in accordance with 10CFR50 Appendix B quality program.
  - Shows that quality requirements for the non-safety, safety significant SSCs are identified in documents approved for procurement and construction in accordance with the D-RAP.

Confirmation of these Reliability Assurance (RA) 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.

3.3 D-RAP Program Implementation

3.3.1 Overview

After the D-RAP program is established and charter issued, organizations identified and procedures prepared, the program is implemented in two phases:

- a scoping phase, and
- a treatment phase.

The scoping phase involves determining the within-scope SSCs and the treatment phase involves describing and establishing the treatment and controls on the within-scope SSCs.

3.3.2 Scoping

The within-scope SSCs are determined by a documented categorization process. Both PRA and deterministic methods are addressed and used by the Expert Panel to establish the D-RAP Scope and the Basis for the determination. A determination that an SSC is within scope by one method (e.g. PRA) may make it unnecessary to consider the other method (e.g., deterministic). Either PRA or deterministic considerations are sufficient to place an SSC within scope. Both are not required. Operational experience is appropriately considered.

The ultimate determination of the categorization is made by the Expert Panel. The process for categorization is documented and the within-scope SSCs listed (see Section 5). The procedures and practices of the Expert Panel may rely on consensus or require unanimous agreement as decided by the Panel. It is expected that a minority opinion may be appealed for further consideration.

The determination of within-scope SSCs under D-RAP is a dynamic process. Figure 3-2 shows the key steps of D-RAP from the Expert Panel to the development and maintenance of the list of within scope SSCs and subsequent treatment. The need during construction to maintain and revisit the scope results from the design being finalized, the PRA being revised and completed, and implementation through procurement and installation which will undoubtedly develop issues to be resolved by the Expert Panel. The design evolution is shown in the chart on the second line. The third line shows the PRA evolution, which results in the same need. In actuality, the Expert Panel may function for the entire plant lifetime or be replaced in the operations phase with another panel authorized to perform the same function. In the chart this is shown as the arrow even after operation that points to the Expert Panel. In this situation, the Expert Panel would be the one (or alternate) in place during operation.

As an example of the dynamic process involved during construction, it is noted that at licensing the Fire PRA is sufficient but still incomplete due to many reasons including evolving cable location and routing information. In addition, the PRA for other hazard groups will be undergoing refinement as further information is obtained and procedures are completed. Technical specifications are being prepared and will impact the PRA model. These factors could change the PRA Importance measures and could impact the scope determination for D-RAP.

As a result, the D-RAP program is dynamic and will include periodic meetings to assure adequate development and maintenance of the Within-Scope D-RAP list.

The Expert Panel function over time will be enhanced if the information is developed and maintained for all components, that is, those within-scope and their basis as well as those out of scope and their basis. This will reduce the effort if required to revisit decisions made earlier to confirm or revise as appropriate.

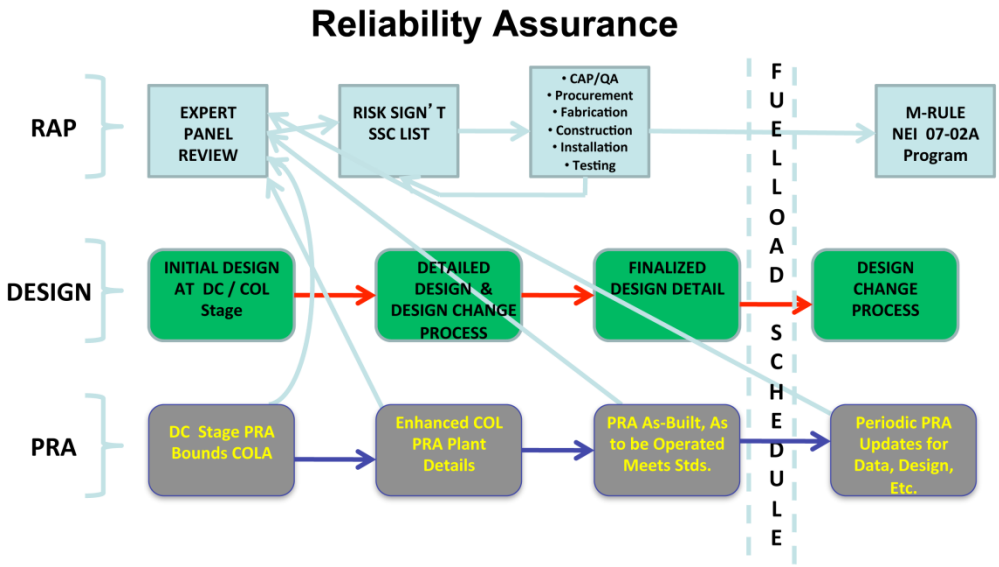

Figure 3-2
Relationship of D-RAP to Design and PRA Programs

3.3.3 Treatment

As stated previously, the work to define treatment for 10CFR50.69 categories can serve as a guide if not a prescription for the development of treatment for SSCs that are in D-RAP scope. The RISC-2 SSCs are neither subject to full Safety Grade treatment nor treated as purely commercial grade. In the 10CFR50.69 methodology, the RISC 2 SSCs are not Safety Grade, but being important to safety (as is also true of Within-Scope D-RAP SSCs) deserve some treatment above commercial. Those SSCs that are defined as RISC 3 are originally Safety Grade, but due to their lack of safety significance may be given lower than full Safety Grade treatment. D-RAP does not address the

requirements for this group of SSCs. All Safety Grade SSCs are treated under deterministic programs not impacted by D-RAP. It is up to the applicant or licensee to define the treatment applicable to the within scope and Safety significant but not Safety Related SSCs defined by D-RAP (also called RISC 2 in 10CFR50.69).

Since the last three groups are specified to receive "special treatment" during DC and COL phases, it is up to the applicant to define the treatment which might be similar. For new plants that have not yet procured the SSCs, the separation between D-RAP treatment and RISC 2 treatment as well as the difference with RISC 3 treatment (if 10CFR50.69 is adopted) would be a matter of choice. As a result, the definitions in 10CFR50.69 can serve as a guide to D-RAP treatment of Within-Scope SSCs.

Much work has been done to define treatment for RISC-3 SSCs. It is possible for this to be used to help define the treatment for D-RAP within scope but not Safety Related SSCs.

Table 3-1
Comparison of SSC Classification with Class Definition and Treatment

SSC CLASSIFICATION	CLASS DEFINITION	TREATMENT
D-RAP Within-Scope SSCs	Safety Related and Safety Significant	Treat as Safety Related i.e. No Change
D-RAP Within-Scope SSCs	Non Safety Related but Safety Significant	"Special" in New Plants Greater than Commercial Treatment
RISC 2 SSCs	Not Safety Related but Safety Significant	"Special" in New Plants Greater than Commercial Treatment
RISC 3 SSCs (only if 10CFR50.69 is adopted)	Safety Related but not safety Significant	"Special" in New Plants Less treatment

Treatment is defined in EPRI Report 1015099, "Option 2, 10CFR50.69 Special Treatment Guidelines," as "Activities, processes, and /or controls that are performed or used in the design, installation, maintenance, and operation of SSCs as a means of the following:

- Specifying and procuring SSCs that satisfy performance requirements
- Verifying over time that performance is maintained
- Controlling activities that could impact performance
- Providing assessment and feedback of results to adjust activities as needed to meet desired outcomes."

For comparison, ISG-18 states the COL licensee is responsible for implementing the D-RAP including:

- 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.
- 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 RAP SSCs.

ISG-18 goes on to state that: SRP Section 17.5, Part V, "Non-safety-Related SSC Quality Controls," addresses QA controls for RAP SSCs that are not safety-related.

The discussion of QA controls from SRP 17.5 is attached in Appendix B.

Section 4: Expert Panel

4.1 Organization

A procedure, policy, or formal charter is required to establish an Expert Panel for D-RAP if it is to be used to implement the program. Thus far use of an Expert Panel is standard practice among the applicants. The functional organization to whom the Expert Panel reports is to be identified as well as the authority for appointing the members of the Expert Panel. The Expert Panel is generally staffed with plant-knowledgeable members whose expertise includes, at a minimum, PRA or risk and reliability analysis, safety analysis, licensing, plant operations, maintenance and work control, and design or system engineering.

A member of the Expert Panel might represent more than one area of expertise but the roles and responsibilities need to be clearly defined. It is expected that the Expert Panel will normally consist of five or more members, which is consistent with NEI 00-04 and Regulatory Guide 1.201. The Expert Panel members will normally have five or more years experience in their areas of expertise. The PRA member of the Expert Panel is expected to have worked on the modeling and updating of the PRA for similar plants for three years or more.

The roles and responsibilities of each member are established by the charter. A chairman, vice chairman, and recording secretary are usually designated. If there is a need for alternates for the members, this can be established in the Charter or procedures.

4.2 Responsibilities

The Expert Panel is normally responsible for the categorization of SSCs for D-RAP. The Expert Panel considers both PRA and deterministic insights in establishing the scope of D-RAP. Practically, this means that they may use or rely on quantitative risk assessment or insights, derived by the PRA member and shared with the group for SSCs modeled in the PRA, or deterministic risk methodology, or a combination of both, to categorize the SSCs. It is further expected that the Expert Panel use operating experience and expert judgment in reaching their decisions. The basis for their decision is documented and recorded so that it can be revisited if required and communicated effectively to implementing organizations. The Expert Panel creates the list of the within-scope SSCs. The methodology for categorizing the SSCs is described in a following section.

The Expert Panel is responsible for assuring that the list of within-scope SSCs is maintained, which requires periodic reviews of design changes to ensure there are no changes to the program. The Expert Panel may elect to complete its work with the definition of within-scope SSCs and basis for D-RAP or, if allowed by the Charter, recommend revisions or adjustments to operations, maintenance, and testing activities for D-RAP within-scope SSCs. It is noted that implementing organizations have great expertise in this area and that the scope determination is a large task making it likely that the implementation would be left to other organizations. This is a decision the applicant or licensee will make and define in the charter and procedures.

4.3 Process

The Expert Panel charter or implementing procedures would establish the frequency of Expert Panel meetings, which might be quarterly or more often, particularly in the initial stages of the process. The charter and implementing procedures establish how decisions are made, whether by consensus or majority, and how dissenting opinions are dealt with. Meetings, decisions, and other actions are expected to be documented.

The Expert Panel is expected to make the final determination of within-scope SSCs. As a by-product the panel will also decide which SSCs are not within-scope and establish the basis for the scope decision including the system or component boundary and assumptions. As plant design changes are made during Design Certification or Combined Licensing, or during construction, SSCs may be affected and the Expert Panel will have to periodically evaluate the categorization of SSCs.

Section 5: Methodology for Categorization

5.1 General/Scoping

The categorization of SSCs is a dynamic process. It uses both PRA and deterministic inputs to evaluate the significance of the SSC and its role relative to achievement of overall safety. In its simplest form, traditional regulatory and design practices define Safety Grade or safety Related SSCs as SSCs whose failure are capable of causing an accident, plus those that are used to mitigate an accident, as well as those that are required to establish safe and orderly shutdown. All other SSCs are traditionally non safety grade, although special types of challenges have led to some specific areas of required treatment. The Safety Related SSCs are subject to Seismic Category I requirements and are under the 10CFR50 Appendix B QA program. This is not changed by identifying that they are within scope for D-RAP.

This traditional deterministic approach is augmented by D-RAP to define the safety significance as an additional attribute. Those SSCs that are non safety grade but are safety significant using the integrated D-RAP process are defined as within-scope and subject to alternative treatment. Under the optional program outlined in 10CFR50.69 this distinction is expanded to recognize that some Safety Grade SSCs are nonetheless not safety significant and also may be given less rigorous (special) treatment.

Categorization in the D-RAP program is required to consider both deterministic evaluations and PRA (i.e., probabilistic risk assessment studies and insights from the PRA practitioner regarding the implications of the studies and the assumptions in them). Deterministic evaluations include consideration of potential for SSCs to cause transients, role in severe accident procedures, impact on defense in depth and safety margins, as well as operational experience considerations.

5.2 System Management, Names and Boundaries

It is important to keep in mind that the categorization process is an ongoing dynamic process. There may be only 20-30 systems considered in the PRA while there are closer to 80 systems in the plant. The names of the systems in the PRA may be similar or identical to the plant systems but may represent different sets

of components and functions. For example, instrumentation may be part of a system or included in a separate instrumentation and control system. The names of the systems and components, and the assumptions regarding dependencies, need to be explicitly defined.

The PRA itself carefully defines systems and components included in simplified diagrams of the system. It is quite common for the PRA system to exclude from consideration certain appurtenance or components that are only used for local instrumentation when they have no safety function. Likewise, the PRA ground rules for inclusion in the model may exclude normally locked open or locked closed valves. In addition, the PRA focuses on only core damage and large early release and by so doing excludes potential serious release from radioactive waste handling or other systems.

The consideration of PRA inputs to the process benefits from the PRA representative on the Expert Panel describing the limitations of treatment in the PRA. This individual may also be able to provide considerable information regarding the basis for exclusion and also offer opinions on the areas not modeled.

The PRA typically models about 3,000 components while the plant will have perhaps 20 times that many components. An example is the emergency diesel generator, which is only one component in the PRA yet comprises several thousand components in the plant. The reason for the composite treatment is the fact that the data exists at the Emergency Diesel Generator level, rather than at the component or sub-component level. Thus the PRA conforms to the available failure data. The PRA representative can define the critical function and share with the Expert Panel insights regarding component significance.

In addition, the PRA presupposes certain initiating events based upon data without performing in many cases evaluations of the potential for a component failure to lead to such an initiator. The PRA representative can provide considerable insight as to the importance of initiators and the need to include components based upon their potential to cause a plant transient.

5.3 PRA Methodology

The determination of safety significance may rely on PRA analyses and use the criteria of NEI 00-04. For the cases in which the SSC is explicitly modeled in the PRA the importance measures Risk Achievement Worth (RAW) and the Fussell-Vesely (F-V) value can be used as screening tools to determine the safety significant SSCs. Such analyses also need to address potential common cause contribution. Generally accepted but not uniform criteria for determining safety significance are:

- Sum of F-V for all basic events modeling the SSC of interest $\geq$ 0.005
- Maximum of component basic event RAW values $\geq$ 2
- Maximum of applicable common cause basic events RAW $\geq$ 20

If any of these or similar criteria adopted by the Expert Panel are exceeded, the SSC being evaluated is considered safety significant. Examples of the application of these criteria are provided in NEI 00-04. It is noted that the PRA representative may have information regarding conservative or even optimistic interim treatment that might be expected to change as design detail is enhanced. It is important for the representative to share this information with the Expert Panel.

5.4 Deterministic Approach

The goal for deterministic categorization is to determine if the failure of the SSC will create a challenge to safety or adversely impact or degrade an important function.

To assure completeness, clarifying considerations for categorizing SSCs deterministically include questions such as:

- Is the SSC credited in the design basis analysis?
- Is the function considered important in the Safety Analysis Report?
- Do the SSC failure modes affect multiple trains/systems?
- Is the SSC used in severe accidents?
- Is there an implicit contribution to the Core Damage Frequency (CDF) or Large Early Release Frequency (LERF)?
- Is there a contribution to seismic margin analysis?
- Is there reason to consider the SSC as a result of operating experience?
- Is there a contribution, real or potential, to initiating events?
- Is the component considered in Technical Specifications?

The clarifying questions can be refined by the Expert Panel or the Program Procedures and then addressed purely judgmentally or weighted to apply a limited quantitative analysis to the deterministic assessment. Either way, the judgment of the Expert Panel remains a judgment. The use of numerical weights may enhance the discussion of the issues.

Table 5-1 identifies example RAP questions considered in deterministically categorizing SSCs and provides weight factors used by some licensees. In this formalism, for each of the questions, the response can be evaluated by a quantitative value between "0" and "5" depending on the impact and frequency, i.e., no impact and no occurrence equals "0" whereas high impact and frequent occurrence equals "5". Examples of values for quantitative assessment are provided in Table 5-2.

Table 5-1
Example D-RAP Questions and Weight

D-RAP Questions	Possible Weight
#1. Is the function used to mitigate accidents or transients?	5
#2. Is the function specifically called out in the Emergency Operating Procedures?	5
#3. Does the loss of the function directly fail another safety significant system?	4
#4. Is the loss of the function safety significant for shutdown or mode changes?	3
#5. Does the loss of the function, in and of itself, directly cause an initiating event?	3

Table 5-2
Example of Quantitative Assessment

Quantitative Value	Deterministic Assessment
0	Negative or no effect
1	Positive response with insignificant impact and/or occurring very rarely
2	Positive response having a minor impact and/or occurring infrequently
3	Positive response having a low impact and/or occurring occasionally
4	Positive response having a medium impact and/or occurring regularly
5	Positive response having a high impact and/or occurring frequently

The D-RAP questions are asked one by one and the quantitative value used to multiply the weight of the question. The total is derived by adding the values. A combined score above a chosen value can be used to determine the scope. In some cases a single question score above say 15 may be sufficient while a combined score above 30 or 40 might be adopted by the Expert Panel and the Procedures. The quantitative value is a combination of impact and occurrence frequency and this will require discussion among the Expert Panel members to reach a consensus. For example, the impact may be discussed first and the occurrence frequency used to increase or decrease the value by judgment. The Panel will decide how to apply such factors if they are adopted.

5.5 Maintenance Rule Considerations

Operating plants (licensees) are accountable for compliance with the Maintenance Rule, 10CFR50.65. Several aspects of the Maintenance Rule are similar to D-RAP. For instance, the Maintenance Rule requires a monitoring program that is based on a categorization as follows [from 10CFR50.65(b)]:

> "(1) Safety-related structures, systems and components that are relied upon to remain functional during and following design basis events to ensure the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, or the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposure comparable to the guidelines in Sec. 50.34(a)(1), Sec. 50.67(b)(2), or Sec. 100.11 of this chapter, as applicable.
>
> (2) Non safety related structures, systems, or components:
>
> (i) That are relied upon to mitigate accidents or transients or are used in plant emergency operating procedures (EOPs); or
>
> (ii) Whose failure could prevent safety-related structures, systems, and components from fulfilling their safety-related function; or
>
> (iii) Whose failure could cause a reactor scram or actuation of a safety-related system."

The Maintenance Rule categorization requirements are very similar to the deterministic questions that can be used to make determinations for D-RAP. However, the method of categorization of SSCs for the Maintenance Rule is not specified and either a deterministic or PRA approach, or a combination of both, are sometimes used. D-RAP requires that both be considered with either being sufficient to place the SSC within scope for D-RAP.

For new build reactors, there have been six phases identified for compliance with the Maintenance Rule: design, equipment procurement, equipment storage, construction, startup and testing, and commercial operation.

EPRI has developed the following three reports for implementing five of the six phases

- EPRI Report 1021415, "Equipment Reliability (ER) for New Nuclear Plant Projects: Industry Recommendations for Design," provides deterministic methodology for component classification based upon single point vulnerabilities. EPRI Report 1021415 provides guidance for design and design control, monitoring, preventive maintenance, corrective action, and self-assessment for the SSCs determined to be within-scope of the Maintenance Rule.
- EPRI Report 1021413, "ER for New Nuclear Plant Projects: Industry Recommendations for Storage, Construction, and Testing," provides guidance for these activities for within-scope SSCs by identifying roles and responsibilities, requirements for shipping and transportation, guidelines for installation, construction maintenance, and testing, and how to perform self-assessment of the storage, construction, and testing program.
- EPRI Report 1021416, "ER for New Nuclear Plant Projects – Industry Recommendations for Procurement," provides guidance for procurement, including Vendor Pre-Qualification, Bidding, Selection Process, Equipment Design and Fabrication, Inspections, Testing, and Final Documentation, Performance Monitoring, Preventive Maintenance, Vendor Corrective Action, and Self-Assessment.

Section 6: Implementation/Treatment

6.1 General

Treatment is defined in EPRI Report 1015099 as "Activities, processes, and /or controls that are performed or used in the design, installation, maintenance, and operation of SSCs as a means of the following:

- Specifying and procuring SSCs that satisfy performance requirements
- Verifying over time that performance is maintained
- Controlling activities that could impact performance
- Providing assessment and feedback of results to adjust activities as needed to meet desired outcomes."

ISG-18 does not provide detailed guidance for treatment of SSCs. Paragraphs A.7 and B.2 of ISG-18 discuss "QA Controls Related to DC Design Activities for Non-Safety-Related RAP SSCs" and refers to SRP Section 17.5 for applicability.

Excerpts from Section 17.5 of the SRP are included as Appendix B.

Figure 6-1 from EPRI Report 1015099 demonstrates the process for establishing the appropriate treatment for the four RISC SSCs. RISC-2 and RISC-3 SSCs require the identification of additional or alternate treatments. In the case of RISC-3 SSCs, the alternate treatments replace the special treatments that are no longer applicable per 10CFR50.69.

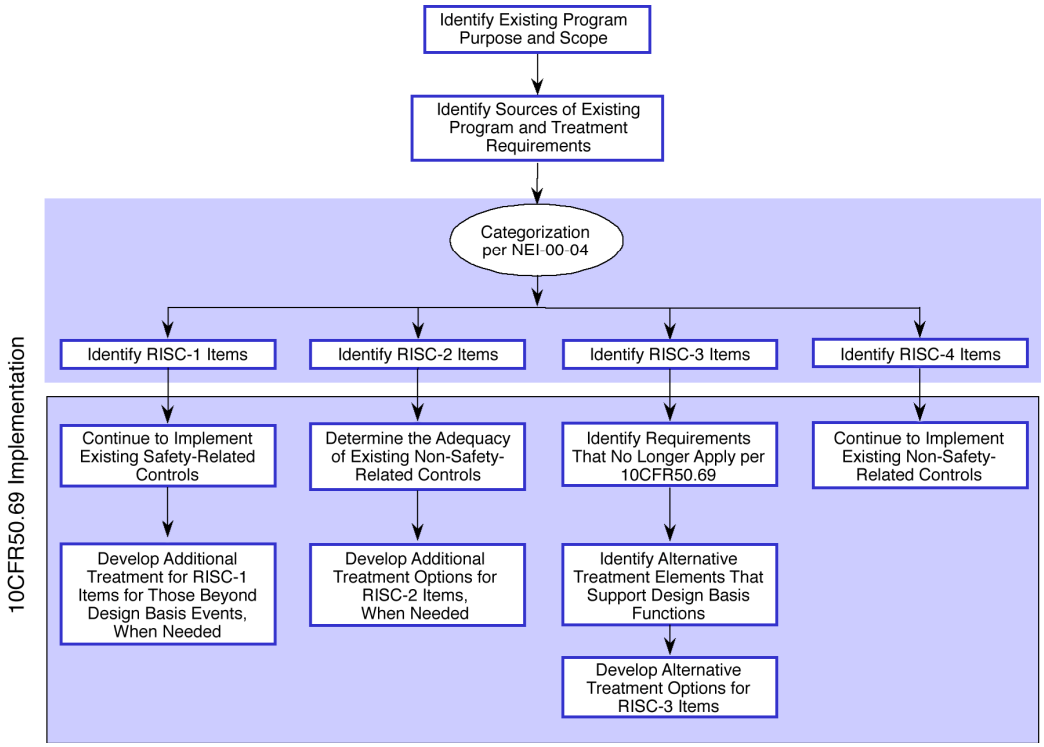

Figure 6-1
Establishing Appropriate Treatments

6.2 Treatment for D-RAP Within-Scope SSCs

Under D-RAP, within scope SSCs are required to receive full treatment (as are RISC-1 above) for the safety related SSCs. Under D-RAP, the non safety related but safety significant SSCs are within scope and receive some augmented treatment. It is possible that 10CFR50.69 positions on alternative treatment may provide guidance on treatment of within-scope SSCs from the D-RAP program. It specifies that RISC-2 SSCs (non safety-related but safety significant) are subject to alternate treatments.

RISC-3 SSCs (safety-related but low safety significance) are not addressed in D-RAP but treatment may also provide guidance on options for D-RAP treatment. Under 10CFR50.69 these SSCs may be granted reduced requirements and this has been interpreted as meaning they are not be subject to the full implementation of:

- 10CFR50 Appendix B, 10CFR21 Reporting Requirements,
- Environmental Qualification requirements of 10CFR50.49,
- Applicable portions of codes and standards of ASME and IEEE [10CFR5055a(f), (g), (h)],
- The Maintenance Rule (10CFR50.65),
- Reporting Requirements of 10CFR50.72 and 10CFR50.73,

- Portions of 10CFR50 Appendix J testing, and
- Seismic qualification with respect to extent of testing and types of analyses required by 10CFR50 Appendix A.

The alternate treatments are not specified in D-RAP and are left to the applicant or licensee to establish based upon the SSCs function, which resulted in the determination that the SSC is within-scope. The reference is to SRP section 17.5 for treatment.

While there is no absolute set of requirements to achieve D-RAP treatment guidance may be obtained by reviewing the alternate treatments for the RISC-2 SSC. The following three EPRI Reports were developed for establishing compliance with 10CFR50.69 for RISC-3 SSCs. Although the EPRI Reports were directed to RISC-3 SSCs, it is possible that the same guidelines could be applied to RISC-2 SSCs. 10CFR50.69 makes a distinction between RISC-2 and RISC-3 SSCs only in the categorization process but not in the treatments that should be applied.

In summary:

- D-RAP scope that includes safety related SSCs that are also safety significant receive no additional requirements for treatment
- D-RAP scope that includes non safety related but safety significant SSCs receives more than commercial treatment but not full safety related treatment – as does RISC 2 under 10CFR50.69.
- 10CFR50.69 SSCs that are RISC-3 receive less than full safety related treatment but more than commercial treatment.

Since RISC-2 and RISC-3 SSCs receive graded treatment as does D-RAP non safety related SSCs the actual treatment guidance is discussed below to guide the decision as to actual treatment. It is suggested that the treatment among all three classes (D-RAP, RISC-2, and RISC-3) might be similar or even the same. In making the treatment decision the following reports may be useful:

- EPRI 1015099: Option 2, 10CFR50.69 Special Treatment Guidelines, December 2007, provides guidance on implementation of 10CFR50.69. EPRI 1015099 endorses NEI 00-04 for categorization and assumes the SSCs have already been categorized. For RISC-2 SSCs, EPRI 1015099 emphasizes that ensuring they continue to perform their functions does not obligate the applicant or licensee to add new programmatic controls. From EPRI 1015099, "RISC-2 SSCs do not change their safety classification and are not intended to be placed under full safety-related regulatory controls. Licensees are only to ensure that appropriate controls are placed on the RISC-2 SSC so that reasonable confidence exists that the critical attributes will be satisfied when called upon." The process for determining the appropriate treatment for RISC-2 SSCs from EPRI 1015099 is:

- Identify the attribute(s) that resulted in the subject SSC to be categorized as safety significant. The treatment assessment should focus only on ensuring that these critical attributes are satisfied.
- Review the adequacy of the existing treatment (current processes and controls) to ensure that the critical attributes are satisfied such that reasonable confidence exists that the SSC will perform as intended over the plant life. This review will include the equipment history, current performance, maintenance and operational practices, and administrative requirements currently in place.
- Following review, if the current controls are deemed to be adequate to ensure that the critical attribute(s) will be satisfied, no additional treatment controls (inspection, testing, and so on) may be necessary. However, the licensee is expected to document the reasonable confidence basis that the critical attributes will be satisfied and should ensure that the RISC-2 SSC is included in the scope of the Maintenance Rule program (10CFR50.65) and is also subject to the corrective action program.
- Following review, if the current controls are deemed to be inadequate to ensure that the critical attribute(s) will be satisfied, the licensee focuses on the specific actions needed to provide reasonable confidence that the critical attribute(s) will be satisfied. Example actions to take could include replacing existing hardware that has shown poor performance over the component's history, bolstering preventive maintenance (PM) scope and/or frequency to address past component failure histories, performing periodic tests or checks to ensure the continued availability of the component, performing inspections (quality or other) to ensure the adequacy of the work performed or the state of component readiness, etc.
    - In addition to the preceding treatment controls, the component is to be included in the scope of the Maintenance Rule program and is also to be subject to the licensee's corrective action program.
    - The licensee should document, based on the additional controls applied, the basis for reasonable confidence that the critical attribute(s) will be satisfied.

For RISC-3 SSCs, the process for determining the appropriate treatment is more detailed in EPRI 1015099 but essentially involves the following steps:

- Identify the existing program purpose and scope
- Identify sources of existing program and treatment requirements
- Identify program requirements that no longer apply per 10CFR50.69
- Identify alternative treatment elements that support design basis
- Develop alternative treatment options for RISC-3 items

- EPRI 1009748, "Guidance for Accident Function Assessment for RISC-3 Applications," October 2005, specifies an alternate treatment to Environmental Qualification for RISC-3 SSCs. EPRI 1009748 establishes reasonable confidence that RISC-3 harsh environment electrical components will perform their design basis accident functions in accordance with the requirements of 10CFR50.69. EPRI 1009748 defines SSC function under

design basis conditions and accident function assessment as "An assessment that establishes reasonable confidence that a device will perform its design basis function under the design basis accident environments throughout its service life." The accident function assessment is the alternate treatment that replaces EQ for RISC-3 SSCs. This report describes how to perform an accident function assessment, considerations for mild and harsh environments, and the effects of aging.

- EPRI 1009669, RISC-3 Seismic Assessment Guidelines (Preliminary Report), December 2004, and EPRI 1011783, Same Title (Final Report), Provides guidance for establishing reasonable confidence that SSCs of nuclear plants, categorized as RISC-3 under 10CFR50.69 will perform their required functions under design seismic conditions. Several approaches are identified for an alternate treatment for RISC-3 SSCs for seismic assessments.

Section 7: Operational Program Reliability Assurance Activities

The NRC determined in SECY-95-132, "Policy and Technical Issues Associated With the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs (SECY-94-084), " dated May 22, 1995, that a distinct and specific Operational RAP should not be required. SECY-95-132 states, "Operations-phase reliability assurance activities will be incorporated into existing programs." Existing programs that should be used include the Maintenance Rule.

ISG-18 Section B.3 provides guidance for the integration of D-RAP into Operational Programs. Essentially, ISG-18 indicates that the applicant or licensee should reference those sections and chapters of the application where the applicable operational programs are described that would ensure the reliability of SSCs. ISG-18 proposes that the operational process address the following:

- Establishment of reliability, availability, or condition performance goals for the RAP SSCs. Implementation of the maintenance rule following the guidance contained in RG 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," is one method for establishing these performance goals, provided that these SSCs are categorized as having high safety significance (HSS).
- Establishment of performance and condition monitoring requirements to provide reasonable assurance that RAP SSCs do not degrade to an unacceptable level of reliability, availability, or condition during plant operations.
- For the non safety-related RAP SSCs, establishment of QA controls during the operations phase (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-Related SSC Quality Controls of SRP Section 17.5.
- Consideration of dominant failure modes of 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.

Once the SSCs have been appropriately categorized, existing programs to be applied are the Maintenance Rule, 10CFR50 Appendix B QA Program for safety-related SSCs, graded QA controls established by SRP 17.5, and Inservice Inspection, Inservice Testing, Surveillance Testing, and Maintenance Programs for the within-scope D-RAP SSCs.

Section 8: References

1. 10CFR50.65, *Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants.* Office of the Federal Register, National Archives and Records Administration, U.S. Government Printing Office, Washington, D.C.
2. 10CFR50.69, *Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors*. Office of the Federal Register, National Archives and Records Administration, U.S. Government Printing Office, Washington, D.C.: 2004.
3. 10CFR50.71(h)(1), Maintenance of Records, Making of Reports, Office of the Federal Register, National Archives and Records Administration, U.S. Government Printing Office, Washington, D.C
4. NUREG-0800, *Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition*, Section 17.4 Reliability Assurance Program and Section 17.5 Quality Assurance. Office of the Federal Register, National Archives and Records Administration, U.S. Government Printing Office, Washington, D.C.: 2007
5. Interim Staff Guidance on NUREG-0800 Standard Review Plan Section 17.4, *Reliability Assurance Program,* DC/COL-ISG-018, Office of the Federal Register, National Archives and Records Administration, U.S. Government Printing Office, Washington, D.C.
6. NEI 00-04, "10CFR50.69 SSC Categorization Guidelines," Nuclear Energy Institute, Washington, D.C.: 2005.
7. EPRI 1015099, "Option 2, 10CFR50.69 Special Treatment Guidelines,"
8. EPRI 1009748, "Guidance for Accident Function Assessment for RISC-3 Applications, Alternate Treatment to Environmental Qualification for RISC-3 Applications,"
9. EPRI 1011783, "Risk Informed Safety Categorization (RISC-3) Seismic Assessment Guidelines," and EPRI 1009669, RISC-3 Seismic Assessment Guidelines (Preliminary Report), December 2004
10. EPRI 1021415,"Equipment Reliability for New Nuclear Plant Projects: Industry Recommendations for Design."
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12. EPRI 1021413, “Equipment Reliability for New Nuclear Plant Projects: Industry Recommendations for Storage, Construction, and Testing.”
13. SECY-89-013, “Design Requirements Related to the Evolutionary Advanced Light Water Reactors (ALWRS),” dated January 19, 1989,
14. SECY-93-087, “Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Design,” dated April 2, 1993
15. SECY-94-084, “Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems [RTNSS] in Passive Plant Designs.”
16. SECY-95-132, “Policy and Technical Issues Associated With the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs (SECY-94-084), Responses to Staff Requirements Memorandum (SRM) on SECY-94-084 dated May 22, 1995, Item A Regulatory Treatment of Non-Safety Systems (RTNSS).”

Appendix A: ISG-18

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. This ISG revises the NRC staff's review responsibilities and clarifies the review and acceptance criteria contained in 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.

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 "RAP SSCs") are identified by using a combination of probabilistic, deterministic, 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 of the RAP is to provide reasonable assurance of the following:

- A plant is designed, constructed, and operated in a manner that is consistent with the risk insights and key assumptions (e.g., SSC design, reliability, and availability) from the probabilistic, deterministic, and other methods of analysis used to identify and quantify risk.
- The 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.
- These SSCs will function reliably when challenged.

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 during the operations phase of the plant's life cycle.

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

- 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 the risk insights and key assumptions are consistent with the plant design and construction, and that the list of RAP SSCs is appropriately developed, maintained, and communicated to the appropriate organizations.
- Implement the appropriate quality assurance (QA) 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 SSCs. QA controls for safety-related SSCs are established through Title 10 of the *Code of Federal Regulations* (CFR), Part 50, "Domestic Licensing of Production and Utilization Facilities." The QA requirements are specified in Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." SRP Section 17.5, Part V, "Nonsafety-Related SSC Quality Controls," addresses QA controls for RAP SSCs that are not safety-related.

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) developing

a comprehensive list of RAP SSCs (within the scope 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 QA controls for DC design activities for the non-safety-related RAP SSCs in accordance with Part V of SRP Section 17.5. In addition, the DC applicant proposes in the DC application a Tier 1 inspections, tests, 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, which 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) developing a comprehensive list of SSCs within the scope of the COL's plant-specific 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 QA controls for COL design activities for the non-safety-related 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, which may include audits.

  In addition, the COL applicant proposes in its application a process for integrating RAP 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) QA controls for non-safety-related RAP SSCs established in accordance with Part V of SRP Section 17.5, and (4) the inservice inspection, inservice testing, surveillance testing, and maintenance programs.
- Prior to initial fuel load, the COL licensee is responsible for implementing the D-RAP, which includes (1) applying the essential elements of D-RAP during COL design and construction activities (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 QA controls for COL design and construction activities for the non-safety-related RAP SSCs in accordance with Part V of SRP Section 17.5, and (3) completing the ITAAC for the D-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 licensee identifies dominant failure modes and integrates RAP 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 SSCs do not degrade to an unacceptable level of reliability, availability, or condition.

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 identifying the list of RAP SSCs were often difficult due to the wording of the acceptance criteria in SRP Section 17.4. 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 RAP to only risk-significant SSCs modeled in the PRA. The staff addressed these issues during the RAP reviews through requests for additional information (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 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 RAP SSC to be at least equal to the reliability assumed in the PRA. However, D-RAP should not be based solely on numerical values. For one reason, the estimated reliability of each as-built RAP SSC 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 from probabilistic, deterministic, and other methods of analysis used to identify and quantify risk. The staff concluded that implementation of D-RAP should be a process that would control reliability and availability of RAP SSCs. This process includes implementing the appropriate QA programs to provide control over activities affecting the quality of the 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 difficult due to the wording of the acceptance criteria in SRP Section 17.4. In addition, COL applicants, in general, did not describe the essential elements related to their

plant-specific 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 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 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 SSCs
- acceptance criteria for how procurement, fabrication, construction, and test specifications for the RAP SSCs ensure that significant assumptions are realistic and achievable
- acceptance criteria for D-RAP ITAAC
- acceptance criteria for COL action items in a DC application
- acceptance criteria for integrating RAP 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

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

(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 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 to support DC design activities. These essential elements are processes and controls that ensure the risk insights and key assumptions 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 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 needed, an audit(s) can be performed to verify that the applicant appropriately applied these essential elements during DC design activities.

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 plant will be designed 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.

b. Design Control

- The application should describe how the design change control process provides a mechanism to notify the appropriate organizations of plant changes (e.g., changes to the design, programs, and procedures) that could affect the RAP SSCs (e.g., the design, operation, testing, and maintenance of these SSCs) or relevant D-RAP inputs (e.g., the list of RAP SSCs, PRA models, risk insights, and key assumptions).
- 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 specifications. It is acceptable to cite the specific sections or chapters of the application that specify these quality controls. For example, describing the quality controls 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 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 SSCs.

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 are promptly identified, reported, and corrected. For example, information used to identify RAP SSCs may be determined to be incorrect, or there may be a failure to communicate a key assumption to the design organization.

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 SSCs

The application should describe an acceptable methodology for identifying the SSCs within the scope of the RAP as determined by using a combination of probabilistic, deterministic, 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-fault tree/event tree-type risk evaluations (e.g., fire-induced vulnerability evaluation or seismic margins analysis)

   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 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) 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 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 comprise members knowledgeable 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.

A.5 List of RAP SSCs

The application should contain a comprehensive list of RAP SSCs, within the scope 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 SSC should be described. 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 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 QA Controls Related to DC Design Activities for Non-Safety-Related RAP SSCs

For non-safety-related RAP SSCs, the application should specify the QA controls for DC design activities in accordance with the provisions in Part V, "Nonsafety- Related SSC Quality Controls," of SRP Section 17.5. The review of these QA controls is conducted in accordance with Part V of SRP Section 17.5. Section 17.4 of the application should cite the specific sections or chapters of the application where these QA controls are described.

A.8 ITAAC for D-RAP

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.

A.9 COL 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 RAP (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 QA controls for the non-safety-related RAP SSCs in accordance with the provisions in Part V, "Nonsafety-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 RAP SSCs.

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

B. COL Application

B.1 Plant-Specific 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 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 QA Controls Related to COL Design and Construction Activities for Non-Safety-Related RAP SSCs

For the non-safety-related RAP SSCs, the application should specify the QA controls for COL design and construction activities (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-Related SSC Quality Controls," of SRP Section 17.5. The review of these 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 QA controls are described.

B.3 Integration of RAP into Operational Programs

The application should propose an acceptable process for integrating RAP into operational programs to meet the objectives of the RAP during the operations phase. The application should 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., a 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 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 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 actual equipment, train, or system performance and other operational history.)

c. For the non-safety-related RAP SSCs, establishment of QA controls for activities during the operations phase (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-Related SSC Quality Controls," of SRP Section 17.5. The review of these QA controls is conducted in accordance with Part V of SRP Section 17.5.

d. Consideration of dominant failure modes of 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., inservice inspection, inservice testing, surveillance testing, monitoring, and maintenance) to maintain equipment performance consistent with the risk insights and key assumptions for the 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 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) QA controls for nonsafety-related RAP SSCs established in accordance with Part V of SRP Section 17.5, and (4) inservice inspection, inservice testing, surveillance testing, and maintenance programs for the 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 as approved in the DC (see Section A.8 of this ISG).

(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 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 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.

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 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.

Appendix B: Excerpts from NUREG 0800 (SRP 17.5)

V. NONSAFETY-RELATED SSC QUALITY CONTROLS (NOT APPLICABLE TO ESP APPLICANTS)

1. Nonsafety-related SSCs that are significant contributors to plant safety

   This review addresses the SRM on SECY 95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs (SECY 94-084)," Item A, RTNSS and Item E, Reliability Assurance Program, which contains the Commission policy on non safety-related SSCs that are identified as being significant contributors to plant safety. The reviewer shall verify that DC and COL applicants specify the following quality controls for SSCs that are identified as being significant contributors to plant safety.

   a. Organization

      The normal line organization may verify compliance with the following criteria. A separate or dedicated QA organization is not required.

   b. QA Program

      The supplier's procedures describe the quality controls applied to the subject equipment. A new or separate QA program is not required.

   c. Design Control

      Measures are established to ensure that the contractually established design requirements are included in the design. Applicable design inputs are included or correctly translated into design documents, and deviations therefrom are controlled. Normal supervisory review of the designer's work is an adequate control measure.

d. Procurement Document Control

Applicable design bases and other requirements necessary to ensure component performance, including design requirements, are included or referenced in documents for procurement of items and services, and deviations therefrom are controlled.

e. Instructions, Procedures, and Drawings

Activities affecting quality shall be performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. This may include such things as written instructions, plant procedures, cautionary notes on drawings, and special instructions on work orders. Any methodology which provides the appropriate degree of guidance to personnel performing activities important to the component functional performance is acceptable.

f. Document Control

The issuance and change of documents that specify quality requirements or prescribe activities affecting quality are controlled to ensure that correct documents are used.

g. Control of Purchased Items and Services

Measures are established that ensure that all purchased items and services conform to appropriate procurement documents.

h. Identification and Control of Purchased Items

Measures are established where necessary, to identify purchased items and preserve their functional performance capability. Examples of circumstances requiring such control include the storage of environmentally sensitive equipment or material, and the storage of equipment or material that has a limited shelf life.

i. Control of Special Processes

Measures are established to control special process, including welding, heat treating, and nondestructive testing. Applicable codes, standards, specification, criteria, and other special requirements may serve as the basis of these controls.

j. Inspection

Inspections are performed where necessary to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. Inspections need not be performed by personnel who are independent of the line organization. However, personnel that perform inspections are required to be knowledgeable.

k. Test Control

Measures are established that demonstrate that equipment conforms with design requirements. Tests are performed in accordance with test procedures. Test results are recorded and evaluated to ensure that test requirements are met.

l. Control of Measuring and Test Equipment

Measures are established to control, calibrate, and adjust measuring and test equipment at specific intervals.

m. Handling, Storage, and Shipping

Handling, storage, cleaning, packaging, shipping, and preservation of items are controlled to prevent damage or loss and to minimize deterioration.

n. Inspection, Test, and Operating Status

Measures are established to identify items that have satisfactorily passed required tests and inspection and to indicate the status of inspection, test, and operability as appropriate.

o. Control of Nonconforming Items

Items that do not conform to specified requirements are identified and controlled to prevent inadvertent installation or use.

p. Corrective Action

Measures are established to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected.

q. Records

Records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, inspection and test activities have been met.

r. Audits

Audits independent of line management are not required, if line management periodically reviews and documents the adequacy of the supplier's process and takes any necessary corrective action. Line management is responsible for determining whether reviews conduced by line management or audits conducted by any organization independent

of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities.

2. Nonsafety-Related SSCs Credited for Regulated Events

   The following criteria apply to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), and station blackout (SBO) (10 CFR 50.63) SSCs that are not safety related. The reviewer shall verify that QAPDs address the documents listed below. The reviewer shall notify the organization responsible for the applicable document for review of any proposed exceptions or alternatives to the standard.

   a. The applicant or holder commits to implement quality requirements to the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in RG 1.189, "Fire Protection for Operating Nuclear Power Plants."

   b. The applicant or holder commits to implement the quality requirements to ATWS equipment in accordance with Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related."

   c. The applicant or holder commits to implement quality requirements to 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."

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Electric Power Research Institute
3420 Hillview Avenue, Palo Alto, California 94304-1338 • PO Box 10412, Palo Alto, California 94303-0813 USA
800.313.3774 • 650.855.2121 • askepri@epri.com • www.epri.com